DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 415, 418, 422, 423, 424, 425, 455, 489, 491, 495, 498, and 600

[CMS–1784–P]

RIN 0938–AV07

Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

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

ACTION: Proposed rule.

SUMMARY: This major proposed 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; payment for dental services inextricably linked to specific covered medical services; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare and Medicaid provider and supplier enrollment policies, electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act); updates to the Ambulance Fee Schedule regulations and the Medicare Ground Ambulance Data Collection System; codification of the Inflation Reduction Act and Consolidated Appropriations Act, 2023 provisions; expansion of the diabetes screening and diabetes definitions; pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation expansion of supervising practitioners; appropriate use criteria for advanced diagnostic imaging; early release of Medicare Advantage risk adjustment data; a social determinants of health risk assessment in the annual wellness visit and Basic Health Program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 11, 2023.

ADDRESSES: In commenting, please refer to file code CMS–1784–P.

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–1784–P, P.O. Box 8016, Baltimore, MD 21244–8016.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1784–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for any issues not identified below. Please indicate the specific issue in the subject line of the email.

Michael Soracoe, (410) 786–6312, and Morgan Kitzmiller, (410) 786–1623, for issues related to practice expense, work RVUs, conversion factor, and PFS specialty-specific impacts.

Kris Corwin, (410) 786–8864, for issues related to the comment solicitation on strategies for updates to practice expense data collection and methodology.

MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to caregiver training services, community health integration services, social determinants of health risk assessment, and principal illness navigation services.

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

Kris Corwin, (410) 786–8864, Patrick Sartini, (410) 786–9252, and Larry Chan, (410) 786–6864, for issues related to direct supervision using two-way audio/video communication technology, telehealth, and other services involving communications technology.

Tamika Brock, (312) 886–7904, for issues related to teaching physician services.

Lindsey Baldwin, (410) 786–1694, Regina Walker-Wren, (410) 786–9160, Erick Carrera, (410) 786–8949, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to advancing access to behavioral health.

MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to PFS payment for evaluation and management services.

Morgan Kitzmiller, (410) 786–1623, for issues related to geographic practice cost indices (GPCIs).

Zehra Hussain, (214) 767–4463, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to payment of skin substitutes.

Pamela West, (410) 786–2302, for issues related to supervision of outpatient therapy services, KX modifier thresholds, diabetes self-management training (DSMT) services, and DSMT telehealth services.

Laura Ashbaugh, (410) 786–1113, and Erick Carrera, (410) 786–8949, Zehra Hussain, (214) 767–4463, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to dental services inextricably linked to specific covered medical services.

Laura Kennedy, (410) 786–3377, Adam Brooks, (202) 205–0671, and Rachel Radzyner, (410) 786–8215, for issues related to Drugs and Biological Products Paid Under Medicare Part B.

MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to complex drug administration.

Laura Ashbaugh, (410) 786–1113, Ariana Pitcher, *ariana.pitcher@cms.hhs.gov,* Rasheeda Arthur, (410) 786–3434, or *CLFS_Inquiries@cms.hhs.gov* for issues related to Clinical Laboratory Fee Schedule.

Lisa Parker, (410) 786–4949, or *FQHC–PPS@cms.hhs.gov,* for issues related to FQHC payments.

Michele Franklin, (410) 786–9226, or *RHC@cms.hhs.gov,* for issues related to RHC and FQHC Conditions for Certification or Coverage.

Kianna Banks (410) 786–3498 and Cara Meyer (667) 290–9856, for issues related to RHCs and FQHCs definitions of staff.

Sarah Fulton, (410) 786–2749, for issues related to pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation expansion of supervising practitioners.

Lindsey Baldwin, (410) 786–1694, Ariana Pitcher, *ariana.pitcher@cms.hhs.gov,* or *OTP_Medicare@cms.hhs.gov,* for issues related to Medicare coverage of opioid use

disorder treatment services furnished by opioid treatment programs.

Sabrina Ahmed, (410) 786–7499, or *SharedSavingsProgram@cms.hhs.gov,* for issues related to the Medicare Shared Savings Program (Shared Savings Program) Quality performance standard and quality reporting requirements.

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 and benchmarking methodology.

Lucy Bertocci, (667) 290–8833, or *SharedSavingsProgram@cms.hhs.gov,* for inquiries related to Shared Savings Program advance investment payments, and eligibility requirements.

Rachel Radzyner, (410) 786–8215, and Michelle Cruse, (443) 478–6390, for issues related to preventive vaccine administration services.

Mollie Howerton (410) 786–5395, for issues related to Medicare Diabetes Prevention Program.

Sarah Fulton (410) 786–2749, for issues related to appropriate use criteria for advanced diagnostic imaging.

Frank Whelan, (410) 786–1302, for issues related to Medicare and Medicaid provider and supplier enrollment regulation updates.

Daniel Feller (410) 786–6913 for issues related to expanding diabetes screening and definitions.

Daniel Feller (410) 786–6913 for issues related to a social determinants of health risk assessment in the annual wellness visit.

Mei Zhang, (410) 786–7837, and Kimberly Go, (410) 786–4560, 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 (section 2003 of the SUPPORT Act).

Amy Gruber, (410) 786–1542, or *AmbulanceDataCollection@cms.hhs.gov,* for issues related to the Ambulance Fee Schedule (AFS) and the Medicare Ground Ambulance Data Collection System.

Mary Rossi-Coajou (410) 786–6051, for issues related to hospice Conditions of Participation.

Cameron Ingram (410) 409–8023 for issues related to Histopathology, Cytology, and Clinical Cytogenetics Regulations under CLIA of 1988.

Meg Barry (410) 786–1536, for issues related to the Basic Health Program (BHP) provisions.

Renee O'Neill, (410) 786–8821, or Sophia Sugumar, (410) 786–1648, for inquiries related to Merit-based Incentive Payment System (MIPS).

Richard Jensen, (410) 786–6126, for inquiries related to Alternative Payment Models (APMs).

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 commenter will take actions to harm an 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 proposed 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 2024 PFS proposed rule, refer to item CMS–1784–P. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this proposed rule and posted on the CMS website identified above should contact *MedicarePhysicianFeeSchedule@cms.hhs.gov*.

CPT (Current Procedural Terminology) Copyright Notice: Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2020 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

This major annual rule proposes to revise payment polices under the Medicare PFS and makes other policy changes, including proposals to implement certain provisions of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328, September 29, 2022), Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, August 16, 2022), Consolidated Appropriations Act, 2022 (Pub. L. 117–103, March 15, 2022), Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020), 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 for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, October 24, 2018), related to Medicare Part B payment. In addition, this major proposed rule includes proposals regarding other Medicare payment policies described in sections III. and IV. of this proposed rule.

This rulemaking proposes to update the Rural Health Clinic (RHC) and Federally Qualified Health Clinic (FQHC) Conditions for Certification and Conditions for Coverage (CfCs), respectively, to implement the provisions of the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328, December 29, 2022), now allowing payment under Medicare Part B for services furnished by a Marriage and Family Therapist (MFT) or Mental Health Counselor (MHC).

This rulemaking would also update the Hospice Conditions of Participation (CoPs) to implement division FF, section 4121 of the CAA 2023 regarding the addition of marriage and family therapists (MFTs) or mental health counselors (MHCs) as part of the hospice interdisciplinary team and would make changes to the hospice personnel requirements. This rulemaking would also seek to further advance Medicare's overall value-based care strategy of growth, alignment, and equity through the Medicare Shared Savings Program (MSSP) and the Quality Payment Program (QPP). The structure of the programs enables us to develop a set of tools for measuring and encouraging improvements in care, which may support a shift to clinician payment over time into Advanced Alternative Payment Models (APMs) and accountable care arrangements which reduce care fragmentation and unnecessary costs for patients and the health system.

This rulemaking would also update the Ambulance Fee Schedule regulations to implement division FF, section 4103 of the CAA 2023 regarding the ground ambulance extenders provisions and would also provide further changes and clarifications to the

Medicare Ground Ambulance Data Collection System.

This rulemaking would also update Medicare and Medicaid provider and supplier enrollment regulations.

B. 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 each year we establish, by regulation, the payment amounts for physicians' services paid under the PFS, including geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

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In this major proposed rule, we are proposing to establish RVUs for CY 2024 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 proposed rule also includes discussions and provisions regarding several other Medicare Part B payment policies, Medicare and Medicaid provider and supplier enrollment policies, and other policies regarding programs administered by CMS.

Specifically, this proposed rule addresses:

- Background (section II.A.)
- Determination of PE RVUs (section II.B.)
- Potentially Misvalued Services Under the PFS (section II.C.)
- Payment for Medicare Telehealth Services Under Section 1834(m) of the Social Security Act (the Act) (section II.D.)
- Valuation of Specific Codes (section II.E.)
- Evaluation and Management (E/M) Visits (section II.F.)
- Geographic Practice Cost Indices (GPCI) (section II.G.)
- Payment for Skin Substitutes (section II.H.)
- Supervision of Outpatient Therapy Services, KX Modifier Thresholds, Diabetes Self-Management Training (DSMT) Services by Registered Dietitians and Nutrition Professional, and DSMT Telehealth Services (section II.I.)
- Advancing Access to Behavioral Health (section II.J.)
- Proposals on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Medical Services (section II.K.)
- Drugs and Biological Products Paid Under Medicare Part B (section III.A.)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (section III.B.)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) Conditions for Certification or Coverage (CfCs) (section III.C.)
- Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions (section III.D.)
- Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation Expansion of Supervising Practitioners (section III.E.)
- Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs) (section III.F.)
- Medicare Shared Savings Program (section III.G.)
- Medicare Part B Payment for Preventive Vaccine Administration Services (section III.H.)
- Medicare Diabetes Prevention Program Expanded Model (section III.I.)
- Appropriate Use Criteria for Advanced Diagnostic Imaging (section III.J.)
- Medicare and Medicaid Provider and Supplier Enrollment (section III.K.)
- Expand Diabetes Screening and Diabetes Definitions (section III.L.)
- Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA–PD Plan (section 2003 of the SUPPORT Act) (section III.M.)
- Proposed Changes to the Regulations Associated with the Ambulance Fee Schedule and the Medicare Ground Ambulance Data Collection System (GADCS) (section III.N.)
- Hospice: Changes to the Hospice Conditions of Participation (section III.O.)
- RFI: Histopathology, Cytology, and Clinical Cytogenetics Regulations under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 (section III.P.)
- Changes to the Basic Health Program Regulations (section III.Q.)
- Updates to the Definitions of Certified Electronic Health Record Technology (section III.R.)
- A Social Determinants of Health Risk Assessment in the Annual Wellness Visit (section III.S.)
- Updates to the Quality Payment Program (section IV.)
- Collection of Information Requirements (section V.)
- Response to Comments (section VI.)
- Regulatory Impact Analysis (section VII.)

3. Summary of Costs and Benefits

We have determined that this proposed rule is economically significant. For a detailed discussion of the economic impacts, see section VII., Regulatory Impact Analysis, of this proposed rule.

II. Provisions of the Proposed Rule for the PFS

A. Background

In accordance with section 1848 of the Act, CMS has paid for physicians' services under the Medicare physician fee schedule (PFS) since January 1, 1992. 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 (OBRA '89) (Pub. L. 101–239, December 19, 1989), and the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Pub. L. 101–508, November 5, 1990). The final rule published in the November 25, 1991 **Federal Register** (56 FR 59502) set forth the first fee schedule used for Medicare payment for physicians' services.

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

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 malpractice (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 Physician Fee Schedule (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 Relative Value Scale Update Committee (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 in the CY 2007 PFS proposed rule (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 Socioeconomic Monitoring System (SMS). The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice 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 cross-walking 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 cross-walked PE/HR, we instead used the PPIS based PE/HR. We use cross-walks for specialties that did not participate in the PPIS. These cross-walks have been generally established through notice and comment rulemaking and are available in the file titled ''CY 2024 PFS proposed rule PE/HR'' on the CMS website under downloads for the CY 2024 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

c. Allocation of PE to Services

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

(1) Direct Costs

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

(2) Indirect Costs

We allocate the indirect costs at the code level based on 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 direct 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 2024 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. This file contains a table that illustrates the calculation of PE RVUs as described in this proposed rule for individual codes.

(a) Setup File

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

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

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

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the 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 an 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 52983) 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 interested parties. 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 interested parties 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 52983) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

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 BN. (See ''Specialties excluded from ratesetting calculation'' later in this proposed 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

- *Cross-walk certain low volume physician specialties:* Cross-walk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.
- *Physical therapy utilization:* Cross-walk 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%
CO, CQ	Physical and Occupational Therapy Assistant Services	88%	88%

We also adjust 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.

Beginning in CY 2022, section 1834(v)(1) of the Act required that we apply a 15 percent payment reduction for outpatient occupational therapy services and outpatient physical therapy services that are provided, in whole or in part, by a physical therapist assistant (PTA) or occupational therapy assistant (OTA). Section 1834(v)(2)(A) of the Act required CMS to establish modifiers to identify these services, which we did in the CY 2019 PFS final rule (83 FR 59654 through 59661), creating the CQ and CO payment modifiers for services provided in whole or in part by PTAs and OTAs, respectively. These payment modifiers are required to be used on claims for services with dates of service beginning January 1, 2020, as specified in the CY 2020 PFS final rule (84 FR 62702 through 62708). We applied the 15 percent payment reduction to therapy services provided by PTAs (using the CQ modifier) or OTAs (using the CO modifier), as required by statute. Under sections 1834(k) and 1848 of the Act, payment is made for outpatient therapy services at 80 percent of the lesser of the actual charge or applicable fee schedule amount (the allowed charge). The remaining 20 percent is the beneficiary copayment. For therapy services to which the new discount applies, payment will be made at 85 percent of the 80 percent of allowed charges. Therefore, the volume discount factor for therapy services to which the CQ and CO modifiers apply is: (0.20 + (0.80* 0.85), which equals 88 percent.

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

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

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/(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 proposed rule
price = price of the particular piece of equipment
life of equipment = useful life of the particular piece of equipment
maintenance = factor for maintenance; 0.05
interest rate = variable, see discussion below in this proposed rule

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

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 final rule, we finalized a 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 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 a more detailed discussion of the methodology associated with very short equipment life durations, we refer readers to the CY 2021 PFS final rule (85 FR 84482 through 84483).

- *Maintenance:* We finalized the 5 percent factor for annual maintenance 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 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 3.

TABLE 3: 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 are not proposing any changes to the equipment interest rates for CY 2024.

3. Adjusting RVUs To Match the PE Share of the Medicare Economic Index (MEI)

In the past, we have stated that we believe that the MEI is the best measure available of the relative weights of the three components in payments under the PFS—work, practice expense (PE), and malpractice (MP). Accordingly, we believe that to assure that the PFS payments reflect the relative resources in each of these PFS components as required by section 1848(c)(3) of the Act, the RVUs used in developing rates should reflect the same weights in each component as the Medicare Economic Index (MEI). In the past, we have proposed (and subsequently, finalized) to accomplish this by holding the work RVUs constant and adjusting the PE RVUs, MP RVUs, and CF to produce the appropriate balance in RVUs among the three PFS components and payment rates for individual services, that is, that the total RVUs on the PFS are proportioned to approximately 51 percent work RVUs, 45 percent PE RVUs, and 4 percent MP RVUs. As the MEI cost shares are updated, we would typically propose to modify steps 3 and 10 to adjust the aggregate pools of PE costs (direct PE in step 3 and indirect PE in step 10) in proportion to the change in the PE share in the rebased and revised MEI cost share weights, and to recalibrate the relativity adjustment that we apply in step 18 as described ''3. Adjusting RVUs To Match PE Share of the Medicare Economic Index (MEI)'' of the CY 2023 PFS final rule (87 FR 69414 and 69415) and CY 2014 PFS final rule (78 FR 74236 and 74237). The most recent recalibration was done for the CY 2014 RVUs.

In the CY 2014 PFS proposed rule (78 FR 43287 through 43288) and final rule (78 FR 74236 through 74237), we detailed the steps necessary to accomplish this result (see steps 3, 10, and 18). The CY 2014 proposed and final adjustments were consistent with our longstanding practice to make adjustments to match the RVUs for the PFS components with the MEI cost share weights for the components, including the adjustments described in the CY 1999 PFS final rule (63 FR 58829), CY 2004 PFS final rule (68 FR 63246 and 63247), and CY 2011 PFS final rule (75 FR 73275).

In the CY 2023 PFS final rule (87 FR 69688 through 69711), we finalized to rebase and revise the Medicare Economic Index (MEI) to reflect more current market conditions faced by physicians in furnishing physicians' services. We also finalized a delay of the adjustments to the PE pools in steps 3 and 10 and the recalibration of the relativity adjustment in step 18 until the public had an opportunity to comment on the rebased and revised MEI (87 FR 69414 through 69416). Because we finalized significant methodological and data source changes to the MEI in the CY 2023 PFS final rule and significant time has elapsed since the last rebasing and revision of the MEI in CY 2014, we believed that delaying the implementation of the finalized CY

2023 rebased and revised MEI was consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. We refer readers to the discussion of our comment solicitation in the CY 2023 PFS final rule (87 FR 69429 through 69432), where we reviewed our ongoing efforts to update data inputs for PE to aid stability, transparency, efficiency, and data adequacy. We also solicited comment in the CY 2023 PFS proposed rule on when and how to best incorporate the CY 2023 rebased and revised MEI into PFS ratesetting, and whether it would be appropriate to consider a transition to full implementation for potential future rulemaking. We presented the impacts of implementing the rebased and revised MEI in PFS ratesetting through a 4-year transition and through full immediate implementation, that is, with no transition period in the CY 2023 PFS proposed rule. We also solicited comment on other implementation strategies for potential future rulemaking in the CY 2023 PFS proposed rule. In the CY 2023 PFS final rule, we discussed that many commenters supported our proposed delayed implementation and many commenters expressed concerns with the redistributive impacts of the implementation of the rebased and revised MEI in PFS ratesetting. Many commenters also noted that the AMA has said it intends to collect practice cost data from physician practices in the near future which could be used to derive cost share weights for the MEI and RVU shares.

In light of the AMA's intended data collection efforts in the near future and because the methodological and data source changes to the MEI finalized in the CY 2023 PFS final rule would have significant impacts on PFS payments, we continue to believe that delaying the implementation of the finalized 2017-based MEI cost weights for the RVUs is consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. Therefore, we are not proposing to incorporate the 2017-based MEI in PFS ratesetting for CY 2024.

As discussed above, in the CY 2023 PFS rulemaking, we finalized to rebase and revise the MEI to reflect more current market conditions faced by physicians in furnishing physicians' services. The final 2017-based MEI relies on a methodology that uses publicly available data sources for input costs that represent all types of physician practice ownership, not limited to only self-employed physicians. The 2006-based MEI relied on the 2006 AMA PPIS survey data; as of this CY 2024 rulemaking, this survey had not been updated. Given the changes in the physician and supplier industry and the time since the last update to the base year, we finalized a methodology that would allow us to update the MEI on a consistent basis in the future. The 2017-based MEI cost weights are derived predominantly from the annual expense data from the U.S. Census Bureau's Services Annual Survey (SAS, *https://www.census.gov/programs-surveys/sas.html*). We supplement the 2017 SAS expense data by using several data sources to further disaggregate compensation costs and all other residual costs (87 FR 69688 through 69708).

We continue to review more recently available data from the Census Bureau Services Annual Survey, the main data source for the major components of the 2017-based MEI weights. Data is currently available through 2021. Given that the impact of the PHE may influence the 2020 and 2021 data, we continue to evaluate whether the recent trends are reflective of sustained shifts in cost structures or were temporary as a result of the COVID–19 PHE. The 2022 data from the Services Annual Survey will be available later this year. We will monitor that data and any other data that may become available related to physician services' input expenses and will propose any changes to the MEI, if appropriate, in future rulemaking.

4. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2024 direct PE input public use files, which are available on the CMS website under downloads for the CY 2024 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640 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, one 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 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 2023, we are continuing to display two versions of the Labor Task Detail public use file: one version with the old listing of clinical labor tasks, and one with the same tasks cross-walked to the new listing of clinical labor activity codes. These lists are available on the CMS website under downloads for the CY 2024 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

b. 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. Beginning in CY 2019 and continuing through CY 2022, we conducted a market-based supply and equipment pricing update, using information developed by our contractor, StrategyGen, which updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs. Given the potentially significant changes in payment that would occur, in the CY 2019 PFS final rule we finalized a policy 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. We believed that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy, while maintaining stability and allowing interested parties the opportunity to address potential concerns about changes in payment for particular items. This 4-year transition period to update supply and equipment pricing concluded in CY 2022; for a more detailed discussion, we refer readers to the CY 2019 PFS final rule with comment period (83 FR 59473 through 59480).

For CY 2024, we are proposing to update the price of 16 supplies and two equipment items in response to the public submission of invoices following the publication of the CY 2023 PFS final rule. The 16 supply and equipment items with proposed updated prices are listed in the valuation of specific codes section of the preamble under Table 14, CY 2024 Invoices Received for Existing Direct PE Inputs.

We are not proposing to update the price of another eleven supplies which were the subject of public submission of invoices. Our rationale for not updating these prices is detailed below:

- Extended external ECG patch, medical magnetic tape recorder (SD339): We received additional invoices for the SD339 supply from an interested party. Upon review of the invoices, we determined that they contained the identical price point that we previously incorporated into last year's rule when we finalized a price of $260.35 for the supply item (87 FR 69514 through 69516). Since these invoices did not contain any new information, we are maintaining the previously finalized price of $260.35 for the SD339 supply.
- Permanent marking pen (SL477), Liquid coverslip (Ventana 650–010) (SL479), EZ Prep (10X) (Ventana 950–102) (SL481), Cell Conditioning 1 (Ventana 950–124) (SL482), and Hematoxylin II (Ventana 790–2208) (SL483): We received invoices from interested parties for use in updating the price of these laboratory supplies. In each case, however, we were able to find the same supply item available for sale online at the current price or cheaper. Therefore, we do not believe that the submitted invoices represent typical market pricing for these supplies and we are not proposing to update their prices.
- Mask, surgical (SB033), scalpel with blade, surgical (#10–20) (SF033), eye shield, non-fog (SG049), gauze, non-sterile 4in x 4in (SG051), and towel, paper (Bounty) (per sheet) (SK082): We received invoices from interested parties for use in updating the price of these common supply items. In each case, we received a single invoice and once again we were able to find the same supply items available for sale online at the current price or cheaper. Generally speaking, we avoid updating the price for common supply items like the SB033 surgical mask (included in approximately 380 HCPCS codes) based on the submission of a single invoice, as an invoice unrepresentative of current market pricing will have far-reaching effects across the PFS. We did not find that the typical price for a surgical mask had increased by more than 60% since the supply and equipment pricing update concluded in CY 2022, and as such we are maintaining the current price for these supply items.

(1) Invoice Submission

We remind readers that 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. Interested parties are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

c. Clinical Labor Pricing Update

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

Beginning in CY 2019, we updated the supply and equipment prices used for PE as part of a market-based pricing transition; CY 2022 was the final year of this 4-year transition. We initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the supply and equipment pricing for CY 2019, and we finalized a policy in CY 2019 to phase in the new pricing over a period of 4 years. However, we did not propose to update the clinical labor pricing, and the pricing for clinical labor has remained unchanged during this pricing transition. Clinical labor rates were last updated for CY 2002 using Bureau of Labor Statistics (BLS) data and other supplementary sources where BLS data were not available; we refer readers to the full discussion in the CY 2002 PFS final rule for additional details (66 FR 55257 through 55262).

Interested parties raised concerns that the long delay since clinical labor pricing was last updated created a significant disparity between CMS' clinical wage data and the market average for clinical labor. In recent years, a number of interested parties suggested that certain wage rates were inadequate because they did not reflect current labor rate information. Some interested parties also stated that updating the supply and equipment pricing without updating the clinical labor pricing could create distortions in the allocation of direct PE. They argued that since the pool of aggregated direct PE inputs is budget neutral, if these rates are not routinely updated, clinical labor may become undervalued over time relative to equipment and supplies, especially since the supply and equipment prices are in the process of being updated. There was considerable interest among interested parties in updating the clinical labor rates, and when we solicited comment on this topic in past rules, such as in the CY 2019 PFS final rule (83 FR 59480), interested parties supported the idea.

Therefore, we proposed to update the clinical labor pricing for CY 2022, in conjunction with the final year of the supply and equipment pricing update (86 FR 39118 through 39123). We believed it was important to update the clinical labor pricing to maintain relativity with the recent supply and equipment pricing updates. We proposed to use the methodology outlined in the CY 2002 PFS final rule (66 FR 55257), which draws primarily from BLS wage data, to calculate updated clinical labor pricing. As we stated in the CY 2002 PFS final rule, the BLS' reputation for publishing valid estimates that are nationally representative led to the choice to use the BLS data as the main source. We believe that the BLS wage data continues to be the most accurate source to use as a basis for clinical labor pricing and this data will appropriately reflect changes in clinical labor resource inputs for purposes of setting PE RVUs under the PFS. We used the most current BLS survey data (2019) as the main source of wage data for our CY 2022 clinical labor proposal.

We recognized that the BLS survey of wage data does not cover all the staff types contained in our direct PE database. Therefore, we cross-walked or extrapolated the wages for several staff types using supplementary data sources for verification whenever possible. In situations where the price wages of clinical labor types were not referenced in the BLS data, we used the national salary data from the Salary Expert, an online project of the Economic Research Institute that surveys national and local salary ranges and averages for thousands

of job titles using mainly government sources. (A detailed explanation of the methodology used by Salary Expert to estimate specific job salaries can be found at *www.salaryexpert.com*). We previously used Salary Expert information as the primary backup source of wage data during the last update of clinical labor pricing in CY 2002. If we did not have direct BLS wage data available for a clinical labor type, we used the wage data from Salary Expert as a reference for pricing, then cross-walked these clinical labor types to a proxy BLS labor category rate that most closely matched the reference wage data, similar to the crosswalks used in our PE/HR allocation. For example, there is no direct BLS wage data for the Mammography Technologist (L043) clinical labor type; we used the wage data from Salary Expert as a reference and identified the BLS wage data for Respiratory Therapists as the best proxy category. We calculated rates for the ''blend'' clinical labor categories by combining the rates for each labor type in the blend and then dividing by the total number of labor types in the blend.

As in the CY 2002 clinical labor pricing update, the proposed cost per minute for each clinical staff type was derived by dividing the average hourly wage rate by 60 to arrive at the per minute cost. In cases where an hourly wage rate was not available for a clinical staff type, the proposed cost per minute for the clinical staff type was derived by dividing the annual salary (converted to 2021 dollars using the Medicare Economic Index) by 2080 (the number of hours in a typical work year) to arrive at the hourly wage rate and then again by 60 to arrive at the per minute cost. We ultimately finalized the use of median BLS wage data, as opposed to mean BLS wage data, in response to comments in the CY 2022 PFS final rule. To account for the employers' cost of providing fringe benefits, such as sick leave, we finalized the use of a benefits multiplier of 1.296 based on a BLS release from June 17, 2021 (USDL–21–1094). As an example of this process, for the Physical Therapy Aide (L023A) clinical labor type, the BLS data reflected a median hourly wage rate of $12.98, which we multiplied by the 1.296 benefits modifier and then divided by 60 minutes to arrive at the finalized per-minute rate of $0.28.

After considering the comments on our CY 2022 proposals, we agreed with commenters that the use of a multi-year transition would help smooth out the changes in payment resulting from the clinical labor pricing update, avoiding potentially disruptive changes in payment for affected interested parties, and promoting payment stability from year-to-year. We believed it would be appropriate to use a 4-year transition, as we have for several other broad-based updates or methodological changes. While we recognized that using a 4-year transition to implement the update means that we will continue to rely in part on outdated data for clinical labor pricing until the change is fully completed in CY 2025, we agreed with the commenters that these significant updates to PE valuation should be implemented in the same way, and for the same reasons, as for other major updates to pricing such as the recent supply and equipment update. Therefore, we finalized the implementation of the clinical labor pricing update over 4 years to transition from current prices to the final updated prices in CY 2025. We finalized the implementation of this pricing transition over 4 years, such that one quarter of the difference between the current price and the fully phased-in price is implemented for CY 2022, one third of the difference between the CY 2022 price and the final price is implemented for CY 2023, and one half of the difference between the CY 2023 price and the final price is implemented for CY 2024, with the new direct PE prices fully implemented for CY 2025. (86 FR 65025) An example of the transition from the current to the fully-implemented new pricing that we finalized in the CY 2022 PFS final rule is provided in Table 4.

TABLE 4: Example of Clinical Labor Pricing Transition

Current Price	$1.00	
Final Price	$2.00	
Year 1 (CY 2022) Price	$1.25	1/4 difference between $1.00 and $2.00
Year 2 (CY 2023) Price	$1.50	1/3 difference between $1.25 and $2.00
Year 3 (CY 2024) Price	$1.75	1/2 difference between $1.50 and $2.00
Final (CY 2025) Price	$2.00	

(1) CY 2023 Clinical Labor Pricing Updates

For CY 2023, we received information from one interested party regarding the pricing of the Histotechnologist (L037B) clinical labor type. The interested party provided data from the 2019 Wage Survey of Medical Laboratories which supported an increase in the per-minute rate from the $0.55 finalized in the CY 2022 PFS final rule to $0.64. This rate of $0.64 for the L037B clinical labor type is a close match to the online salary data that we had for the Histotechnologist and matches the $0.64 rate that we initially proposed for L037B in the CY 2022 PFS proposed rule. Based on the wage data provided by the commenter, we proposed this $0.64 rate for the L037B clinical labor type for CY 2023; we also proposed a slight increase in the pricing for the Lab Tech/Histotechnologist (L035A) clinical labor type from $0.55 to $0.60 as it is a blend of the wage rate for the Lab Technician (L033A) and Histotechnologist clinical labor types. We also proposed the same increase to $0.60 for the Angio Technician (L041A) clinical labor type, as we previously established a policy in the CY 2022 PFS final rule that the pricing for the L041A clinical labor type would match the rate for the L035A clinical labor type (86 FR 65032).

Based on comments received on the CY 2023 proposed rule, we finalized a change in the descriptive text of the L041A clinical labor type from ''Angio Technician'' to ''Vascular Interventional Technologist''. We also finalized an update in the pricing of three clinical labor types: from $0.60 to $0.84 for the Vascular Interventional Technologist (L041A), from $0.63 to $0.79 for the Mammography Technologist (L043A), and from $0.76 to $0.78 for the CT Technologist (L046A) based on submitted wage data from the 2022 Radiologic Technologist Wage and Salary Survey (87 FR 69422 through 69425).

(2) CY 2024 Clinical Labor Pricing Update Proposals

We did not receive new wage data or other additional information for use in clinical labor pricing from interested parties prior to the publication of the CY 2024 PFS proposed rule. Therefore, our proposed clinical labor pricing for CY 2024 is based on the clinical labor pricing that we finalized in the CY 2023 PFS final rule, incremented an additional step for Year 3 of the update:

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TABLE 5: Proposed CY 2024 Clinical Labor Pricing

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Rate Per Minute	Y3 Phase-In Rate Per Minute	Total % Change
L023A	Physical Therapy Aide	BLS 31-2022	0.23	0.28	0.268	22%
L026A	Medical/Technical Assistant	BLS 31-9092	0.26	0.36	0.335	38%
L030A	Lab Tech/MTA	L033A, L026A	0.30	0.46	0.420	53%
L032B	EEG Technician	BLS 29-2098	0.32	0.44	0.410	38%
L033A	Lab Technician	BLS 29-2010	0.33	0.55	0.495	67%
L033B	Optician/COMT	BLS 29-2081, BLS 29-2057	0.33	0.39	0.375	18%
L035A*	Lab Tech/Histotechnologist	L033A, L037B	0.35	0.60	0.534	70%
L037A	Electrodiagnostic Technologist	BLS 29-2098	0.37	0.44	0.423	19%
L037B*	Histotechnologist	BLS 29-2010	0.37	0.64	0.573	73%
L037C	Orthoptist	BLS 29-1141	0.37	0.76	0.663	105%
L037D	RN/LPN/MTA	L051A, BLS 29-2061, L026A	0.37	0.54	0.498	46%
L037E	Child Life Specialist	BLS 21-1021	0.37	0.49	0.460	32%
L038A	COMT/COT/RN/CST	BLS 29-2057, BLS 29-2055, L051A, BLS 19-4010	0.38	0.52	0.485	37%
L038B	Cardiovascular Technician	BLS 29-2031	0.38	0.60	0.545	58%
L038C	Medical Photographer	BLS 29-2050	0.38	0.38	0.383	0%
L039A	Certified Retinal Angiographer	BLS 29-9000	0.39	0.52	0.488	33%
L039B	Physical Therapy Assistant	BLS 31-2021	0.39	0.61	0.555	56%
L039C	Psychometrist	BLS 21-1029	0.39	0.64	0.579	62%
L041A*	Vascular Interventional Technologist	ASRT Wage Data	0.41	0.84	0.731	104%
L041B	Radiologic Technologist	BLS 29-2034	0.41	0.63	0.575	54%
L041C	Second Radiologic Technologist for Vertebroplasty	BLS 29-2034	0.41	0.63	0.575	54%
L042A	RN/LPN	L051A, BLS 29-2061	0.42	0.63	0.578	50%
L042B	Respiratory Therapist	BLS 29-1126	0.42	0.64	0.585	52%
L043A*	Mammography Technologist	ASRT Wage Data	0.43	0.79	0.702	84%
L045A	Cytotechnologist	BLS 29-2035	0.45	0.76	0.683	69%
L045B	Electron Microscopy Technologist	BLS 29-1124	0.45	0.89	0.780	98%
L045C	CORF social worker/psychologist	BLS 21-1022, BLS 19-3031	0.45	0.70	0.638	56%
L046A	CT Technologist*	ASRT Wage Data	0.46	0.78	0.703	70%
L047A	MRI Technologist	BLS 29-2035	0.47	0.76	0.688	62%
L047B	REEGT (Electroencephalographic Tech)	BLS 29-2035	0.47	0.76	0.688	62%
L047C	RN/Respiratory Therapist	L051A, L042B	0.47	0.70	0.643	49%
L047D	RN/Registered Dietician	L051A, BLS 29-1031	0.47	0.70	0.643	49%
L049A	Nuclear Medicine Technologist	BLS 29-2033	0.62	0.81	0.761	32%
L050A	Cardiac Sonographer	BLS 29-2032	0.50	0.77	0.703	54%
L050B	Diagnostic Medical Sonographer	BLS 29-2032	0.50	0.77	0.703	54%
L050C	Radiation Therapist	BLS 29-1124	0.50	0.89	0.793	78%
L050D	Second Radiation Therapist for IMRT	BLS 29-1124	0.50	0.89	0.793	78%
L051A	RN	BLS 29-1141	0.51	0.76	0.698	49%
L051B	RN/Diagnostic Medical Sonographer	L051A, BLS 29-2032	0.51	0.77	0.705	51%
L051C	RN/CORF	L051A	0.51	0.76	0.698	49%
L052A	Audiologist	BLS 29-1181	0.52	0.81	0.738	56%
L053A	RN/Speech Pathologist	L051A, L055A	0.53	0.79	0.725	49%
L054A	Vascular Technologist	BLS 19-1040	0.54	0.91	0.818	69%
L055A	Speech Pathologist	BLS 29-1127	0.55	0.82	0.753	49%
L056A	RN/OCN	BLS 29-2033	0.79	0.81	0.805	3%
L057A	Genetics Counselor	BLS 29-9092	0.57	0.85	0.779	50%

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Rate Per Minute	Y3 Phase-In Rate Per Minute	Total % Change
L057B	Behavioral Health Care Manager	BLS 21-1018	0.57	0.57	0.570	0%
L063A	Medical Dosimetrist	BLS 19-1040	0.63	0.91	0.840	44%
L107A	Medical Dosimetrist/Medical Physicist	L063A, L152A	1.08	1.52	1.409	41%
L152A	Medical Physicist	AAPM Wage Data	1.52	2.14	1.986	41%

As was the case for the market-based supply and equipment pricing update, the clinical labor rates will remain open for public comment over the course of the 4-year transition period. We updated the pricing of a number of clinical labor types in the CY 2022 and CY 2023 PFS final rules in response to information provided by commenters. For the full discussion of the clinical labor pricing update, we direct readers to the CY 2022 PFS final rule (86 FR 65020 through 65037).

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

Following the publication of the CY 2023 PFS proposed rule, an interested party notified CMS that CPT code 86153 (*Cell enumeration using immunologic selection and identification in fluid specimen (e.g., circulating tumor cells in blood); physician interpretation and report, when required*) appeared to be missing its work time in the Physician Work Time public use file. We reviewed the request from the interested party and determined that this was indeed an unintended technical error; we stated in the CY 2013 PFS final rule that we were finalizing 0 minutes pre-service time, 20 minutes intraservice time, and 0 minutes post-service time to CPT code 86153 (77 FR 69059), however work time was inadvertently completely missing for this code. Therefore, we are proposing to add the correct 20 minutes of intraservice work time to CPT code 86153 for CY 2024.

5. Soliciting Public Comment on Strategies for Updates to Practice Expense Data Collection and Methodology

a. Background

The AMA PPIS was first introduced in 2007 as a means to collect comprehensive and reliable data on the direct and indirect PEs incurred by physicians (72 FR 66222). In considering the use of PPIS data, the goal was to improve the accuracy and consistency of PE RVUs used in the PFS. The data collection process included a stratified random sample of physicians across various specialties, and the survey was administered between August 2007 and March 2008. Data points from that period of time that are integrated into PFS calculations today. In the CY 2009 PFS proposed rule (73 FR 38507 through 3850), we discussed the indirect PE methodology that used data from the AMA's survey that predated the PPIS. In CY 2010 PFS rulemaking, we announced our intent to incorporate the AMA PPIS data into the PFS ratesetting process, which would first affect the PE RVU. In the CY 2010 PFS proposed rule, we outlined a 4-year transition period, during which we would phase in the AMA PPIS data, replacing the existing PE data sources (74 FR 33554). We also explained that our proposals intended to update survey data only (74 FR 33530 through 33531). In our CY 2010 final rule, we finalized our proposal, with minor adjustments based on public comments (74 FR 61749 through 61750). We responded to the comments we received about the transition to using the PPIS to inform indirect PE allocations (74 FR 61750). In the responses, we acknowledged concerns about potential gaps in the data, which could impact the allocation of indirect PE for certain physician specialties and suppliers, which are issues that remain important today. The CY 2010 PFS final rule explains that section 212 of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113, November 29, 1999) directed 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. BBRA required us to establish criteria for accepting supplemental survey data. Since the supplemental surveys were specific to individual specialties and not part of a comprehensive multispecialty survey, we had required that certain precision levels be met in order to ensure that the supplemental data was sufficiently valid, and acceptable for use in the development of the PE RVUs. At the time, our rationale included the assumption that because the PPIS is a contemporaneous, consistently collected, and comprehensive multispecialty survey, we do not believe similar precision requirements are necessary, and we did not propose to establish them for the use of the PPIS data (74 FR 61742). We noted potential gaps in the data, which could impact the allocation of indirect PE for certain physician and suppliers. The CY 2010 final rule adopted the proposal, with minor adjustments based on public comments, and explained that these minor adjustments were in part due to non-response bias that results when the characteristics of survey respondents differ in meaningful ways, such as in the mix of practices sizes, from the general population (74 FR 61749 through 61750).

Throughout the 4-year transition period, from CY 2010 to CY 2013, we gradually incorporated the AMA PPIS data into the PFS rates, replacing the previous data sources. The process involved addressing concerns and making adjustments as necessary, such as refining the PFS ratesetting methodology in consideration of interested party feedback. For background on the refinements that we considered after the transition began, we refer readers to discussions in the CY 2011–2014 final rules (75 FR 73178 through 73179; 76 FR 73033 through 73034; 77 FR 98892; 78 FR 74272 through 74276).

In the CY 2011 PFS proposed rule, we requested comments on the methodology for calculating indirect PE RVUs, explicitly seeking input on using survey data, allocation methods, and potential improvements (75 FR 40050). In our CY 2011 PFS final rule, we addressed comments regarding the methodology for indirect PE calculations, focusing on using survey data, allocation methods, and potential improvements (75 FR 73178 through 73179). We recognized some limitations of the current PFS ratesetting methodology but maintained that the approach was the most appropriate at the time. In the CY 2012 PFS final rule, we responded to comments related to indirect PE methodology, including concerns about allocating indirect PE to specific services and using the AMA

PPIS data for certain specialties (76 FR 73033 through 73034). We indicated that CMS would continue to review and refine the methodology and work with interested parties to address their concerns. In the CY PFS 2014 final rule, we responded to comments about fully implementing the AMA PPIS data. By 2014, the AMA PPIS data had been fully integrated into the PFS, serving as the primary source for determining indirect PE inputs (78 FR 74235). We continued to review data and the PE methodology annually, considering interested party feedback and evaluating the need for updates or refinements to ensure the accuracy and relevance of PE RVUs (79 FR 67548). In the years following the full implementation of the AMA PPIS data, we further engaged with interested parties, thought leaders and subject matter experts to improve our PE inputs' accuracy and reliability. For further background, we refer readers to our discussions in final rules for CY 2016–2022 (80 FR 70892; 81 FR 80175; 82 FR 52980 through 52981; 83 FR 59455 through 59456; 84 FR 62572; 85 FR 84476 through 84478; 86 FR 62572).

In our CY 2023 PFS final rule, we issued an RFI to solicit public comment on strategies to update PE data collection and methodology (87 FR 69429 to 69432). We solicited comments on current and evolving trends in health care business arrangements, the use of technology, or similar topics that might affect or factor into PE calculations. We remind readers that we have worked with interested parties and CMS contractors for years to study the landscape and identify possible strategies to reshape the PE portion of physician payments. The fundamental issues are clear, but thought leaders and subject matter experts have advocated for more than one tenable approach to updating our PE methodology.

As described in last year's rule, we have continued interest in developing a roadmap for updates to our PE methodology that account for changes in the health care landscape. Of various considerations necessary to form a roadmap for updates, we reiterate that allocations of indirect PE continue to present a wide range of challenges and opportunities. As discussed in multiple cycles of previous rulemaking, our PE methodology relies on AMA PPIS data, which may represent the best aggregated available source of information at this time. However, we acknowledge the limitations and challenges interested parties have raised about using the current data for indirect PE allocations, which we have also examined in related ongoing research. We noted in last year's rule that there are several competing concerns that CMS must take into account when considering updated data sources, which also should support and enable ongoing refinements to our PE methodology.

Many commenters last year asked that CMS wait for the AMA to complete a refresh of AMA survey data. We responded to these comments by explaining the tension that waiting creates in light of concerns raised by other interested parties. Waiting for refreshed survey data would result in CMS using data nearly 20 years old to form indirect PE inputs to set rates for services on the PFS. We remind readers that many of the critical issues discussed in the background and history above are mainly unchanged and possibly would not be addressed by an updated survey alone but may also require revisions to the PFS ratesetting methodology.

b. Request for Information

We continue to encourage interested parties to provide feedback and suggestions to CMS that give an evidentiary basis to shape optimal PE data collection and methodological adjustments over time. Submissions should discuss the feasibility and burden of implementing any suggested adjustments and highlight opportunities to optimize the cadence, frequency, and phase-in of resulting adjustments. We continue to consider ways that we may engage in dialogue with interested parties to better understand how to address possible long-term policies and methods for PFS ratesetting. We believe some of those concerns may be alleviated by having ways to refresh data and make transparent how the information affects valuations for services payable under the PFS more accurately and precisely.

Considering our ratesetting methodology and prior experiences implementing new data, we are issuing a follow-up solicitation for general information. We seek comments from interested parties on strategies to incorporate information that could address known challenges we experienced in implementing the initial AMA PPIS data. Our current methodology relies on the AMA PPIS data, legislatively mandated supplemental data sources (for, example, we use supplemental survey data collected in 2003, as required by section 1848(c)(2)(H)(i) of the Act to set rates for oncology and hematology specialties), and in some cases crosswalks to allocate indirect PE as necessary for certain specialties and provider types.

We also seek to understand whether, upon completion of the updated PPIS data collection effort by the AMA, contingencies or alternatives may be necessary and available to address lack of data availability or response rates for a given specialty, set of specialties, or specific service suppliers who are paid under the PFS.

In light of the considerations discussed above, we request feedback on the following:

(1) If CMS should consider aggregating data for certain physician specialties to generate indirect allocators so that PE/HR calculations based on PPIS data would be less likely to over-allocate (or under-allocate) indirect PE to a given set of services, specialties, or practice types. Further, what thresholds or methodological approaches could be employed to establish such aggregations?

(2) Whether aggregations of services, for purposes of assigning PE inputs, represent a fair, stable and accurate means to account for indirect PEs across various specialties or practice types?

(3) If and how CMS should balance factors that influence indirect PE inputs when these factors are likely driven by a difference in geographic location or setting of care, specific to individual practitioners (or practitioner types) versus other specialty/practice-specific characteristics (for example, practice size, patient population served)?

(4) What possible unintended consequences may result if CMS were to act upon the respondents' recommendations for any of highlighted considerations above?

(5) Whether specific types of outliers or non-response bias may require different analytical approaches and methodological adjustments to integrate refreshed data?

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.E. of this proposed rule, under 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), MedPAC, and other interested parties. 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 statute. 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 considered information provided by other interested parties such as from the general medical-related community and the public. We conducted 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 rise.

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 (76 FR 73026, 73058 through 73059), other individuals and groups submit nominations for review of potentially misvalued codes as well. Individuals and 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 at *MedicarePhysicianFeeSchedule@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 CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the same CY 2012 PFS final rule with comment period, we finalized our policy to consolidate the review of physician work and PE at the same time, and established a process for the annual public nomination of potentially misvalued services.

In the CY 2013 PFS final rule with comment period (77 FR 68892, 68896 through 68897), 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'').[1] In the CY 2019 PFS proposed rule (73 FR 38589), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth Five-Year Review of Work RVUs proposed rule (76 FR 32410, 32419), 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 2024 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 67548, 67606 through 67608), we modified this process whereby the public and interested parties 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 each year's final rule, we finalize our list of potentially misvalued codes.

a. Public Nominations

In each proposed rule, we seek nominations from the public and from interested parties of codes that they believe we should consider as potentially misvalued. We receive public nominations for potentially misvalued codes by February 10th and we display these nominations on our public website, where we include the submitter's name and their associated organization for full transparency. We sometimes receive submissions for specific, PE-related inputs for codes, and discuss these PE-related submissions, as necessary under the Determination of PE RVUs section of the rule. We summarize below this year's submissions under the potentially misvalued code initiative. For CY 2024, we received 10 nominations concerning various codes. The nominations are as follows:

(1) CPT Code 59200

In the CY 2022 PFS proposed rule, an interested party nominated CPT code 59200 (*Insertion cervical dilator (e.g., laminaria, prostaglandin*)) (000 zero day global code) as potentially misvalued, because the direct PE inputs for this code do not include the supply item, Dilapan-S. Previous parties had initially sought to establish a Level II HCPCS code for Dilapan-S, but CMS did not find sufficient evidence to support that request. The same interested party then submitted Dilapan-S to be considered as a practice expense (PE) supply input to a Level I CPT code 59200 (86 FR 65045). This year, a different interested party has nominated CPT code 59200 again, and provided the same reasoning as to why this code is potentially misvalued.

[1] The research team and panels of experts at the Harvard School of Public Health developed the original work RVUs for most CPT codes, in a cooperative agreement with the Department of Health and Human Services (HHS). Experts from both inside and outside the Federal Government obtained input from numerous physician specialty groups. This input was incorporated into the initial PFS, which was implemented on January 1, 1992.

Specifically, the current nominee recommends adding 4 rods of Dilapan-S at $80.00 per unit, for a total of $320.00 to this one PE supply inputs, as a replacement for the current PE supply item—laminaria tent (a small rod of dehydrated seaweed that rehydrates, absorbing the water from the surrounding tissue). The laminaria tent is currently listed at $4.0683 per unit, with a total of 3 units, for a total of $12.20. The current nominee stated that Dilapan-S is more consistent and reliable, and suggested that it had higher patient satisfaction than the laminaria tent, and that it was less likely to cause leukocytosis. CPT code 59200 is a relatively low volume code, with respect to Medicare claims and, as the nominator has stated, this service is more typically billed for the Medicaid population, as evidenced by 1.3 million Medicaid claims for this service. Medicaid programs are able to set their own payment policies, which can be different from Medicare payment policies. The current Medicare payment for CPT code 59200 in CY 2023 is about $108.10 in the nonfacility/office setting, which is much less than the typical cost of the Dilapan-S supplies requested by the interested party. The requested 4 rods of Dilapan-S would increase the supply costs of CPT code 59200 by a factor of five and represent an enormous increase in the direct costs for the service.

We do not agree that CPT code 59200 is potentially misvalued, and we do not agree with interested parties that the use of the Dilapan-S supply would be typical for this service. By including the increased direct costs of the service ($320.00, the typical cost of four units of this supply item, Dilapan-S) in the valuation for this code, the cost of this service will expand both Medicare spending and cost sharing for any beneficiary who receives this service. The cost of Dilapan-S is over 19 times higher than the cost of the current supply item (laminaria tent) for CPT code 59200. We do agree with the nominator that CPT code 59200 is much more frequently reported in the Medicaid population, and therefore, we suggest that interested parties submit a request for new and separate Medicaid payments to Medicaid.

We are not proposing to consider this code as potentially misvalued for CY 2024, though we welcome comments on this nomination for further consideration. We are soliciting comments on CPT code 59200 and whether the absence of supply item Dilapan-S makes the nonfacility/office Medicare payment for this service potentially misvalued.

(2) CPT Code 27279

CPT code 27279 (*Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device*) (090 day global code) has been nominated as misvalued due to the absence of separate direct PE inputs for this 090 day global code in the nonfacility office setting. Currently, the PFS only prices CPT code 27279 in the facility setting, at about $826.85 for the physician's professional services, but the nominators are seeking separate direct PE inputs for this service to better account for valuation when performed in the nonfacility/office setting. These PE amounts for CPT code 27279 are expected to be approximately $21,897.63 in total, which is the Medicare outpatient payment amount for CY 2023.

The nominator claims that CPT code 27279 can be safely and effectively furnished in the nonfacility setting, and that this procedure has a low risk profile, similar to kyphoplasty (CPT codes 22513, 22514, and 22515), which is currently furnished in the nonfacility setting. The nominator describes Kyphoplasty as ''a percutaneous minimally invasive procedure depositing poly methyl methacrylate via canula into vertebral bodies near neural structures.'' The nominator states that permitting payment for direct PE inputs for CPT code 27279 in the nonfacility/office setting would increase access to this service for Medicare patients. One sample invoice for $17,985.00 with three units of the itemized supply item IFuse-3D Implant 7.0 mm × 55 mm, US ($5,995.00 per unit) was submitted with this nomination to illustrate the high direct PE costs for CPT code 27279, should CMS value this code in the nonfacility/office setting.

We are concerned about whether this 090 day surgical service can be safely and effectively furnished in the non-facility/office setting (for example, in an office-based surgical suite). We welcome comments on the nomination of CPT code 27279 for consideration as potentially misvalued.

(3) CPT Codes 99221, 99222, and 99223

An interested party nominated the Hospital Inpatient and Observation Care visit CPT codes 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.*), and 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.)* as potentially misvalued. CMS reviewed these codes in the CY 2023 final rule (87 FR 69588) and established new physician work times and new work RVU payments for these codes. The nominator disagrees with these values and asserts that these ''facility-based codes are always inherently (or proportionately) more intense than E/M services provided in other settings [in particular],'' with patients presenting with potentially infectious diseases, such as meningitis; pneumonia; tuberculosis; HIV/AIDS; Ebola virus; Zika virus; and, most recently, SARS–CoV–2 and mpox, and that the inpatient setting has a predominance of more seriously ill patients, who are sometimes immunocompromised and/or have multiple drug interaction issues and/or with comorbidities, making them extraordinarily more complex than those patients typically found in the

office setting (with many of these infections being health care-associated infections and antibiotic-resistant bacterial infections). It should be noted that these new requests did not offer appreciably new information relative to last year's nomination/consideration.

The nominator seeks a new work RVU value of 1.92 for CPT code 99221, a new work RVU of 2.79 for CPT code 99222, and a new work value of 4.25 for CPT code 99223. Currently, CPT code 99221 has a work RVU of 1.63, a reduction of 15.1 percent from its 1.92 work RVU from CY 2022. CPT code 99222 had a work RVU of 2.61 in CY 2022 and is now at 2.60. CPT code 99223 had a work RVU of 3.86 in CY 2022. It now has a value of 3.50, which is a reduction of 9.3 percent. The nominator has requested that the work RVU for CPT code 99221 be restored back to 1.92, that the work RVU of CPT code 99222 be increased to 2.79, and that the work RVU of CPT code 99223 be increased to 4.25 (please see Table 6 for a comparison of work RVU values for CY 2022, CY 2023, and of those requested by the nominator).

TABLE 6: A Comparison of Work RVU values for CY 2022, CY 2023, and Those Requested by the Nominator

CPT Code	CY 2022 Work RVU	CY 2023 Work RVU	Requested Work RVU
99221 - 1st hosp ip/obs sf/low 40	1.92	1.63	1.92
99222 - 1st hosp ip/obs moderate 55	2.61	2.60	2.79
99223 - 1st hosp ip/obs high 75v	3.86	3.50	4.25

After consideration of this nomination and their requests for higher work RVUs for CPT codes 99221, 99222, and 99223, we are proposing to maintain the values that we finalized for these codes in the CY 2023 PFS final rule (87 FR 69588). Even so, we welcome comments on the nomination of these codes as potentially misvalued.

(4) CPT Codes 36514, 36516, 36522

An interested party nominated CPT codes 36514 (*Therapeutic apheresis; for plasma pheresis*), 36516 (*Therapeutic apheresis; with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion*), and 36522 (*Photopheresis, extracorporeal*) (all 000 zero day global codes) as potentially misvalued. The interested party stated that the direct PE of clinical labor L042A, ''RN/LPN'' (for labor rate of $0.525 per minute) was incorrect and should be changed to a more specific entry of ''a therapeutic apheresis nurse specialist (RN)'' (for a labor rate of about $1.06 to $1.14 per minute), which would approximately double all three of these codes' clinical labor PE entries. In addition, the nominator disagrees with the current direct PE of supply item SC085, ''Tubing set, plasma exchange'' at $186.12 per item, and believes that this should be worth $248.77 per item with CPT code 36514, using a quantity of one item. The nominator believes that supply item SC084, ''Tubing set, blood warmer,'' that we currently have listed at $8.01 per item, should be worth $14.71 per item with CPT code 36514, also using a quantity of one item. Sample invoices (not actual invoices) were submitted for illustration and support. We welcome comments on the nomination of these codes as potentially misvalued, or not.

(5) CPT Codes 44205 and 44204

An interested party nominated CPT code 44205 (*Laparoscopy, surgical; colectomy, partial, with removal of terminal ileum with ileocolostomy*), as potentially misvalued, requesting that payment for this code be made equivalent to the payment for CPT code 44204 (*Laparoscopy, surgical; colectomy, partial, with anastomosis*), which is a higher amount. Both codes are 090 day global codes, currently valued only in the facility setting. CPT code 44204 has a total RVU of 45.62 for CY 2023 and CPT code 44205 has a total RVU of 39.62 for CY 2023, with a difference of 6.00 RVUs. CPT code 44204 is associated with 5 to 6 percent more physician work time: 455.0 minutes in total, as compared to 428.5 minutes in total for CPT code 44205. The work RVU for CPT code 44204 is also 15 percent higher than the work RVU for CPT code 44205. The direct PE entries for both codes are the same with regard to supplies, equipment, and clinical labor, except that in the clinical labor and equipment entries, the number of usage minutes is higher for CPT code 44204.

Though these two codes appear to be similar, they are still different in their purpose, physician work times, and direct PEs, with CPT code 44204 involving more time and resources (and having a higher payment, accordingly). For these reasons, we are not inclined to agree that CPT code 44205 is potentially misvalued when compared to CPT code 44204, or to modify this payment differential by paying a higher amount for CPT code 44205. We are soliciting feedback regarding the nomination of CPT code 44205 as potentially misvalued.

(6) CPT Codes 93655 and 93657

An interested party nominated CPT codes 93655 (*Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure))* and 93657 *(Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to code for primary procedure)),* as potentially misvalued. These two add-on codes were part of our code review in the cardiac ablation code family in the CY 2022 (86 FR 65108) and CY 2023 (87 FR 69516) final rules.

The nominator reiterates that the primary procedures involve ''high intensity clinical decision making, complexity in the intraoperative skills required for treatment, morbidity/mortality risks to the patient, and work intensity'' and that the work RVUs for both of these add-on codes should reflect the AMA RUC recommended 7.00 work RVUs. We disagreed with this value in CY 2022, and we continue to believe that a work RVU of 5.50 is appropriate for the 60 minutes of physician service time for both codes. We see no reason to reconsider our valuation of CPT codes 93655 and

93657 for CY 2022 or CY 2023, and we do not consider these codes to be potentially misvalued now. We are not proposing to nominate these codes as potentially misvalued for CY 2024.

(7) CPT Code 94762 and 95800

An interested party nominated CPT code 94762 (*Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring (separate procedure)*) as potentially misvalued due to the PE items listed for this code, which were last reviewed in 2009. There is no physician work/professional component associated with this code. The nominator states that the technology behind this code has changed considerably over the last 14 years, and that the listed equipment items for CPT code 94762, EQ212 ''pulse oxymetry recording software (prolonged monitoring)'' and EQ353 ''Pulse oximeter 920 M Plus'' are now typically found in a one-time use supply item: SD263 ''WatchPAT pneumo-opt slp probes'' (extended external overnight pulse oximeter device probe and battery with bluetooth, medical magnetic tape recorder) (WatchPAT One Device) costing $99.00 each, derived from two sample invoices (not actual invoices) that were included with the nomination. According to our PE supply list, item SD263 costs $73.32, which is $25.68 less than the amounts found in the sample invoices submitted by the nominators. The nominator retains equipment item EQ212 ''pulse oxymetry recording software (prolonged monitoring)'', and replaces equipment item EQ353 with ED021, a ''computer, desktop, w-monitor.'' Payment for CPT code 94762 is currently $25.75 in the nonfacility office setting. There were 122,207 allowed service claims for CPT code 94762 in CY 2021. The facility payment amount for CPT code 94762 under the Medicare Hospital Outpatient Prospective Payment System (OPPS) is currently $145.43.

The same interested party who nominated CPT code 94762 also nominated CPT code 95800 (*Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time*) as potentially misvalued, requesting that CMS update PE items for this code, which were last reviewed in 2017. CPT code 95800 currently includes the entry of a one-time use supply item, SD263 ''WatchPAT pneumo-opt slp probes'' (extended external overnight pulse oximeter device probe and battery with bluetooth, medical magnetic tape recorder) (WatchPAT One Device), which costs $73.32 per item, in contrast to the pricing in the sample invoice—$99.00 each (case of 12 × $99.00 = $1,188.00). This is a $25.68 difference in this supply item's cost.

The nominator excludes the current equipment for this code (EQ335 ''WatchPAT 200 Unit with strap, cables, charger, booklet and patient video'' and EQ336 ''Oximetry and Airflow Device'') and instead includes ED021 (''computer, desktop, w-monitor'') in the PE for this code. We note that we have not previously included ED021 as a specialized equipment item dedicated to this function (and EQ212 ''pulse oxymetry recording software (prolonged monitoring)'' is also not included in the PE for CPT code 95800, as it is with CPT code 94762). The nominator included the PE listings for CPT code 93245 (*Heart rhythm recording, analysis, interpretation and report of continuous external EKG over more than 1 week up to 1 weeks*) as an example of how PE supply items for CPT code 95800 should be structured, but this code includes a supply item, SD339 ''extended external ECG patch, medical magnetic tape recorder'' and equipment item ED021 ''computer, desktop, w-monitor,'' which is presumed to be used to record the data from the ECG patch and to be used to analyze this data. CMS currently pays a total of $150.80 for CPT code 95800 in the non-facility office setting, and there were 53,793 allowed services for this code in CY 2021.

There is not clear evidence whether the WatchPAT One Device needs, or does not need, the specific monitoring and recording system (equipment item EQ212 ''pulse oxymetry recording software (prolonged monitoring)'') for CPT code 95800 as opposed to any other system/process. The interested party has requested the practice expense changes discussed above as support for their argument that these CPT codes are potentially misvalued (See Table 7.)

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TABLE 7: Listing of Nominator's Practice Expense Items for Addition or Deletion to CPT codes 94762 and 95800

CPT code	Current Equipment Code	Equipment Description	Non-Facility/ Office Equipment PE Cost	Equipment Status	Current Supply Code	Supply Description	Non-Facility/ Office Supply PE Cost	Supply Status
94762	EQ212	pulse oxymetry recording software (prolonged monitoring) (480 min)	$0.7360	Retain				
94762	EQ353	Pulse oximeter 920 M Plus (480 min)	$7.1155	Delete	SD263	WatchPAT pneumo-opt slp probes" (extended external overnight pulse oximeter device probe and battery with bluetooth, medical magnetic tape recorder) (WatchPAT One Device)	$73.32 Or $99.00	Add
95800	EQ335	WatchPAT 200 Unit with strap, cables, charger, booklet and patient video	$4.7071	Delete				
95800	EQ336	Oximetry and Airflow Device	$4.5454	Delete				
95800	ED021	computer, desktop, w-monitor (assume 480 min)	$2.5339	Add	SD263	WatchPAT pneumo-opt slp probes" (extended external overnight pulse oximeter device probe and battery with bluetooth, medical magnetic tape recorder) (WatchPAT One Device)	$73.32 Or $99.00	Retain

We welcome comments as to whether or not these codes are potentially misvalued.

(8) CPT Codes 0596T and 0597T

An interested party has nominated CPT codes 0596T (*Initial insertion of temporary valve-pump in female urethra*) and 0597T (*Replacement of temporary valve-pump in female urethra*) as potentially misvalued due to MAC pricing, which is determined on a case-by-case basis. These temporary CPT category III codes are all procedure status ''C'' (contractor priced), and the interested party is seeking status ''A'' (for active payment status) to account for physician work, nonfacility PE, and professional liability costs. The nominator states that the MAC-determined payment amounts have been inappropriately low, and do not account for the time and the work that the physician expends for these services, or for all of the PE costs associated with the Vesiflo inFlow System. For CPT code 0596T, the nominator expects a physician to spend 60 minutes of work on installing this Vesiflo inFlow System. The nonfacility office PE items include a power table, a mayo stand, an examination light, clinical labor time of a RN/LPN/MTA totaling to 73 minutes, and a list of supplies summing to $1,902.76, primarily from the inFlow Measuring Device of $140.00, the inflow Device of $495.00, and the inflow Activator Kit of $1,250.00, making up about 99 percent of the total cost of supplies.

For CPT code 0597T, the nominator expects a physician to spend 25 minutes of work replacing this Vesiflo inFlow System. The nonfacility office PE items include a power table, a mayo stand, an examination light, clinical labor time of a RN/LPN/MTA totaling to 38 minutes, and a list of supplies summing to $505.30, primarily from the inflow device of $495.00, making up about 98 percent of the total cost of supplies. A sample invoice is included in this nomination (as opposed to an actual invoice).

We welcome comments as to whether or not these two temporary category II CPT codes, CPT codes 0596T and 0597T, are potentially misvalued, and whether these codes should remain contractor priced or not.

(9) CPT Code 93000

An interested party has nominated CPT code 93000 (*Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report*) as potentially misvalued, arguing that we should increase Medicare payment for CPT code 93000 to $35.64, when used in conjunction with other supplies and services, to adequately compensate practitioners for their PE item costs for: (1) $6.10 for EKG leads; (2) $21.19 for a nurse visit of typically 5 minutes time (as illustrated by 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.)*); and (3) $7.64 for the interpretation and report for the EKG service (as illustrated by CPT code 93010 (*Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only*). The interested party is asking for the grouping of these services to be valued at $35.64 (the actual sum of these inputs is $34.93). No invoices or other evidence were provided for consideration.

For CY 2023, the national payment amounts under the PFS for CPT codes 93000, 93010, and 99211 in the nonfacility office setting are as follows:

- CPT code 93000; total RVUs 0.43 × CF $33.8872 = $14.57.
- CPT code 93010; total RVUs 0.24 × CF $33.8872 = $8.13.
- CPT code 99211; total RVUs 0.69 × CF $33.8872 = $23.38.
- Sum total $46.08.

After consideration, we are not proposing to nominate CPT code 93000 as potentially misvalued for CY 2024. The sum of a mix of services is not a persuasive indication that one code—in this case, CPT code 93000—is potentially misvalued.

(10) 19 Therapy codes

An interested party has nominated 19 therapy codes as potentially misvalued. These 19 therapy codes were last reviewed by CMS in the CY 2018 PFS final rule (82 FR 53073 through 53074). The interested party stated that the direct PE clinical labor minutes as recommended by the AMA Relative Value Scale Update Committee (RUC) and Healthcare Professional Advisory Committee (HCPAC) Review Board might have had inappropriate multiple procedure payment reductions (MPPR) applied to their PE clinical labor time entries. The nominators are now seeking correction for those clinical labor time entries, which, if adjusted in accordance with the recommendations of the nominators, would likely result in slightly higher or nominally changed payments for the 19 therapy codes.

We have reviewed the clinical labor time entries for these 19 therapy codes, and we are now reconsidering the values established in the CY 2018 final rule. We do not believe that MPPR should be applied to these 19 nominated therapy codes' clinical labor time entries (listed in Table 8), and as a result, we would like the AMA RUC HCPAC recommendations from January 2017 to be re-reviewed. We recommend nomination of these 19 codes as potentially misvalued for CY 2024, and we welcome comments on this nomination.

TABLE 8: 19 "Always Therapy" Service Codes Nominated for Potential Misvaluation

HCPCS 2023	LONG DESCRIPTION	CY 2023 STATUS CODE
97012	Application of mechanical traction	A
97014	Application of electrical stimulation	I
97016	Application of blood vessel compression device	A
97018	Application of hot wax bath	A
97022	Application of whirlpool therapy	A
97032	Application of electrical stimulation with therapist present, each 15 minutes	A
97033	Application of medication using electrical current, each 15 minutes	A
97034	Application of hot and cold baths, each 15 minutes	A
97035	Application of ultrasound, each 15 minutes	A
97110	Therapy procedure using exercise to develop strength, endurance, range of motion, and flexibility, each 15 minutes	A
97112	Therapy procedure to re-educate brain-to-nerve-to-muscle function, each 15 minutes	A
97113	Therapy procedure using water pool to exercises, each 15 minutes	A
97116	Therapy procedure for walking training, each 15 minutes	A
97140	Therapy procedure using manual technique, each 15 minutes	A
97530	Therapy procedure using functional activities	A
97533	Therapy procedure using sensory experiences	A
97535	Training for self-care or home management, each 15 minutes	A
97537	Training for community or work reintegration, each 15 minutes	A
97542	Evaluation for wheelchair, each 15 minutes	A
G0283	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care	A

Note: Status code A = Active code – separately paid under the PFS. Status code I = Invalid code – not valid for Medicare purposes.

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

As discussed in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. See further details and full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006) and CY 2021 PFS final rule (85 FR 84502) and in 42 CFR 410.78 and 414.65.

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

a. Changes 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 (42 CFR 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 other clinical benefits that we consider 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 signs or symptoms.
  - Reduced recovery time.
- *Category 3:* In the CY 2021 PFS final rule (85 FR 84507), we created a third category of criteria for adding services to the Medicare Telehealth Services List on a temporary basis following the end of the public health emergency (PHE) for the COVID–19 pandemic. This new category describes services that were added to the Medicare Telehealth Services List during the PHE, for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition under the Category 1 or Category 2 criteria. Services added on a temporary, Category 3 basis will ultimately need to meet the criteria under Category 1 or 2 in order to be permanently added to the Medicare Telehealth Services List. 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. We considered the following factors:

++ Whether, outside of the circumstances of the PHE for COVID–19, there are 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.

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

In the CY 2021 PFS final rule (85 FR 84507), we also temporarily added several services to the Medicare Telehealth Services List using the Category 3 criteria described above. In this proposed rule, we are considering additional requests to add services to the Medicare Telehealth Services List on a Category 3 basis using the previously described Category 3 criteria. 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*.

Beginning in CY 2019, we stated that for CY 2019 and onward, we intend to accept requests through February 10, consistent with the deadline for our receipt of code valuation recommendations from the RUC (83 FR 59491). For CY 2024, requests to add services to the Medicare Telehealth Services List must have been submitted and received by February 10, 2023. 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 2024

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 also note that section 4113 of Division FF, Title IV, Subtitle A of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328, December 29, 2022) extends the telehealth policies enacted in the Consolidated Appropriations Act, 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022) through December 31, 2024, if the PHE ends prior to that date, as discussed in section II.D.c. of this proposed rule.

We received several requests to permanently add various services to the Medicare Telehealth Services List effective for CY 2024. We found that none of the requests we received by the February 10th submission deadline met our Category 1 or Category 2 criteria for permanent addition to the Medicare Telehealth Services List. The requested services are listed in Table 9.

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TABLE 9: CY 2024 Requests for Permanent Addition – Services Not Proposed for Permanent Addition to the Medicare Telehealth Services List

Service Type	HCPCS	Long Descriptor
Cardiovascular Procedures	93793	Anticoagulant management for a patient taking warfarin, must include review and interpretation of a new home, office, or lab international normalized ratio (INR) test result, patient instructions, dosage adjustment (as needed), and scheduling of additional test(s), when performed
Cardiovascular and Pulmonary Rehabilitation	93797	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)
	94625	Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; without continuous oximetry monitoring (per session)
Deep Brain Stimulation	95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
	95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional
	95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)
Therapy	90901	Biofeedback training by any modality
	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)
	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 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

Service Type	HCPCS	Long Descriptor
		measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.
Therapy	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.
	97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes
	97750	Physical performance test or measurement (eg, musculoskeletal, functional capacity), with written report, 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
Hospital Care, Emergency Department and Hospital	99221	Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.
	99222	Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 55 minutes must be met or exceeded.
	99223	Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 75 minutes must be met or exceeded.
	99234	Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.
	99235	Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 70 minutes must be met or exceeded.
	99236	Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 85 minutes must be met or exceeded.
	99238	Hospital inpatient or observation discharge day management; 30 minutes or less on the date of the encounter
	99239	Hospital inpatient or observation discharge day management; more than 30 minutes on the date of the encounter
	99281	Emergency department visit for the evaluation and management of a patient that may not require the presence of a physician or other qualified health care professional
	99282	Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making
	99283	Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making
Health and Well-Being Coaching	0591T	Health and well-being coaching face-to-face; individual, initial assessment
	0592T	Health and well-being coaching face-to-face; individual, follow-up session, at least 30 minutes
	0593T	Health and well-being coaching face-to-face; group (2 or more individuals), at least 30 minutes

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We remind interested parties that the criterion for adding services to the Medicare telehealth list under Category 1 is that the requested services are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare Telehealth Services List, and that the criterion for adding services under Category 2 is that there is evidence of clinical benefit if provided as telehealth. As explained below, we find that none of the requested services listed in Table 9 1 met the Category 1 criterion.

(1) Cardiovascular Procedures

We received a request to permanently add CPT code 93793 *(Anticoagulant management for a patient taking warfarin, must include review and interpretation of a new home, office, or lab international normalized ratio (INR) test result, patient instructions, dosage adjustment (as needed), and scheduling*

of additional test(s), when performed)) to the Medicare Telehealth Services List. We do not consider this service to be a Medicare telehealth service, because the service is not an inherently face-to-face service—a patient need not be present in order for the service to be furnished in its entirety. For example, in many instances, clinical staff will not change a patient's warfarin dosage as a result of the lab INR test result, and they may or may not confirm the need for a follow-up test via phone; either way there is no need for a face-to-face encounter with a practitioner. As we have explained in previous rulemaking (83 FR 59483), certain 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 section 1834(m) of the Act and do not usually include patient interaction such as the remote interpretation of diagnostic tests. We do not consider CPT code 93793 to be a telehealth service under section 1834(m) of the Act or our regulation at § 410.78. Therefore, we are not proposing to add this service to the Medicare Telehealth Services List on a Category 1 basis.

(2) Cardiovascular and Pulmonary Rehab

We received multiple requests to permanently add the following CPT codes to the Medicare Telehealth Services List:

- 93797 (*Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)*); and
- 94624 *(Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; without continuous oximetry monitoring (per session)).*

In the CY 2022 PFS final rule (86 FR 65048), we explained that some services were added temporarily to the Medicare Telehealth Services List on an emergency basis to allow practitioners and beneficiaries to have access to medically necessary care while avoiding both risk for infection and further burdening healthcare settings during the PHE for COVID–19. In the same rule, we considered available evidence and noted that as evidence evolves on this subject matter, we welcome further discussions with interested parties on the topic. In subsequent cycles of annual rulemaking, we have continued conversations with interested parties that furnish, support, and use Cardiovascular and Pulmonary Rehabilitation services. In our CY 2022 PFS final rule (86 FR 65055), we acknowledged that commenters provided a number of studies on the safety and efficacy of these services when furnished via telehealth, and we added the codes to the list on a temporary, Category 3 basis.

We note that some evidence submissions and ongoing discussions with interested parties have focused on the clinical benefits of patients receiving these services in the home. We note that, while demonstrating the clinical benefits of services is important to our decision whether to add a service to the Medicare Telehealth Services List, there are other considerations when deciding whether to add codes to the list on a permanent basis. For example, while the CAA, 2023, does extend certain COVID–19 PHE flexibilities, including allowing the beneficiary's home to serve as an originating site, such flexibilities are only extended through the end of CY 2024. Under current law, beginning on January 1, 2025, the beneficiary's home can be an originating site only for Medicare telehealth services furnished for: (1) the diagnosis, evaluation, or treatment of a mental health disorder; or (2) a beneficiary with a diagnosed substance use disorder (SUD) for purposes of treatment of the SUD or a co-occurring mental health disorder; or (3) monthly ESRD-related clinical assessments furnished to a beneficiary who is receiving home dialysis, beginning January 1, 2025. Therefore, in the absence of further action by Congress, CPT codes 93797 and 94626 will not be able to be furnished via telehealth to a beneficiary in the home beginning January 1, 2025. As such, we are not proposing to include these services permanently on the Medicare Telehealth Services List on a Category 1 basis. We are instead proposing to continue to include these services on the Medicare Telehealth Services List through CY 2024. We would then remove CPT codes 93797 and 94626 from the Medicare Telehealth Services List for CY 2025.

(3) Deep Brain Stimulation

We received a request to permanently add the following CPT codes to the Medicare Telehealth Services List:

- 95970 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming*);
- 95983 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional*); and
- 95984 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)*).

In our CY 2023 proposed rule (85 FR 45891), we explained that these services do not meet the Category 1 criterion for permanent addition to the Medicare Telehealth Services List. Additionally, we discussed concerns about whether the full scope of service elements could be furnished via two-way, audio-video communication technology, particularly since it is unclear whether the connection between the implanted device and the analysis/calibration equipment can be done remotely. Additionally, we are concerned about the immediate safety of the patient if the calibration of the neurostimulator were done incorrectly or if some other problem occurred. However, we did include these services on the Medicare Telehealth Services List on a temporary basis during the PHE to allow additional time for additional information to be gathered and presented. Based on this information, we believe there is some possible clinical benefit for these services when furnished via telehealth; however, there is not yet sufficient evidence available to consider the services for permanent addition under

the Category 2 criterion. We are proposing to keep these services on the Medicare Telehealth Services List for CY 2024. We would consider additional evidence in future rulemaking to determine whether to add the services to the Medicare Telehealth Services List on a permanent basis.

(4) Therapy

We received requests to add Therapy Procedures: CPT codes 97110, 97112, 97116; Physical Therapy Evaluations: CPT codes 97161–97164; Therapy Personal Care services: CPT code 97530; and Therapy Tests and Measurements services: CPT codes 97750, 97763 and Biofeedback: 90901, to the Medicare Telehealth Services List on a Category 1 or 2 basis. We have considered these codes over several years, in multiple cycles of annual rulemaking. In the CY 2017 final rule (81 FR 80198), we first assessed a request to add CPT codes 97110, 97112, and 97116 (the therapy codes) to the Medicare Telehealth Services List. We did not add the codes to the Medicare Telehealth Services List at the time, because there was no emergency waiver providing an exception to the requirements under section 1834(m)(4)(E) of the Act, and physical therapists, occupational therapists, and speech-language pathologists were not eligible telehealth practitioners. In the CY 2018 final rule (82 FR 53008 and 53009), we reiterated our initial assessment that the codes were not appropriate to add to the Medicare Telehealth Services List, because the majority of the therapy codes listed above are furnished over 90 percent of the time by therapy professionals who are not included on the list of distant site practitioners who can furnish telehealth services at section 1834(m)(4)(E) of the Act. We stated that 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 (82 FR 53009).

Section 3703 of Division A, Title III, Subtitle D of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, enacted March 27, 2020) amended section 1135(b)(8) of the Act to give the Secretary emergency authorities to waive or modify Medicare telehealth payment requirements under section 1834(m) of the Act during the PHE for COVID–19. Using this authority, CMS issued a set of emergency waivers that included waiving the restrictions in section 1834(m)(4)(E) of the Act on the types of practitioners who may furnish telehealth services. This allowed for therapy professionals to furnish telehealth services for the duration of the PHE. In the CY 2022 final rule (86 FR 65051), we reviewed another round of submissions requesting that CMS add therapy codes to the Medicare Telehealth Services List, and we again determined that these codes did not meet the Category 1 criterion for addition to the list. In the CY 2023 PFS final rule (87 FR 69451), through our review of evidence that was submitted by interested parties in support of adding these services to the Medicare Telehealth Services List on a Category 2 basis, we concluded that there was not sufficient information to determine whether all of the necessary elements of these services could be furnished remotely.

In reviewing this year's request, the evidence submission includes evidence similar to what was submitted last year, with a few new additions suggesting that some elements of the individual services may have clinical benefit when furnished via telehealth, but not resolving uncertainty about whether other elements of the services can be fully furnished remotely via telehealth. The evidence submitted also suggests that receiving therapy services via telehealth in the home may offer some practical benefits, such as use of actual stairs in therapy exercise instead of artificial stairs, or meal preparation instructions focused on available kitchen tools and equipment. However, the evidence submitted for review leaves open questions as to whether such differences in the setting of care translate to a clinical benefit that is more than minor or incidental, in typical circumstances for the typical population of beneficiaries who may receive therapy services via telehealth.

We note that for any submission, including submissions received for these therapy services, we consider all elements of a service as described by a particular HCPCS code and apply our review criteria to the specific code. While some submitted information may focus on an individual service within one specific clinical scenario, and furnished within one specific individual model of care delivery, that information may not be generalizable to the varied settings and scenarios under which the service would be typically furnished via telehealth. We reiterate that available evidence should give a reasonable degree of certainty that all elements of the service could fully and effectively be furnished by a remotely-located clinician using two-way, audio/video telecommunications technology.

Based on the evidence we reviewed, we continue to question whether the findings from therapy studies that focused on a specific clinical issue for a narrow population (for example, joint replacement of a specific joint) translate to clinical benefit for some or many of the various other clinical issues that would typically be addressed when therapists furnish therapy services via telehealth to beneficiaries. Despite the evidence, we are still uncertain as to whether all of the elements of a therapy service could typically be furnished through use of only real-time, two-way audio/video communications technology. Because we continue to have these questions, we are not proposing to add these services to the Medicare Telehealth Services List on a Category 1 or 2 basis, for the same reasons described in our CY 2018 through CY 2023 rulemaking cycles. Also, we continue to believe that adding these therapy services to the Medicare Telehealth Services List permanently would potentially generate confusion. As discussed in last year's final rule, we note that we do not have authority to expand the list of eligible Medicare telehealth practitioners to include therapists (PTs, OTs, or SLPs) after CY 2024 (87 FR 69449 through 69451). We note that the CAA, 2023, did not permanently change the list of practitioners who can furnish and bill for telehealth services; rather, the CAA, 2023, extended the current telehealth flexibilities through the end of CY 2024. That said, we are proposing to keep these therapy services on the Medicare Telehealth Services List until the end of CY 2024. We will consider any further action with regard to these codes in future rulemaking.

(5) Hospital Care, Emergency Department and Hospital

We received a request to permanently add the following CPT codes to the Medicare Telehealth Services List:

- 99221 (*Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.*)
- 99222 (*Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the*

encounter for code selection, 55 minutes must be met or exceeded.)
- 99223 (*Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 55 minutes must be met or exceeded.*)
- 99234 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*)
- 99235 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 70 minutes must be met or exceeded.*)
- 99236 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 85 minutes must be met or exceeded.*)
- 99238 (*Hospital inpatient or observation discharge day management; 30 minutes or less on the date of the encounter*)
- 99239 (*Hospital inpatient or observation discharge day management; more than 30 minutes on the date of the encounter*)
- 99281 (*Emergency department visit for the evaluation and management of a patient that may not require the presence of a physician or other qualified health care professional*)
- 99282 (*Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making*)
- 99283 (*Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making*)

In the March 31, 2020 interim final rule with comment period (IFC–1) (85 FR 19234), we added the above services to the Medicare Telehealth Services List on a Category 2 basis for the duration of the PHE for COVID–19, for telehealth services with dates of service beginning March 1, 2020 through the end of the PHE (including any renewals of the PHE). 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 to the Medicare Telehealth Services List on a Category 1 basis, but did not receive or identify information that allowed us to determine whether these services should be added on a Category 2 basis (CY 2017 PFS final rule, at 81 FR 80194 to 80197). We reiterate that, while we do not believe the context of the PHE for COVID–19 changes the assessment of whether these services meet the Category 1 criterion, we reassessed all of these services to determine whether they meet the criteria for inclusion on the Medicare Telehealth Services List 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, in-person interaction between professionals and patients posed an immediate potential risk that would not have been present when we previously reviewed these services in 2017. This risk created a unique circumstance where health care professionals needed to weigh the risks associated with disease exposure. For further background, in the CY 2021 final rule (FR 84506 through 84509), we explained the reasoning and considerations necessary for assigning a Category 3 status to certain codes that were added to the Medicare Telehealth Services List on a temporary basis during the PHE for COVID–19. We believe that some risk of COVID–19 remains, but also remain uncertain that available evidence gives clear support for continuing to include these services on a permanent basis under the Category 2 criterion.

As discussed in the CY 2023 PFS final rule (86 FR 69450), we believe these hospital and emergency department services may continue to be furnished safely via two-way, audio-video communication technology. We are not proposing to add these services to the list on a permanent basis at this time, but we are proposing that they would remain available on the Medicare Telehealth Services List through CY 2024.

(6) Health and Well-Being Coaching

We received a request to permanently add the following three Health and Well-being Coaching services to the Medicare Telehealth Services List:
- CPT code 0591T (*Health and well-being coaching face-to-face; individual, initial assessment*);
- CPT code 0592T (*Health and well-being coaching face-to-face; individual, follow-up session, at least 30 minutes*); and
- CPT code 0593T (*Health and well-being coaching face-to-face; group (2 or more individuals), at least 30 minutes*).

We are not proposing to add these health and well-being coaching services to the Medicare Telehealth Services List on a permanent basis, but we are proposing to add them to the list on a temporary basis for CY 2024. The evidence included in the submitter's request notes that these codes are similar to others already available on the Medicare Telehealth Services List. Further, it appears that all elements of these services may be furnished when using two-way interactive communications technology to replace the face-to-face elements of the service. The submission, which contained two published metanalyses of literature on the clinical topic and an additional pre-publication meta-analysis that focuses on outcomes and benefits of the delivery of virtual health and well-being coaching, leaves some open questions as to whether Medicare beneficiaries would receive meaningful clinical benefit from receiving virtual-only health and well-being coaching. While the evidence is clearly evolving, it does suggest that these services could possibly meet Category 2 criteria for inclusion on the Medicare Telehealth Services List as more evidence builds. We also note that the published meta-analyses in the submission make clear that further study is necessary for a broader range of medical professionals, because conceptual articles and research and existing practice articles focus on nurses, but are sparse or silent about other general categories of medical professionals. As a reminder, we would expect that any evidence in support of adding these codes on a permanent basis should also establish clinical benefit when delivered directly by or under the supervision of the types of professionals who are Medicare telehealth practitioners. The metanalyses demonstrate that health

coaching only requires a few hours of training, and few articles submitted to CMS discuss the intensity of health coach training at all. The pre-publication metanalysis submitted for review draws less than definitive conclusions about ''potential benefits'' of health and well-being coaching and hedges that authors, ''did not find evidence of long-term benefit, possibly due to the paucity of studies examining longer-term outcomes. We caution that the certainty in the evidence for the majority of outcomes was either very low or low, primarily due to high risk of bias, heterogeneity, and impression.'' The submission and its content are sufficient to serve as a basis for adding the codes to the Medicare Telehealth Services List on a temporary basis, and we appreciate the thoughtful and transparent way the submission lays out gaps in available evidence. More time is needed to potentially close these gaps. We are not aware of any evidence to suggest that it would be inappropriate to assign a temporary status. Therefore, we are proposing to add the services to the Medicare Telehealth Services List on a temporary basis.

(7) CMS Proposal To Add New Codes to the List

In addition to the health and wellbeing coaching services submitted as requests, we are proposing to add HCPCS code GXXX5 (*Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment tool, 5–15 minutes*) to the Medicare Telehealth Services List. Our proposal to add HCPCS code GXXX5 to the list is contingent upon finalizing the service code description that we propose in section II.E of this proposed rule. We refer readers to the proposal in section II.E for further background. We are proposing that HCPCS code GXXX5, if finalized as proposed, receive a permanent status on the Medicare Telehealth Services List. One element of the service describes a face-to-face encounter between the clinician and beneficiary. Practitioners use clinical judgement to determine whether to complete the SDOH screening with or without direct patient interaction. Because the service description, as defined in section II.E. of this proposed rule, expects that a patient encounter may be necessary for accurate and complete screening, we believe that this element of the service describes an inherently face-to-face clinical activity. Further, the use of two-way interactive audio-video technology, as a substitute to in-person interaction, means an analogous level of care, in that using either modality would not affect the accuracy or validity of the results gathered via a standardized screening tool. As discussed in section II.E. of this proposed rule, we are proposing that this service must be furnished by the practitioner on the same date they furnish an E/M visit, as the SDOH assessment would be reasonable and necessary when used to inform the patient's diagnosis, and treatment plan established during the visit. Therefore, we believe it describes a service that is sufficiently similar to services currently on the Telehealth list, specifically E/M services, and that this service be added on a permanent basis.

c. Proposed Clarifications and Revisions to the Process for Considering Changes to the Medicare Telehealth Services List

1. Overview

In CY 2020, CMS issued an array of waivers and new flexibilities for Medicare telehealth services to respond to the serious public health threats posed by the spread of COVID–19 (85 FR 19230). Our goal was to give individuals and entities that provide services to Medicare beneficiaries needed flexibilities to respond effectively to the serious public health threats posed by the spread of COVID–19. Recognizing the urgency of this situation and understanding that some pre-existing Medicare payment rules (including the statutory restrictions on telehealth originating sites and telehealth practitioners) needed to be modified in order to allow patients and practitioners to have access to necessary care while mitigating the risks from COVID–19, we used waiver and regulatory authorities to change certain Medicare payment rules during the PHE for COVID–19 so that physicians and other practitioners, home health and hospice providers, inpatient rehabilitation facilities, rural health clinics (RHCs), and federally qualified health centers (FQHCs) would be allowed broad flexibilities to furnish services using remote communications technology to avoid exposure risks to health care providers, patients, and the community.

In 2003, as required by section 1834(m)(4)(F)(ii), we established a process for adding or deleting services from the Medicare Telehealth Services List, which included consideration under two categories of criteria (Categories 1 and 2) (67 FR 79988). We finalized revisions to the Category 2 review criterion in the CY 2012 PFS final rule (76 FR 73102). Prior to CY 2020, CMS had not added any service to the Medicare Telehealth Services List on a temporary basis. In CY 2020, in response to the PHE for COVID–19, we revised the criteria for adding or removing services on the Medicare Telehealth Services List using a combination of emergency waiver authority and interim final rule making, so that some services would be available for the duration of the PHE on a ''temporary Category 2 basis.'' (85 FR 19234). In the CY 2021 PFS final rule (85 FR 84507), we created a third, temporary category for services included on the Medicare Telehealth Services List on a temporary basis. This new Category 3 includes many, but not all of the services that we added temporarily to the Medicare Telehealth Services List during the COVID–19 PHE. Specifically, we reviewed the services we added temporarily in response to the COVID–19 PHE and identified those for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to add the services as permanent additions to the list. Services added to the Medicare Telehealth Services List on a temporary, Category 3 basis will ultimately need to meet the Category 1 or 2 criteria in order to be added to the Medicare Telehealth Services List on a permanent basis.

Between CY 2020 and CY 2023, we added many services to the Medicare Telehealth List on a temporary basis during the PHE, and through rulemaking, we also added many of these services on a Category 3 basis. Subsequent requests and evidence submitted to CMS supported possible status changes for some of the services that are currently included on the Medicare Telehealth Services List on a Category 3 basis. However, submissions sometimes confused our use of waiver authority and regulatory flexibilities tied to the COVID–19 PHE which allow us to temporarily add services to the Medicare Telehealth Services List through the end of the PHE, with the generally applicable categories and criteria we use to consider changes to the Medicare Telehealth Services List outside the circumstances of the COVID–19 PHE. Now that the PHE for COVID–19 has ended, we intend to clarify and modify our process for making changes to the Medicare Telehealth Services List. We believe these clarifications will help address potential confusion among interested parties that submit requests for additions to the Medicare Telehealth List stemming from the distinction between services that were added to the telehealth list on the basis of COVID–19 PHE-related authorities versus services that were added temporarily on a

Category 3 basis, which does not rely on any PHE-related authority. Specifically, we created the Category 3 basis for considering changes in the Medicare Telehealth Services List as part of the process we are required to establish under section 1834(m)(4)(F)(2) for considering changes to the list in part because, with the significant expansion of remotely-furnished services in response to the COVID–19 PHE, we recognized the emergence of new data suggesting that there may be clinical benefit when certain services are delivered via telehealth, but more time is needed to develop additional evidence to support potential addition of the services on a permanent, Category 1 or Category 2 basis. Under Category 3, services are added to the list on a temporary basis to allow them to continue to be furnished via telehealth while additional evidence is developed.

In brief, throughout the COVID–19 PHE, we have reviewed all requests to add services to the Medicare Telehealth Services List and assessed whether the services in question should be added to the list, temporarily or permanently, under any of the criteria for Category 1, 2, or 3. Further, we did not reject any submissions from interested parties simply because they requested consideration under a specific category, and the submitted data did not support adding the service to the Medicare Telehealth Services List on that basis. Instead, we considered whether the service(s) should be added to the Medicare Telehealth Services List on any basis.

To avoid potential continuing confusion among those who submit requests to add services to the Medicare Telehealth Services List, and as we consider the expiration of the Medicare telehealth flexibilities extended by the CAA, 2023 through the end of CY 2024, we believe it would be beneficial to simplify our current taxonomy and multicategory approach to considering submitted requests. Further, we believe that simplification toward a binary classification approach could address the confusion we have noticed from interested parties submitting requests during the PHE. Our proposal would restore the simple binary that existed with Category 1 and 2, without displacing or disregarding the flexibility of Category 3. We propose to simply classify and consider additions to the Medicare Telehealth Services List as either permanent, or provisional.

At bottom, to consider a request to add a service to the Medicare Telehealth Services List, we need evidence that supports how the telehealth service is either clinically equivalent to a telehealth service already permanently on the list, or evidence that presents studies where findings suggest a clinical benefit sufficient for the service to remain on the list to allow time for confirmative study. We reemphasize the need for clinical evidence because that evidence serves as the principal basis for our consideration of a request; and it is sometimes missing from submissions we receive.

For example, we have received some submissions requesting the addition of services to the Medicare Telehealth Services List that are essentially framed as position papers advocating for changes in statutory requirements of section 1834(m) of the Act. While we do give such requests due consideration, the omission of clinical evidence to support the addition of a service to the Medicare Telehealth Services List using our established criteria generally leads us to conclude that the service should not be proposed for addition to the list. A fair and consistent review process for any and all submissions relies on a standard application of uniform, repeatable procedures for any individual submission, just as sound evidence should describe repeatable methods and replicable findings. Submissions that rely on narrative arguments for changes in the substantive requirements do not fit within such a fair and consistent review process. Therefore, we believe the following restatement of requirements and our review process is appropriate. We also propose some procedural refinements to the review process, specifically incorporating additional considerations into our evaluation of services, that we believe would serve to maintain scope and focus in a post-PHE context. We discuss these proposed changes in detail in the following section.

Section 1834(m)(4)(F)(ii) of the Act requires that the Secretary establish a process that provides, on an annual basis, for the addition or deletion of services (and HCPCS codes), to the definition of telehealth services for which payment can be made when furnished via telehealth under the conditions specified in section 1834(m). As specified at § 410.78(f), with the exception of a temporary policy that was limited to the PHE for COVID–19, we make changes to the list of Medicare telehealth services through the annual physician fee schedule rulemaking process. The proposed revisions to our current permanent policies, specifically our proposed assignment of a ''permanent'' or ''provisional'' status to a service and changes in status as described below, reflect the stepwise method by which we propose to consider future requests to add services to, remove services from, or change the status of, services on the Medicare Telehealth Services List, beginning for the CY 2025 Medicare Telehealth Services List, which will include submissions received no later than February 10, 2024.

2. Proposed Steps of Analysis for Services Under Consideration for Addition, or Removal, or a Change in Status, as Updates to the Medicare Telehealth Services List

Step 1. Determine whether the service is separately *payable under the PFS.*

When considering whether to add, remove, or change the status of a service on the Medicare Telehealth Services List, we are proposing to first determine whether the service, as described by the individual HCPCS code, is separately payable under the PFS. Under section 1834(m)(1) of the Act, Medicare telehealth services are limited to those for which payment can be made to the physician or practitioner when furnished using an interactive telecommunications system notwithstanding that the practitioner furnishing the services is not in the same location as the beneficiary; and under section 1834(m)(2)(A) of the Act, Medicare pays the same amount for a telehealth service as if the service is furnished in person. As such, Medicare telehealth services are limited to those services for which separate Medicare payment can be made under the PFS. Thus, through Step 1, we would answer the threshold question of whether a service is separately payable under the PFS. During the PHE, many submissions for addition to the Medicare Telehealth Services List advocated for CMS to change the definition of ''Medicare telehealth service'' for their specific service; some of those submissions were for services that were not separately payable under the PFS.[2] (87 FR 69449). We anticipate that Step 1, if finalized, will encourage submissions that focus on a separately payable PFS service, and that the evidence included with those submissions will show how use of interactive, two-way, audio/video telecommunications technology allows a practitioner to complete an entire, specific service, described by a HCPCS

[2] Services on the Medicare Telehealth List are used in the definition of Medicare telehealth. Some submissions may have conflated the distinction. Step 1 clarifies. Refer to the CMS website instructions for a Request for Addition at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Addition.*

code, that is equivalent to an in-person service.

We recognize that certain codes that had non-payable or bundled (not separately payable) status under the PFS before the PHE for COVID–19 were temporarily included on the Medicare Telehealth Services List to facilitate access to health care services during the PHE. However, the PHE for COVID–19 has now expired.

We believe that proposed Step 1, if finalized, would lessen the administrative burden of our telehealth services review process for both CMS and the public. We note that before gathering evidence and preparing to submit a request to add a service to the Medicare Telehealth Services List, the submitter should first check the payment status for a given service and ensure that the service (as identified by a HCPCS code), is a covered and separately payable service under the PFS (as identified by payment status indicators A, C, T, or R on our public use files). For a full list of all PFS payment status indicators and descriptions, see the Medicare Claims Processing Manual (IOM Pub. 100–04, chapter 23, section 30.2.2) and the Addendum for the MPFSDB File Record Layout. Researchers and others preparing submissions should also refer to the data dictionaries available at *https://resdac.org/cms-data/files/carrier-ffs/data-documentation*, to review whether the methodology and conclusions contained in supporting evidence, or a submission itself, applies an appropriate methodology to study both individual services and individuals that are representative of the Medicare population.

We further propose that, if we find that a service identified in a submission is not separately payable under the PFS, we would not conduct any further review of that service. We would identify the code submitted for consideration and explain that we are not proposing it for addition. CMS sends confirmation from *CMS_telehealthreview@cms.hhs.gov* when we receive a submission requesting addition of a service to, removal of a service from, or a change in status for a service included on, the Medicare Telehealth Services List. We are proposing to inform each submitter in the confirmation whether the submission was complete, lacking required information, or outside the scope of issues we consider under the process for considering changes in the Medicare Telehealth Services List. We note that we also expect submissions to include copies of any source material used to support assertions, which has been the longstanding direction included in our website instructions. For further background, refer to details available on our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Addition*.

Step 2. Determine whether the service is subject to the provisions of section 1834(m) of the Act.

If we determine at Step 1 that a service is separately payable under the PFS, we propose to apply Step 2 under which we would determine whether the service at issue is subject to the provisions of section 1834(m) of the Act. A service is subject to the provisions of section 1834(m) of the Act when at least some elements of the service, when delivered via telehealth, are a substitute for an in-person, face-to-face encounter, and all of those face-to-face elements of the service are furnished using an interactive telecommunications system as defined in § 410.78(a)(3). The aim of this step is to determine whether the service is, in whole or in part, inherently a face-to-face service. As we discussed in the CY 2018 PFS final rule (83 FR 59483), it has long been the case that certain services that are furnished remotely using communications technology are not considered Medicare telehealth services and are not subject to the requirements of section 1834(m) of the Act. We are proposing Step 2 to emphasize the circumstances under which the criteria under section 1834(m) of the Act apply, and also highlight circumstances in which the criteria under section 1834(m) of the Act do not apply. As previously noted, section 1834(m) of the Act provides for payment to a physician or practitioner for a service furnished via an interactive telecommunications system notwithstanding that the furnishing practitioner and patient are not in the same location at the same amount that would have been paid if the service was furnished without the telecommunications system. We read this to mean that the scope of section 1834(m) of the Act is limited to services that would ordinarily be furnished with the furnishing practitioner and patient in the same location.

Our application of Step 2 remains consistent with longstanding policy. We reiterate that there is a range of services delivered using certain telecommunications technology that do not fall within the scope of Medicare telehealth services, though they are separately payable under the PFS. Such services generally include services that do not require the presence of, or involve interaction with, the patient (for example, remote interpretation of diagnostic imaging tests, and certain care management services). Other examples include virtual check-ins, e-visits, and remote patient monitoring services which involve the use of telecommunications technology to facilitate interactions between the patient and practitioner, but do not serve as a substitute for an in-person encounter, for example, to assess whether an in-person or telehealth visit is needed or to transmit health information to the practitioner.

In determining whether a service is subject to the provisions of section 1834(m) of the Act, we will consider whether one or more of the elements of the service, as described by the particular HCPCS code at issue, ordinarily involve direct, face-to-face interaction between the patient and practitioner such that the use of an interactive telecommunications system to deliver the service would be a substitute for an in-person visit. For interested parties preparing a request to add a service to the Medicare Telehealth Services List, we believe this Step 2 clarifies that a service must be inherently a face-to-face service. We believe reframing this Step 2 has the practical advantage of refining and improving consistency. We do not believe it would be appropriate to add a service to the Medicare Telehealth Services List if it is not subject to section 1834(m) of the Act. We would explain our finding in notice and comment rulemaking.

Step 3. Review the elements of the service as described by the HCPCS code and determine whether each of them is capable of being furnished using an interactive telecommunications system as defined in § 410.78(a)(3).

We believe that the proposed Step 3 is fundamental to our commitment to health equity, as this step could have a beneficial impact on access to care for vulnerable populations. Step 3 is corollary to Step 2, and used to determine whether one or more elements of a service are capable of being delivered via an interactive telecommunication system as defined in § 410.78(a)(3). In Step 3, we consider whether one or more face-to-face component(s) of the service, if furnished via audio-video communications technology, would be equivalent to the service being furnished in-person, and we seek information from submitters to demonstrate evidence of substantial clinical improvement in different beneficiary populations that may benefit from the requested service when furnished via telehealth, including, for example, in rural populations. The services are not equivalent when the

clinical actions, or patient interaction, would not be of similar content as an in-person visit, or could not be completed. We note that completing each element of the defined service is a different question than whether a beneficiary receives any benefit at all from the telehealth-only form of a candidate service. The practical basis for Step 3 mirrors the practical basis for proposed Step 1 and 2, which is a consistent application of review criteria. Many submissions that CMS received during the PHE lacked evidence indicating that some or all elements of a service could be completed using an interactive telecommunications system without still requiring an in-person interaction with a patient to furnish the complete service. We note that studies of patient satisfaction alone, and submissions with an excessive focus on patient satisfaction alone, present risks of bias in many ways, possibly complicating or obfuscating the question of whether it is possible, or potentially safe, to deliver an inherently face-to-face service via telehealth. Step 3 is integral to avoiding the possible unintended consequences of creating new gaps in care when telehealth is used as a substitute for in-person care.

Step 4. Consider whether the service elements of the requested service map to the service elements of a service on the list that has a permanent status described in previous final rulemaking.

The purpose of the proposed Step 4 of our analysis is to simplify and reduce the administrative burden of submission and review. For Step 4, we are proposing to consider whether the service elements of a code that we are considering for addition to, or removal from, the Medicare Telehealth Services List map to the service elements of a service that is already on the list and has a permanent status, because any code that satisfies this criterion would require no further analysis: if a code describes a service that maps to the service elements of a code that is included on the Medicare Telehealth Services List on a permanent basis, we would add the code to the Medicare Telehealth Services List on a permanent basis.

We note that section 1834(m)(4)(F)(i) of the Act defines telehealth services as professional consultations, office visits, and office psychiatry services (as identified as of July 1, 2000, by HCPCS codes 99241–99275, 99201–99215, 90804–90809, and 90862 (and as subsequently modified by the Secretary)), and any additional service specified by the Secretary. Over the years, CMS has assigned Category 1 (permanent) status to services that were either included in the list of codes specified in section 1834(m)(4)(F)(i) of the Act or added as successor codes to those enumerated by statute. Successor codes are updates to or replacements for the codes listed in section 1834(m)(4)(F)(i) of the Act. Therefore, this proposed step would ensure that CMS includes successor codes on the Medicare Telehealth Services List. We note that even if a code that we are considering for addition to the Medicare Telehealth Services List is not a successor code, we would consider whether the service described in the submission is similar to professional consultations, office visits, and office psychiatry services that are already on the Medicare Telehealth Services List on a permanent basis. While we have not previously found that the elements of service we are considering for addition to the list map to the elements of a service that was previously added to the list on a permanent basis using the Category 2 criteria, we believe that it would be appropriate to apply this step 4 analysis to compare the candidate service with *any permanent code that is on the list on a permanent basis.* As such, in step 4, we propose to maintain any previous analytical determinations from Steps 1 through 3 and directly map the successor code to a code on the list that has a permanent status described in previous final rulemaking. For example, if a code currently categorized as a finalized Category 2 permanent code was replaced or revised by a successor code in a future year, CMS would ensure that these revisions did not change the Step 1–3 results and add the successor code under Step 4. For example, in a future year, if a code that would otherwise exist under the current categories as a finalized Category 2 permanent code, and was subsequently replaced or revised by a successor code, CMS would ensure any revisions did not alter results under Steps 1–3, and add the successor code using this Step 4. We further propose that if we find that the service we are considering satisfies Step 4, we would end our review and propose to add the service to the Medicare Telehealth Services List on a permanent basis in the next PFS proposed rule. When Step 4 is met, further evidence review is not necessary. If Step 4 is not met, then we propose to continue to Step 5.

Step 5. Consider whether there is evidence of clinical benefit analogous to the clinical benefit of the in-person service when the patient, who is located at a telehealth originating site, receives a service furnished by a physician or practitioner located at a distant site using an interactive telecommunications system.

Similar to Steps 3, 4, and 5 above, the purpose of the proposed step 5 is to simplify and reduce the administrative burden. Under proposed Step 5, we would review the evidence provided with a submission to determine the clinical benefit of a service. We would then compare the clinical benefit of that service, when provided via telehealth, to the clinical benefit of the service if it were to be furnished in person. Proposed Step 5 would continue the existing standard that we have applied when considering whether to add a code to the Medicare Telehealth Services List on a Category 2 basis. We further propose that: if there is enough evidence to suggest that further study may demonstrate that the service, when provided via telehealth, is of clinical benefit, CMS would assign the code a ''provisional'' status on the Medicare Telehealth Services List. Where the clinical benefit of a service, when provided via telehealth, is clearly analogous to the clinical benefit of the service when provided in person, CMS would assign the code ''permanent'' status on the Medicare Telehealth Services List, even if the code's service elements do not map to the service elements of a service that already has permanent status.

We remind readers that our evidentiary standard of demonstrated clinical benefit does not include minor or incidental benefits (81 FR 80194), and if finalized, our proposal would not alter or displace this longstanding requirement. We will review the evidence submitted by interested parties, and other evidence that CMS has on hand. The evidence should indicate that the service can be safely delivered using two-way interactive audio-video communications technology. Clinical practice guidelines, peer-reviewed literature, and similar materials, should illustrate specifically how the methods and findings within the material establish a foundation of support that each element of the defined, individual service described by the existing face-to-face service code has been studied in the typical setting of care, typical population of beneficiaries, and typical clinical scenarios that practitioners would encounter when furnishing the service using only interactive, two-way audio-video communications technology to complete the visit or encounter with Medicare beneficiaries. This analysis is fundamental to either of the current Category 1 or Category 2 descriptions.

General evidence may also answer the question of whether a certain

beneficiary population requiring care for a specific illness or injury may benefit from receiving a service via telehealth versus receiving no service at all, but must establish that the service is a substitute for an equivalent in-person service. Evidence should demonstrate how all elements described by the individual service code can be met when two-way, interactive audio-video communications technology is used as a complete substitute for any face-to-face interaction required between the patient and practitioner that are described in the individual code descriptor. We further remind readers that submissions reflecting practitioner services furnished to Medicare beneficiaries are helpful in our considerations.

Proposed Assignment of ''permanent'' or ''provisional'' Status to a Service and Changes in Status.

We are proposing to assign ''permanent'' or ''provisional'' status to any services for which the service elements map to the service elements of a service on the list that has a permanent status described in previous final rulemaking (see proposed step 4) or for which there is evidence of clinical benefit analogous to the clinical benefit of the in-person service when the service is furnished via telehealth by an eligible Medicare telehealth physician or practitioner (see proposed steps 5). These two designations (that is, ''permanent'' or ''provisional'') are intended to replace the Category 1–3 taxonomy that CMS currently uses. This proposed change is intended to reduce confusion regarding the status of codes on the Medicare Telehealth Services List and to simplify the outcome of our analysis. After a code receives the ''provisional'' status, as evidence generation builds, we may assign ''permanent'' status in a future year or we may remove the service from the list in the interest of patient safety based on findings from ongoing monitoring of telehealth services within CMS and informed by publicly available information. We would revisit provisional status through our regular annual submissions and rulemaking processes where a submission provides new evidence, or our claims monitoring shows anomalous activity, or as indicated by patient safety considerations. CMS would handle changes in status by revisiting the same steps 1 through 5 above.

Summary and Request for Feedback on Proposals To Update the Process of Review for Adding, Removing, or Changing the Status of Services on the Medicare Telehealth List

We note that the timeline for our proposed process to analyze submissions would remain the same. CY 2025 submissions would be due by February 10, 2024. Additionally, we would continue to address each submitted request for addition, deletion, or modification of services on the Medicare Telehealth Services List through annual notice and comment rulemaking.

As the end of the PHE for COVID–19 was uncertain at the time of last year's rule, many of the submissions for both CY 2023 and CY 2024 involved requests to change the status of services on the Medicare Telehealth Services List from temporary to permanent. In other words, many requestors asked CMS to consider changing the status of one or more services from Category 3 to Category 1 or 2. Based on the number of requests we received asking that CMS assign a different status to a given service, we believe a clarification is necessary to remind readers of the steps that we take when analyzing a given service for addition to, removal from, or a change in status on the Medicare Telehealth Services List. This proposal intends to refine our process and reduce confusion going forward.

To reiterate some of our discussion above, our proposals are consistent with the existing principles that CMS has applied to requests to add, remove, or change the status of a code during the COVID–19 PHE. When reviewing submissions during the PHE, in the absence of evidence supporting clinical benefit, but public comment expressing support for possible clinical benefit, CMS would generally accept a temporary addition to the Medicare Telehealth Services list, allowing more time for evidence generation. We anticipate that our approach would generally remain consistent with this particular point of flexibility if this proposal is finalized; a code could potentially receive provisional status on the Medicare Telehealth Services List in such a situation, with the caveat that our proposed Steps 1, 2, and 3, are thresholds for inclusion on the Medicare Telehealth Services List. If CMS finds that a service is not separately payable under the PFS (see proposed step 1) or it is not subject to section 1834(m) of the Act (see proposed Step 2), that service would not be added to the Medicare Telehealth Services List on any basis (and notice of the rejection would be provided to the submitter, as noted above). We do not intend to reject a submission based solely on the fact that the requestor did not request the appropriate basis for consideration; we would still analyze the submission based on the proposed steps, and then we would propose to add, remove, or change the status of the service, or we would explain why we were not doing so.

We are soliciting comments on our proposed analysis procedures for additions to, removals from, or changes in status for services on the Medicare Telehealth Services List.

d. Consolidation of the Categories for Services Currently on the Medicare Telehealth Services List

We are also proposing to consolidate Categories 1, 2, and 3, as proposed above, for all services that are currently on the Medicare Telehealth Services List. For CY 2024, we are proposing to redesignate any services that are currently on the Medicare Telehealth Services List on a Category 1 or 2 basis and would be on the list for CY 2024 to the proposed new ''permanent,'' category while any services currently added on a ''temporary Category 2'' or Category 3 basis would be assigned to the ''provisional'' category. We believe that redesignations in this calendar year would help ease confusion in future years, including in the event that there is subsequent legislation regarding Medicare telehealth services.

Further, for a code that receives provisional status, as evidence generation builds, we may grant the code a permanent status in a future year or remove the service from the list in the interest of patient safety based on findings from ongoing monitoring of telehealth services within CMS and informed by publicly available information. We propose not to set any specific timing for reevaluation of services added to the Medicare Telehealth Services List on a provisional basis because evidence generation may not align with a specific timeframe. Our proposal not to establish any specific timing for considering changes from provisional to permanent status would avoid a potential situation in which we must remove provisional services from the Medicare Telehealth Services List because the set period tolls, only to later find evidence demonstrating that the removed service should receive permanent status. Under our proposal, we would assign a provisional status for codes that satisfy the proposed threshold steps (1, 2, and 3), and then the evidence available leaves a ''close call'' between permanent

and provisional status. We do not assign provisional status when it is improbable that the code would ever achieve permanent status.

e. Implementation of Provisions of the CAA, 2023

(1) Overview and Background

The CAA, 2022 included several provisions that extend certain Medicare telehealth flexibilities adopted during the COVID–19 PHE for 151 days after the end of the PHE. Specifically, sections 301 through 305 of Division P, Title III, Subtitle A of the CAA, 2022 amended section 1834(m) of the Act to generally extend certain PHE-related telehealth policies for services that were on the Medicare Telehealth Services List as of the date of enactment (March 15, 2021). The CAA, 2022, temporarily removed restrictions on telehealth originating sites for those services to allow telehealth services to patients located in any site in the United States at the time of the telehealth service, including an individual's home; expanded the definition of telehealth practitioners to include qualified occupational therapists, qualified physical therapists, qualified speech-language pathologists, and qualified audiologists; continued payment for telehealth services furnished by FQHCs and RHCs using the methodology established for those telehealth services during the PHE; delayed the requirement for an in-person visit with the physician or practitioner within 6 months prior to initiating mental health telehealth services to a beneficiary in their home, and again at subsequent intervals as the Secretary determines appropriate, as well as similar requirements for RHCs and FQHCs; and continued to provide for payment of telehealth services included on the Medicare Telehealth Services List as of the March 15, 2020, that are furnished via an audio-only telecommunications system. A full discussion of these policies available in the CY 2023 PFS final rule at 87 FR 69462.

In addition, section 309 of the CAA, 2022 authorized the Secretary to implement the amendments described above, made by sections 301 through 305, through program instruction or otherwise. In the CY 2023 PFS final rule (87 FR 69446), we finalized specific telehealth policies to conform to and align with amendments made by the CAA, 2022. In our CY 2023 PFS final rule (87 FR 69462–69464), we described how CMS would issue program instructions to implement specific requirements of the CAA, 2022. We also implemented the provisions enacted in the CAA, 2022 for a 151-day extension period of certain telehealth flexibilities (discussed previously in this proposed rule). On December 29, 2022, the President signed the CAA, 2023 into law. Section 4113 of the CAA, 2023 further extends the previously-extended PHE-related telehealth policies; it requires CMS to extend the telehealth flexibilities that were previously extended (initially for 151 days after the end of the PHE) under the CAA, 2022, through December 31, 2024.

We seek to address various telehealth policies that we finalized in the CY 2023 final rule, in light of the CAA, 2023. For example, the 151-day extension period for certain flexibilities discussed in our CY 2023 final rule (and previously in this proposed rule) no longer applies, since section 4113 of the CAA, 2023 extends these flexibilities until December 31, 2024 (the extended flexibilities include: temporary expansion of the scope of telehealth originating sites for services furnished via telehealth to include any site in the United States where the beneficiary is located at the time of the telehealth service, including an individual's home; expansion of the definition of eligible telehealth practitioners to include qualified occupational therapists, qualified physical therapists, qualified speech-language pathologists, and qualified audiologists; continued payment for telehealth services furnished by FQHCs and RHCs using the methodology established for those telehealth services during the PHE; delaying the requirement for an in-person visit with the physician or practitioner within 6 months prior to initiating mental health telehealth services, and again at subsequent intervals as the Secretary determines appropriate, as well as similar requirements for RHCs and FQHCs; and continued coverage and payment of telehealth services included on the Medicare Telehealth Services List as of March 15, 2020) until December 31, 2024. Both the CAA, 2022 and CAA, 2023 have the same operative effect on the scope of Medicare telehealth services; both the CAA, 2022 and CAA, 2023 give the Secretary the authority to implement the relevant telehealth provisions outside of notice and comment rulemaking through program instruction or otherwise. We intend to implement the provisions discussed above, as enacted by the CAA, 2023.

Similar to the goals of our telehealth policies addressed in last year's final rule, for CY 2024, we again seek to retain payment stability, reduce confusion and burden, and conform to all statutory requirements without unnecessary restrictions on beneficiaries' access to telehealth care. Our discussion here does not alter payment amounts or billing rules that are in effect as of January 1, 2023, and those policies will remain in effect through December 31, 2024. Instead, it is our intent in this proposed rule to clarify that certain telehealth flexibilities that were previously extended until 151 days after the end of the PHE, by the CAA, 2022, have been extended until December 31, 2024, in accordance with the amendments made by provisions of the CAA, 2023.

(2) In-Person Requirements for Mental Health Telehealth

Section 4113(d)(1) of section FF, Title IV, Subtitle B of the CAA, 2023 amends section 1834(m)(7)(B)(i) of the Act to delay the requirement for an in-person visit with the physician or practitioner within 6 months prior to the initial mental health telehealth service, and again at subsequent intervals as the Secretary determines appropriate. In light of this amendment, the in-person requirements for telehealth services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder will again be effective on January 1, 2025. In addition, 4113(d)(2) of Section FF, Title IV, Subtitle B of the CAA, 2023 modified sections 1834(y) and 1834(o)(4) of the Act, respectively, to similarly delay in-person visit requirements for mental health visits furnished by Rural Health Clinics and Federally Qualified Health Centers via telecommunications technology. Therefore, we propose to revise the regulatory text at § 410.78(b)(3)(xiv) and (b)(4)(iv)(D) to recognize the delay of the in-person requirements for mental health visits furnished by RHCs and FQHCs through telecommunication technology under Medicare until January 1, 2025, rather than until the 152nd day after the end of the PHE, to conform with the CAA, 2023. See section III.B. of this proposed rule for our proposal to implement similar changes for RHC and FQHC mental health visits.

(3) Originating Site Requirements

Section 4113(a)(2) of the CAA, 2023 amends section 1834(m)(4)(C)(iii) of the Act to temporarily expand the telehealth originating sites for any service on the Medicare Telehealth Services List to include any site in the United States where the beneficiary is located at the time of the telehealth service, including an individual's home, beginning on the first day after the end of the PHE for COVID–19 through December 31, 2024. We would not issue any program

instructions or proposals to limit or modify telehealth originating sites for CY 2023 or CY 2024. The list of telehealth originating sites remains as listed in our regulation at § 410.78(b)(3).

(4) Telehealth Practitioners

Section 4113(b) of the CAA, 2023 amends section 1834(m)(4)(E) of the Act to require that qualified occupational therapists, qualified physical therapists, qualified speech-language pathologists, and qualified audiologists continue to be included as telehealth practitioners beginning on the first day after the end of the PHE for COVID–19 through December 31, 2024. Therefore, the list of telehealth practitioners remains as described in our CY 2023 final rule. We will also recognize marriage and family therapists (MFT) and mental health counselors (MHC) as telehealth practitioners, effective January 1, 2024, in accordance with amendments made by section 4121 of the CAA, 2023. That section of the CAA, 2023 amends section 1861(s)(2) of the Act by adding a new subparagraph (II) that establishes a new benefit category under Part B for marriage and family therapist services (as defined in section 1861(lll)(1)) of the Act and mental health counselor services (as defined in section 1861(lll)(3) of the Act). Further, section 4121(a)(5) of the CAA, 2023 amended section 1842(b)(18)(C) of the Act to add MFTs and MHCs to the list of practitioners to whom Medicare payment may be made for their services on a reasonable charge or fee schedule basis only on an assignment-related basis. Because the definition of practitioners in section 1834(m)(4)(E) of the Act for purposes of Medicare telehealth services includes the practitioners described in section 1842(b)(18)(C) of the Act, this provision also has the effect of adding MFTs and MHCs as practitioners who can furnish telehealth services.

We are proposing to amend § 410.78(b)(2) to add new paragraphs (xi) and (xii) to specify that a marriage and family therapist as described in proposed § 410.53 and a mental health counselor as described in proposed § 410.54 are included as distant site practitioners for purposes of furnishing telehealth services.

(5) Audio-Only Services

Section 4113(e) of Division FF, Title IV, Subtitle C of the CAA, 2023 amends section 1834(m)(9) of the Act to require that the Secretary shall continue to provide for coverage and payment of telehealth services via an audio-only communications system during the period beginning on the first day after the end of such emergency period and ending on December 31, 2024. This provision applies only to telehealth services specified on the Medicare Telehealth Services List under section 1834(m)(4)(F)(i) of the Act that are permitted to be furnished via audio-only technology as of the date of enactment of the CAA, 2023 (that is, December 29, 2022).

e. Place of Service for Medicare Telehealth Services

When a physician or practitioner submits a claim for their professional services, including claims for telehealth services, they include a Place of Service (POS) code that is used to determine whether a service is paid using the facility or non-facility rate. Under the PFS, there are two payment rates for many physicians' services: the facility rate, which applies when the service is furnished in hospital or skilled nursing facility (SNF) setting, and the non-facility rate, which applies when the service is furnished in an office or other setting. The PFS non-facility rate is the single geographically adjusted fee schedule amount paid to a physician or other practitioner for services furnished in their office or other non-facility outpatient setting. The PFS facility rate is the single, geographically adjusted amount paid to a physician or other practitioner when a service is furnished in a hospital or SNF setting where Medicare is making a separate payment for the services to the facility in addition to the payment to the billing physician or practitioner for their professional services. This separate payment to the facility (hospital or SNF), often referred to as a ''facility fee,'' is made under other payment systems and reflects the facility's costs associated with the service (clinical staff, supplies, equipment, overhead) and is paid in addition to what is paid to the professional under the PFS.

Prior to CY 2017, Medicare telehealth services were reported using the GT modifier. In the CY 2017 PFS final rule, we finalized creation of a new Place of Service (POS) code to identify services furnished as Medicare telehealth services, POS ''02'' (81 FR 80199–80201). In the CY 2022 PFS final rule, we created a new POS code ''10'' to identify Medicare telehealth services for which the patient's home is the originating site (87 FR 70110 and 70111).

In response to the PHE for COVID–19, we adopted temporary policies for POS codes and PFS payment rates applicable to Medicare telehealth services. As discussed in the March 31, 2020 IFC, (85 FR 19230), we stated that, as physician practices suddenly transitioned a potentially significant portion of their services from in-person to telehealth visits in the context of the PHE for COVID–19, the relative resource costs of furnishing these services via telehealth may not significantly differ from the resource costs involved when these services are furnished in-person. Therefore, we instructed physicians and practitioners who billed for Medicare telehealth services to report the POS code that they would have reported had the service been furnished in-person. This would allow our systems to make appropriate payment for services furnished via Medicare telehealth, which, if not for the PHE for COVID–19, would have been furnished in-person, at the same rate they would have been paid if the services were furnished in-person. In order to effectuate this change, we finalized on an interim basis (85 FR 19233) the use of the CPT telehealth modifier, modifier ''95'', for the duration of the PHE for COVID–19, which is applied to claim lines that describe services furnished via telehealth; and that the practitioner should report the POS code where the service would have occurred had it not been furnished via telehealth. This allowed telehealth services to be paid at the PFS non-facility rate.

We further noted that we were maintaining the facility payment rate for services billed using the general telehealth POS code ''02'', should practitioners choose to maintain their current billing practices for Medicare telehealth during the PHE for COVID–19. In the CY 2023 PFS final rule (87 FR 69467), we finalized that we would continue to maintain payment at the rate for a service had the service been furnished in person, and that this would allow payments to continue to be made at the non-facility based rate for Medicare telehealth services through the latter of the end of CY 2023 or the end of the calendar year in which the PHE ends.

In the CY 2023 PFS final rule (87 FR 69467), we finalized that, following the end of the end of the calendar year in which the PHE, practitioners will no longer bill claims with Modifier '95' along with the POS code that would have applied had the service been furnished in person, and telehealth claims will instead be billed with the POS indicators:

- POS ''02''—is redefined as Telehealth Provided Other than in Patient's Home (Descriptor: The location where health services and health related services are provided or received, through telecommunication technology. Patient is not located in their home

when receiving health services or health related services through telecommunication technology.); and

• POS ''10''—Telehealth Provided in Patient's Home (Descriptor: The location where health services and health related services are provided or received through telecommunication technology. Patient is located in their home (which is a location other than a hospital or other facility where the patient receives care in a private residence) when receiving health services or health related services through telecommunication technology.).

We recognize that, throughout the PHE for COVID–19, behavioral health services that otherwise would have been furnished in-person have been furnished via telehealth in the patient's home. With few exceptions, prior to the PHE for COVID–19, originating sites were limited to sites such as physician's offices and hospitals. Now that behavioral health telehealth services may be furnished in a patient's home, which would then serve as an originating site, we believe these behavioral health services are most accurately valued the way they would have been valued without the use of telecommunications technology, namely in an office setting. There was an increase in utilization of these mental health services during the PHE that has persisted throughout and after expiration of the PHE for COVID–19. It appears that practice patterns for many mental health practitioners have evolved, and they are now seeing patients in office settings, as well as via telehealth. As a result, these practitioners continue to maintain their office presence even as a significant proportion of their practice's utilization may be comprised of telehealth visits. As such, we believe their practice expenses (PEs) are more accurately reflected by the non-facility rate.

Therefore, we are proposing that, beginning in CY 2024, claims billed with POS 10 (Telehealth Provided in Patient's Home) be paid at the non-facility PFS rate. When considering certain practice situations (such as in behavioral health settings, where practitioners have been seeing greater numbers of patients via telehealth), practitioners will typically need to maintain both an in-person practice setting and a robust telehealth setting. We expect that these practitioners will be functionally maintaining all of their PEs, while furnishing services via telehealth. When valuing services, we believe that there are few differences in PE when behavioral health services are furnished to a patient at home via telehealth as opposed to services furnished in-person (that is, behavioral health settings require few supplies relative to other healthcare services). Claims billed with POS 02 (Telehealth Provided Other than in Patient's Home) will continue to be paid at the PFS facility rate beginning on January 1, 2024, as we believe those services will be furnished in originating sites that were typical prior to the PHE for COVID–19, and we continue to believe that, as discussed in the CY 2017 PFS final rule (81 FR 80199 through 80201), the facility rate more accurately reflects the PE of these telehealth services; this applies to non-home originating sites such as physician's offices and hospitals. In this way, we believe we would be protecting access to mental health and other telehealth services by aligning with telehealth-related flexibilities that were extended via the CAA, 2023, as we will be more accurately recognizing the resource costs of behavioral health providers, given shifting practice models.

f. Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations

When adding some services to the Medicare Telehealth Services List in the past, we have included certain restrictions on how frequently a service may be furnished via Medicare telehealth. These limitations include a limit of once every 3 days for subsequent inpatient visits, added in in the CY 2011 PFS final rule (75 FR 73317 through 73318), and once every 14 days for subsequent nursing facility (NF) visits, added in the CY 2016 final rule (80 FR 71062) furnished via Medicare telehealth and a limit of once per day for critical care consultation services; in establishing these limits, we cited concerns regarding the potential acuity of these patients. End-stage renal disease (ESRD)-related clinical assessments may be furnished via telehealth, subject to the frequency limitations in section 1881(b)(3)(B) of the Act, which provides that patients must receive a face-to-face visit, without the use of telehealth, at least monthly in the case of the initial 3 months of home dialysis and at least once every 3 consecutive months after the initial 3 months.

In the March 31, 2020 COVID–19 IFC (85 FR 19241), we stated that as it was our assessment that there was a patient population who would otherwise not have had access to clinically appropriate in-person treatment, and we did not believe these frequency limitations were appropriate or necessary under the circumstances of the PHE. Therefore, we removed the frequency restrictions for certain subsequent inpatient visits, subsequent NF visits, and for critical care consultations furnished via Medicare telehealth for the duration the PHE for COVID–19. The frequency limitations resumed effect beginning on May 12, 2023, (upon expiration of the PHE), in accordance with the March 31, 2020 IFC. However, we stated that, pursuant to waiver authority added under section 1135(b)(8) of the Act by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020,[3] we were exercising enforcement discretion and will not consider these frequency limitations through December 31, 2023; and that we anticipated considering our policy further through our rulemaking process. As discussed below, we are proposing to once again remove these telehealth frequency limitations beginning CY 2024. We are proposing to remove the telehealth frequency limitations for the following codes:

1. Subsequent Inpatient Visit CPT Codes:

• 99231 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. when using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.*);

• 99232 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. when using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.*); *and*

• 99233 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. when using total time on the date of the encounter for code selection, 50 minutes must be met or exceeded.*)

2. Subsequent Nursing Facility Visit CPT Codes:

• 99307 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward*

[3] *https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf.*

medical decision making. When using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.);

• 99308 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.*);

• 99309 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.*); and

• 99310 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*)

3. Critical Care Consultation Services: HCPCS 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.*)

We are proposing to remove the frequency limitations for these codes for the duration of CY 2024, which will align with other telehealth-related flexibilities extended by the CAA, 2023. CMS is broadly assessing our telehealth regulations, in light of the way practice patterns may have changed in the roughly 3 years of the PHE for COVID–19 and, while we engage in this assessment, we believe it is reasonable to pause certain pre-pandemic restrictions, such as these frequency limitations, to allow us to gather more information. We are seeking information from interested parties on how practitioners have been ensuring that Medicare beneficiaries receive subsequent inpatient and nursing facility visits, as well as critical care consultation services since the expiration of the PHE.

2. Other Non-Face-to-Face Services Involving Communications Technology Under the PFS

a. Direct Supervision via Use of Two-Way Audio/Video Communications Technology

Under Medicare Part B, certain types of services, including diagnostic tests, services incident to physicians' or practitioners' professional services, and other services, are required to be furnished under specific minimum levels of supervision by a physician or practitioner. For most services furnished by auxiliary personnel incident to the services of the billing physician or practitioner (see § 410.26) and many diagnostic tests (see § 410.32), direct supervision is required. Additionally, for pulmonary rehabilitation services (see § 410.47) and for cardiac rehabilitation and intensive cardiac rehabilitation services (see § 410.49), direct supervision by a physician, PA, NP, or CNS is required (see also § 410.27(a)(1)(iv)(B)(*1*) for hospital outpatient services). Outside the circumstances of the PHE, direct supervision requires the immediate availability of the supervising physician or other practitioner, but the professional need not be present in the same room during the service. We have established this ''immediate availability'' requirement to mean in-person, physical, not virtual, availability (please see the April 6, 2020 IFC (85 FR 19245) and the CY 2022 PFS final rule (86 FR 65062)). Through the March 31, 2020 COVID–19 IFC, we changed the definition of ''direct supervision'' during the PHE for COVID–19 (85 FR 19245 through 19246) as it pertains to supervision of diagnostic tests, physicians' services, and some hospital outpatient services, to allow the supervising professional to be immediately available through virtual presence using two-way, real-time audio/video technology, instead of requiring their physical presence. In the CY 2021 PFS final rule (85 FR 84538 through 84540), we finalized continuation of this policy through the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021. In the March 31, 2020 IFC (85 FR 19246) and in our CY 2022 PFS final rule (see 85 FR 65063), we also noted that the temporary exception to allow immediate availability for direct supervision through virtual presence facilitates the provision of Medicare telehealth services by clinical staff of physicians and other practitioners' incident to their own professional services. This is especially relevant for services such as physical therapy, occupational therapy, and speech language pathology services, since those practitioners were previously only able to bill Medicare for telehealth services under Medicare telehealth waivers that were effective during the PHE for COVID–19 (based on the emergency waiver authority established in section 1135(b)(8) of the Act), until the CAA, 2023 extended the time period during which these practitioners could bill for Medicare telehealth services through December 31, 2024. We noted that sections 1834(m)(4)(D) and (E) of the Act specify the types of clinicians who may furnish and bill for Medicare telehealth services. After December 31, 2024, the types of clinicians who may furnish and bill for Medicare telehealth services include only physicians as defined in section 1861(r) of the Act and practitioners described in section 1842(b)(18)(C) of the Act. We note that this will include mental health counselors (MHCs) and marriage and family therapists (MFTs) beginning January 1, 2024.

We noted in the CY 2021 PFS final rule (85 FR 84539) 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; this was the case during the PHE, and will continue to be the case following the PHE. Under current policy as described in the CY 2021 final rule (85 FR 84539 and 84540, after December 31, 2023, the pre-PHE rules for direct supervision at § 410.32(b)(3)(ii) would apply. As noted in the CY 2022 PFS final rule (86 FR 65062), this means the temporary exception allowing immediate availability for direct supervision through virtual presence, which facilitates the provision of telehealth services by clinical staff of physicians and other practitioners incident to their professional services, will no longer apply after CY 2023.

We are concerned about an abrupt transition to our pre-PHE policy that defines direct supervision under § 410.32(b)(3)(ii) to require the physical presence of the supervising practitioner beginning after December 31, 2023, given that practitioners have established new patterns of practice during the PHE for COVID–19. In the absence of evidence that patient safety is

compromised by virtual direct supervision, we believe that an immediate reversion to the pre-PHE definition of direct supervision would prohibit virtual direct supervision, which may present a barrier to access to many services, such as those furnished incident-to a physician's service. We believe physicians and practitioners will need time to reorganize their practice patterns established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology. Recognizing these concerns, we are proposing continue to define direct supervision to permit the presence and ''immediate availability'' of the supervising practitioner through real-time audio and visual interactive telecommunications through December 31, 2024. We believe that extending this definition of direct supervision through December 31, 2024, would align the timeframe of this policy with many of the previously discussed PHE-related telehealth policies that were extended under provisions of the CAA, 2023. We are proposing to revise the regulatory text at § 410.32(b)(3)(ii) to state that, through December 31, 2024, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

We believe this additional time will allow us further opportunity to collect information through the coming year as we consider an appropriate more permanent approach to direct supervision policy following the PHE for COVID–19. We are soliciting comment on whether we should consider extending the definition of direct supervision to permit virtual presence beyond December 31, 2024. Specifically, we are interested in input from interested parties on potential patient safety or quality concerns when direct supervision occurs virtually; for instance, if virtual direct supervision of certain types of services is more or less likely to present patient safety concerns, or if this flexibility would be more appropriate for certain types of services, or when certain types of auxiliary personnel are performing the supervised service. We are also interested in potential program integrity concerns such as overutilization or fraud and abuse that interested parties may have in regard to this policy.

One potential approach to direct supervision which we could consider for future rulemaking, could be to extend or permanently establish this virtual presence flexibility for services that are valued under the PFS based on the presumption that they are nearly always performed in entirety by auxiliary personnel. Such services would include any service wholly furnished incident to a physician or practitioner's professional service, as well as the Level I office or other outpatient evaluation and management visit for established patients and the Level I Emergency Department visit. Allowing virtual presence for direct supervision of these services may balance patient safety concerns with the interest of supporting access and preserving workforce capacity for medical professionals while considering potential quality and program integrity concerns. We are soliciting comment on this potential approach for CY 2025, as well as any other approaches by which direct supervision could occur virtually that would both protect patient access and safety, as well as quality of care and program integrity concerns following CY 2024.

(1) Supervision of Residents in Teaching Settings

In the CY 2021 PFS final rule (85 FR 84577 through 84584), we established a policy that, after the end of the PHE for COVID–19, teaching physicians may meet the requirements to be present for the key or critical portions of services when furnished involving residents through audio/video real-time communications technology (virtual presence), but only for services furnished in residency training sites that are located outside of an Office of Management and Budget (OMB)-defined metropolitan statistical area (MSA). We made this location distinction consistent with our longstanding interest to increase beneficiary access to Medicare-covered services in rural areas and noted the ability to expand training opportunities for residents in rural settings. For all other locations, we expressed concerns that continuing to permit teaching physicians to bill for services furnished involving residents when they are virtually present, outside the conditions of the PHE for COVID–19, may not allow the teaching physician to have personal oversight and involvement 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 addition, we stated concerns about patient populations that may require a teaching physician's experience and skill to recognize specialized needs or testing, and whether it is possible for the teaching physician to meet these clinical needs while having a virtual presence for the key portion of the service. For a more detailed description of our specific concerns, we refer readers to the CY 2021 PFS final rule (85 FR 84577 through 84584). At the end of the PHE for COVID–19, and as finalized in the CY 2021 PFS final rule, we intended for the teaching physician to have a physical presence during the key portion of the service personally provided by residents in order to be paid for the service under the PFS, in locations that were within a MSA. This policy applies to all services, regardless of whether the patient was co-located with the resident or only present virtually (for example, the service was furnished as a 3-way telehealth visit, with the teaching physician, resident, and patient in different locations). However, interested parties have expressed concerns regarding the requirement that the teaching physician have a physical presence with the resident when a service is furnished virtually within a MSA (that is, as a Medicare telehealth service). Some interested parties have stated that during the PHE for COVID–19, when residents provided telehealth services and the teaching physician was virtually present, the same safe and high-quality oversight was provided as when the teaching physician and resident were physically co-located. In addition, these interested parties have stated that during telehealth visits, the teaching physician was virtually present during the key and critical portions of the telehealth service, available immediately in real-time, and had access to the electronic health record. As stated in section II.D.2.a. of this proposed rule, we are concerned that an abrupt transition to our pre-PHE policy may present a barrier to access to many services, and we understand that practitioners have gained clinical experience during the PHE for COVID–19, and could identify circumstances for which the teaching physician can routinely render sufficient personal and identifiable services to the patient, with a virtual presence during the key portion of the telehealth service. Given these considerations and in alignment with the telehealth policies that were extended under the provisions of the CAA, 2023, we are proposing to allow the teaching physician to have a virtual presence in all teaching settings, only in clinical instances when the service is furnished virtually (for example, a 3-way telehealth visit, with all parties in separate locations). This would permit teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service for which payment is sought, through audio/video real-time communications technology,

for all residency training locations through December 31, 2024. The virtual presence policy would continue to require real-time observation (not mere availability) by the teaching physician, and excludes audio-only technology. The documentation in the medical record must continue to demonstrate whether the teaching physician was physically present or present through audio/video real-time communications technology at the time of the telehealth service, this includes documenting the specific portion of the service for which the teaching physician was present through audio/video real-time communications technology. This policy does not preclude teaching physicians from providing a greater degree of involvement in services furnished with residents, and teaching physicians should still use discretion to determine whether it is appropriate to have a virtual presence rather than in person, depending on the services being furnished and the experience of the particular residents involved.

We announced that we are exercising enforcement discretion to allow teaching physicians in all residency training sites, to be present through audio/video real-time communications technology, for purposes of billing under the PFS for services they furnish involving residents. We are exercising this enforcement discretion through December 31, 2023, as we consider our virtual presence policies for services involving teaching physicians and residents further through our rulemaking process for CY 2024. For more background we refer readers to *https://www.cms.gov/files/document/frequently-asked-questions-cms-waivers-flexibilities-and-end-covid-19-public-health-emergency.pdf*.

We seek comment and information to help us consider how telehealth services can be furnished in all residency training locations beyond December 31, 2024, to include what other clinical treatment situations are appropriate to permit the virtual presence of the teaching physician. Specifically, we anticipate considering various types of teaching physician services, when it is appropriate for the teaching physician and resident to be co-located, and how virtual presence could support patient safety for all patients, particularly at-risk patients. We also invite commenters to provide data or other information on how the teaching physician's virtual presence could continue to support patient safety, while meeting the clinical needs for all patients, and ensure burden reduction without creating risks to patient care or increasing opportunities for fraud.

b. Clarifications for Remote Monitoring Services

(1) Background and Overview

In recent years, we have established payment for two code families that describe certain remote monitoring services: remote physiologic monitoring (RPM) and remote therapy monitoring (RTM).

Remote Physiologic Monitoring

- 99453 (*Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment*);
- 99454 (*Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days*);
- 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
- 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)*).

Remote Therapeutic Monitoring

- 98975 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); initial set-up and patient education on use of equipment*);
- 98976 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days*);
- 98977 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days*);
- 98978 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days*);
- 98980 (*Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes*); and
- 98981 (*Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)*)

In our CY 2018 PFS final rule, we summarized feedback solicited from a comment period aimed at informing new payment policies that would allow for separate payment for remote monitoring services (82 FR 53014). In our CY 2019 PFS final rule (83 FR 59574 to 59576), we established valuations and payment policy for the RPM code family. In our CY 2020 PFS final rule (84 FR 62697–8), we explained that the RPM code family describes chronic care RPM services that involve the collection, analysis, and interpretation of digitally collected physiologic data, followed by the development of a treatment plan and the managing of a patient under the treatment plan. (84 FR 62697). In our CY 2020 PFS final rule, we also discussed that remote monitoring codes would be designated as care management services, which means our rules for general supervision would apply (84 FR 62698). In our CY 2023 PFS final rule, in response to comments, we clarified that RTM or RPM services could be billed concurrently with Chronic Care Management (CCM), Transitional Care Management TCM, Principal Care Management (PCM), Chronic Pain Management (CPM), or Behavioral Health Integration (BHI) (86 FR 69528–69539).

We have received many questions from interested parties about billing scenarios and requests for clarifications on the appropriate use of these codes in general. We believe it is important to share with all interested parties a restatement/clarification of certain policies. We refer readers to the CY 2021 PFS final rule (85 FR 84542 to 84546) for further discussion and explanation of the basis for interim policies that expired on the last day of the PHE for COVID–19.

(2) New vs. Established Patient Requirements

In the CY 2021 PFS final rule (85 FR 84542–6), we established that, when the PHE for COVID–19 ends, we again will require that RPM services be furnished only to an established patient. Patients who received initial remote monitoring services during PHE are considered established patients for purposes of the new patient requirements that are effective after the last day of the PHE for COVID–19.

(3) Data Collection Requirements

We have received various comments and inquiries about our temporary exception to minimum data collection for remote monitoring. As discussed in our CY 2021 final rule, we are not extending beyond the end of the PHE the interim policy to permit billing for remote monitoring codes, which require data collection for at least 16 days in a 30-day period, when less than 16 of days data are collected within a given 30-day period. (85 FR 84542 through 84546). As of the end of the PHE, the 16-day monitoring requirement was reinstated. Monitoring must occur over at least 16 days of a 30-day period. We are proposing to clarify that the data collection minimums apply to existing RPM and RTM code families for CY 2024.

The following remote monitoring codes currently depend on collection of no fewer than 16 days of data in a 30-day period, as defined and specified in the code descriptions:

- 98976 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days*);
- 98977 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days*);
- 98978 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days*);
- 98980 (*Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes*); and
- 98981 (*Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)*)

We remind readers that our discussion in the CY 2021 PFS final rule addresses the interim policy on data collection minimums, and provides notice and the rationale for the data collection policy that is in effect now that the PHE for COVID–19 has ended. Remotely monitored monthly services should be reported only once during a 30-day period—and only when reasonable and necessary. As a clarification for either RPM or RTM, only one practitioner can bill CPT codes 99453 and 99454, or CPT codes 98976, 98977, 98980, and 98981, during a 30-day period, and only when at least 16 days of data have been collected on at least one medical device as defined in section 201(h) of the FFDCA.

We reiterate our analysis described in the CY 2021 PFS final rule, in which we explained that CPT code descriptor 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 (85 FR 84545). We refer readers to our CY 2021 PFS final rule (85 FR 84545) for additional background.

(4) Use of RPM, RTM, in Conjunction With Other Services

Practitioners may bill RPM or RTM, but not both RPM and RTM, concurrently with the following care management services: CCM/TCM/BHI, PCM, and CPM. These various codes, which describe other care management services, may be billed with RPM or RTM, for the same patient, if the time or effort is not counted twice. As specified in the CY 2023 PFS final rule, if all requirements to report each service are met, without time or effort being counted more than once, RPM or RTM (not both RPM and RTM) may be billed in conjunction with any one of CCM, TCM, BHI, PCM, or CPM codes. According to the 2023 CPT Codebook (pg. 849), CPT code 98980 (*RTM treatment management*) cannot be reported in conjunction with CPT codes 99457/99458 (*RPM treatment management*). Our intention is to allow the maximum flexibility for a given practitioner to select the appropriate mix of care management services, without creating significant issues of possible fraud, waste, and abuse associated with overbilling of these services. We continue to gain experience with each family of remote monitoring codes, and request feedback from commenters that would provide additional context that could inform us as we continue to develop and clarify our payment policies for these services.

We propose to clarify that RPM and RTM may not be billed together, so that no time is counted twice by billing for concurrent RPM and RTM services. In instances where the same patient receives RPM and RTM services, there may be multiple devices used for monitoring, and in these cases, we will to apply our existing rules, which we finalized when establishing the RPM code family, meaning that the services associated with all the medical devices 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; and that the services must be reasonable and necessary (85 FR 84544 through 84545).

(5) Other Clarifications for Appropriate Billing

We have received inquiries from interested parties during public forums regarding use of remote monitoring during global periods for surgery. We are proposing to clarify that, in circumstances where an individual beneficiary may receive a procedure or surgery, and related services, which are covered under a payment for a global period, RPM services or RTM services (but not both RPM and RTM services concurrently) may be furnished separately to the beneficiary, and the practitioner would receive payment for the RTM or RPM services, separate from the global service payment, so long as other requirements for the global service and any other service during the global period are met. For an individual beneficiary who is currently receiving services during a global period, a practitioner may furnish RPM or RTM services (but not both RPM or RTM services) to the individual beneficiary, and the practitioner will receive separate payment, so long as the remote monitoring services are unrelated to the diagnosis for which the global procedure is performed, and as long as the purpose of the remote monitoring addresses an episode of care that is separate and distinct from the episode of care for the global procedure—meaning that the remote monitoring services address an underlying condition that is not linked to the global procedure or service.

We are soliciting comment on the above proposals and clarifications and request general feedback from the public that may be useful in further development of our payment policies for remote monitoring services that are separately payable under the current PFS.

c. Telephone Evaluation and Management Services

In the March 31st COVID–19 IFC (85 FR 19264 through 19265), we finalized separate payment for CPT codes 99441 through 99443 and 98966 through 98968, which describe E/M and assessment and management services furnished via telephone. CPT codes 99441 through 99443 are telehealth services and will remain actively priced through 2024. CPT codes 98966–98968, however, describe telephone assessment and management services provided by a qualified non-physician healthcare professional, and they are not telehealth services. We are proposing to continue to assign an active payment status to CPT codes 98966 through 98968 for CY 2024 to align with telehealth-related flexibilities that were extended via the CAA, 2023, specifically section 4113(e), which permits the provision of telehealth services through audio-only telecommunications through the end of 2024.

3. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act established the Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001 through December 31, 2002 at $20.00, and specifies that, for telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act. The proposed MEI increase for CY 2024 is 4.5 percent and is based on the expected historical percentage increase of the 2017-based MEI. For the final rule, we propose to update the MEI increase for CY 2024 based on historical data through second quarter of 2023.

Therefore, for CY 2024, the proposed payment amount for HCPCS code Q3014 (*Telehealth originating site facility fee*) is $29.92. Table 10 shows the Medicare telehealth originating site facility fee and the corresponding MEI percentage increase for each applicable time period.

TABLE 10: The Medicare Telehealth Originating Site Facility Fee

Time Period	MEI (%)	Facility Fee for Q3014
Oct. 1, 2001 to Dec. 31, 2002	NA	$ 20.00
2003	3.0	$ 20.60
2004	2.9	$ 21.20
2005	3.1	$ 21.86
2006	2.8	$ 22.47
2007	2.1	$ 22.94
2008	1.8	$ 23.35
2009	1.6	$ 23.72
2010	1.2	$ 24.00
2011	0.4	$ 24.10
2012	0.6	$ 24.24
2013	0.8	$ 24.43
2014	0.8	$ 24.63
2015	0.8	$ 24.83
2016	1.1	$ 25.10
2017	1.2	$ 25.40
2018	1.4	$ 25.76
2019	1.5	$ 26.15
2020	1.9	$ 26.65
2021	1.4	$ 27.02
2022	2.1	$ 27.59
2023	3.8	$ 28.64
2024*	4.5	$ 29.92

*Reflects the most recent estimate of the CY 2024 MEI percentage increase and will be updated in the final rule based on historical data through the second quarter of 2023.

4. Payment for Outpatient Therapy Services, Diabetes Self-Management Training, and Medical Nutrition Therapy When Furnished by Institutional Staff to Beneficiaries in Their Homes Through Communication Technology

a. Background on Outpatient Therapy Services, Diabetes Self-Management Training and Medical Nutrition Therapy

Section 1861(p) of the Act establishes the benefit category for outpatient PT, SLP and OT services, (expressly for PT services and, through section 1861(ll)(2) of the Act, for outpatient SLP services and, through section 1861(g) of the Act, for outpatient OT services). Section 1861(p) of the Act defines outpatient therapy services in the three disciplines as those furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient; and those furnished by a therapist not under arrangements with a provider of services, clinic, rehabilitation agency, or a public health agency. As such, section 1861(p) of the Act defines outpatient therapy services very broadly to include those furnished by providers and other institutional settings, as well as those furnished in office settings. Section 1834(k)(3) of the Act requires payment for outpatient therapy services to be made based on the PFS (via section 1848 of the Act), for all institutional providers listed at sections 1833(a)(8) and (9) of the Act. These providers include clinics, rehabilitation agencies, public health agencies, comprehensive outpatient rehabilitation agencies (CORFs), SNFs, home health agencies (HHAs) (to individuals who are not homebound), hospitals to outpatients or hospital inpatients who are entitled to benefits under part A but have exhausted benefits for inpatient hospital services during a spell of illness or is not so entitled to benefits under part A), and all other CORF services.

Section 1861(qq) of the Act defines Diabetes Self-Management Training (DSMT) services and authorizes CMS to regulate Medicare DSMT outpatient services. A ''certified provider'' of DSMT is further defined in section 1861(qq)(2)(A) of the Act as a physician or other individual or entity designated by the Secretary who meets certain quality requirements described in section 1861(qq)(2)(B) of the Act. In CY 2000, we finalized a standalone rule titled ''Medicare Program; Expanded Coverage for Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements.'' In that rule, we finalized that payment for outpatient DSMT would be made under the PFS (65 FR 83132). We further established that, in the case of payments made to other approved entities, such as hospital outpatient departments, ESRD facilities, and durable medical equipment suppliers, the payment would be equal to the amounts established under the PFS and made under the appropriate payment systems (65 FR 83142).

Section 1861(s)(2)(V) of the Act authorizes Medicare Part B coverage of medical nutrition therapy services (MNT) for certain beneficiaries who have diabetes or a renal disease. In the CY 2000 PFS final rule, we established that payment for MNT services furnished in the institutional setting, including hospital outpatient departments (HOPDs), would be made under the PFS, not under the hospital Outpatient Prospective Payment System (OPPS) (66 FR 55279).

During the PHE for COVID–19, outpatient therapy services, DSMT, and MNT could be furnished via a telecommunications system to beneficiaries in their homes, and bills for these services were submitted and paid either separately or as part of a bundled payment, when either personally provided by the billing practitioner or provided by institutional staff and billed for by institutions, such as HOPDs, SNFs, and HHAs. For professionals, CMS used waiver authority to expand the range of practitioners that can serve as distant site practitioners for Medicare telehealth services as described in section 1834(m)(4)(E) of the Act and § 410.78 (b)(2), as well as to waive the originating site requirements for Medicare telehealth services described in section 1834(m)(4)(C) of the Act. This allowed for outpatient therapy services to be furnished and billed by therapists in private practice, as well as for outpatient therapy services, DSMT, and MNT to be furnished via Medicare telehealth to beneficiaries in urban, as well as rural, areas, including to beneficiaries located in their homes.

When therapists (PTs, OTs and SLPs) were added as distant site telehealth practitioners using waiver authority during the PHE for COVID–19, CMS generally took the position for services furnished in HOPDs that waiver authority was needed to allow hospitals to bill for services furnished by hospital staff through communication technology to beneficiaries in their homes. CMS implemented the Hospitals Without Walls (HWW) policy that relied on waiver authority, which allowed hospitals to reclassify patients' homes as part of the hospital. HWW allowed hospitals to bill two different kinds of fees for services furnished remotely to patients in their homes: (1) hospital facility payment in association with professional services billed under the PFS; and (2) single payment for a limited number of practitioner services, when statute or other applicable rules only allow the hospital to bill for services personally provided by their staff. These services are either billed by hospitals or by professionals, there would not be separate facility and professional billing. This latter category includes outpatient therapy services, DSMT, and MNT. However, while maintaining that waiver authority was needed to allow hospital billing for these services, CMS also issued guidance instructing HOPDs to bill using modifiers consistent with those used for Medicare telehealth services. For further background, we refer readers to *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf*. In the same referenced document, CMS also issued specific guidance for other institutional providers of therapy services to use modifier 95 (indicating a Medicare telehealth service), along with the specific bill types for outpatient therapy services furnished by their staff.

The CAA, 2023 extended many of the flexibilities that were available for Medicare telehealth services during the PHE for COVID–19 under emergency waiver authorities, including adding physical and occupational therapists and speech-language pathologists as distant site practitioners through the end of CY 2024. In developing post-PHE guidance, CMS initially took the position that institutions billing for services furnished remotely by their employed practitioners (where the practitioners do not bill for their own services), would end with the PHE for COVID–19 along with the HWW waivers. However, after reviewing input from interested parties, as well as relevant guidance, including applicable billing instructions, we are considering whether certain institutions, as the furnishing providers, can bill for certain remotely furnished services personally performed by employed practitioners.

b. Proposal To Extend Billing Flexibilities for Certain Remotely Furnished Services Through the End of CY 2024 and Comment Solicitation

While we consider how we might address this ambiguity in future rulemaking, in the interests of maintaining access to outpatient therapy, DSMT, and MNT services furnished remotely by institutional staff

to beneficiaries in their homes consistent with the accessibility of these services when furnished by professionals via Medicare telehealth, we are proposing to continue to allow institutional providers to bill for these services when furnished remotely in the same manner they have during the PHE for COVID–19 through the end of CY 2024. We are seeking comment on current practice for these services when billed, including how and to what degree they continue to be provided remotely to beneficiaries in their homes. We are seeking comment as to whether these services may fall within the scope of Medicare telehealth at section 1834(m) of the Act or if there are other relevant authorities CMS might consider in future rulemaking.

For DSMT specifically, the clinical staff personally delivering the service may be a type of practitioner authorized to furnish Medicare telehealth services under section 1834(m) of the Act; but we also understand that DSMT may be provided by other types of staff. Accordingly, we noted in sub-regulatory guidance that we are exercising enforcement discretion in reviewing the telehealth eligibility status of the practitioner personally providing any part of a remotely furnished DSMT service, so long as the persons were otherwise qualified to provide the service. For more background we refer readers to *https://www.cms.gov/files/document/frequently-asked-questions-cms-waivers-flexibilities-and-end-covid-19-public-health-emergency.pdf*.

As we review our telehealth policies following the end of the PHE for COVID–19, and consider care delivery and beneficiary access concerns raised by practitioners and beneficiary advocates, we are broadly considering billing and payment for telehealth services in institutional settings, including when these services are furnished by practitioners who have reassigned their rights to bill under and receive payment from the Medicare program (billing rights) to an institution. We acknowledge that one such setting where this billing arrangement exists includes Critical Access Hospitals (CAHs), where a practitioner has reassigned their billing rights to the CAH, and CMS makes payment for the practitioner's services under an optional payment method, referred to as CAH method II (Pub. 100–04, Chapter 4, Section 250.2). We note that in situations when a practitioner is furnishing a telehealth service and has reassigned their billing rights to a CAH under Method II, CMS makes payment for the telehealth service at the same rate generally paid for other in-person services (100 percent of the PFS payment amount) rather than the payment amount established under the optional method as discussed in Pub. 100–04, Chapter 4, Section 250.2. We are interested in and are soliciting comment on how telehealth services furnished under CAH method II arrangements are furnished, and whether they would be most accurately characterized in the context of section 1834(m) of the Act or services of the CAH under Method II.

E. 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, CY 2015, and CY 2020. 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 interested parties, 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. Section 1848(c)(1)(A) of the Act specifically defines the work component as the resources that reflect time and intensity 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 interested party reactions to our approach. We note that many commenters and interested parties 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 note that 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 interested parties, 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 interested parties 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.

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 feedback from interested parties, we stated that we would 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. (83 FR 59515) We note that 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 interested parties and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes; and we 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 13 contains a list of codes and descriptors for which are proposing work RVUs for CY 2024; this includes all codes for which we received RUC recommendations by February 10, 2023. The proposed work RVUs, work time and other payment information for all CY 2024 payable codes are available on the CMS website under downloads for the CY 2024 PFS proposed 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 13 details our refinements of the RUC's direct PE recommendations at the code-specific level. In section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units (PE RVUs), we address certain refinements that will be common across codes. Refinements to particular codes are addressed in the portions of that section that are dedicated to particular codes. We note that for each refinement, we indicate the impact on direct costs for that service. We note that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 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.

In this proposed rule, we also note that many of the refinements listed in Table 12 of the proposed rule resulted in changes under the $0.35 threshold and were unlikely to result in a change to the RVUs.

We note that the direct PE inputs for CY 2024 are displayed in the CY 2024 direct PE input files, available on the CMS website under the downloads for the CY 2024 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* The inputs displayed there have been used in developing the CY 2024 PE RVUs as displayed in Addendum B.

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time will 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 noted that we believe these same assumptions will 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 will be available if the room is not being occupied by a particular patient. For additional information, we refer readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of this proposed rule, 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 2024 we received invoices for several new supply and equipment items. Tables 15 and 16 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units, we encourage interested parties to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage interested parties 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 interested parties that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 15 and 16 also include the number of invoices received

and the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that interested parties 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 interested parties 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 interested parties to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we include 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 address code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We note that the list of services for the upcoming calendar year that are subject to the MPPR on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services; and the 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; are displayed in the public use files for the PFS proposed and final rules for each year. The public use files for CY 2024 are available on the CMS website under downloads for the CY 2024 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* For more information regarding the history of the MPPR policy, we refer readers to the CY 2014 PFS final rule with comment period (78 FR 74261 through 74263).

Effective January 1, 2007, section 5102(b)(1) of the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA) amended section 1848(b)(4) of the Act to require that, for imaging services, if—(i) The TC (including the TC portion of a global fee) of the service established for a year under the fee schedule without application of the geographic adjustment factor, exceeds (ii) The Medicare OPD fee schedule amount established under the prospective payment system (PPS) for HOPD services under section 1833(t)(3)(D) of the Act for such service for such year, determined without regard to geographic adjustment under paragraph (t)(2)(D) of such section, the Secretary shall substitute the amount described in clause (ii), adjusted by the geographic adjustment factor [under the PFS], for the fee schedule amount for such TC for such year. As required by the section 1848(b)(4)(A) of the Act, for imaging services furnished on or after January 1, 2007, we cap the TC of the PFS payment amount for the year (prior to geographic adjustment) by the Outpatient Prospective Payment System (OPPS) payment amount for the service (prior to geographic adjustment). We then apply the PFS geographic adjustment to the capped payment amount. Section 1848(b)(4)(B) of the Act defines imaging services as ''imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography.'' For more information regarding the history of the cap on the TC of the PFS payment amount under the DRA (the ''OPPS cap''), we refer readers to the CY 2007 PFS final rule with comment period (71 FR 69659 through 69662).

For CY 2024, we identified new and revised codes to determine which services meet the definition of ''imaging services'' as defined previously in this proposed rule for purposes of this cap. Beginning for CY 2024, we are proposing to include the following services on the list of codes to which the OPPS cap applies: CPT codes 76883 (*Ultrasound, nerve(s) and accompanying structures throughout their entire anatomic course in one extremity, comprehensive, including real-time cine imaging with image documentation, per extremity*), 7X000 (*Ultrasound, intraoperative thoracic aorta (e.g., epiaortic), diagnostic*), 7X001 (*Intraoperative epicardial cardiac (eg, echocardiography) ultrasound for congenital heart disease, diagnostic; including placement and manipulation of transducer*), 7X002 (*Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; placement, manipulation of transducer, and image acquisition only*), 7X003 (*Intraoperative epicardial cardiac (e.g.,)echocardiography) ultrasound for congenital heart disease, diagnostic; interpretation and report only*), 9X000 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; anomalous or persistent superior vena cava when it exists as a* second *contralateral superior vena cava, with native drainage to heart (List separately in addition to code for primary procedure)*), 9X002 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; azygos/hemi-azygos venous system (List separately in addition to code for primary procedure)*), 9X003 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; coronary sinus (List separately in addition to code for primary procedure)*), 9X004 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating at or above the heart (e.g., from innominate vein) (List separately in addition to code for primary procedure)*), and 9X005 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating below the heart (e.g., from the inferior vena cava) (List separately in addition*

to code for primary procedure)). We believe that these codes meet the definition of imaging services under section 1848(b)(4)(B of the Act, and thus, should be subject to the OPPS cap. We note that we previously proposed to add CPT code 76883 to the list of codes to which the OPPS cap applies in the CY 2023 PFS proposed rule, but we did not finalize its addition, noting that it was not within the statutory scope of services to which the OPPS cap applies, as it could not be split into professional and technical components at that time (87 FR 69475). Since that time, we have reinstated CPT code 76883's PC/TC split based on feedback from billing practitioners, therefore we are proposing to add it to the OPPS cap list for CY 2024.

4. Valuation of Specific Codes for CY 2024

(1) Dorsal Sacroiliac Joint Arthrodesis (CPT Code 2X000)

In September 2022, CPT deleted category III CPT code 0775T (*Arthrodesis, sacroiliac joint, percutaneous, with image guidance, includes placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]*) and created a new Category I CPT code 2X000 (*Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]), without placement of transfixation device*), which was surveyed for the January 2023 RUC meeting. CPT codes 27279 (*Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device*) and 27280 (*Arthrodesis, sacroiliac joint, open, includes obtaining bone graft, including instrumentation, when performed*) were added as family codes to the level of interest (LOI) form for the RUC to review. However, the specialty societies indicated that they do not consider CPT codes 27279 and 27280 as part of the same code family and requested that they not be re-reviewed by the RUC for the January 2023 meeting. The RUC agreed with the specialty societies and did not review these codes at the January 2023 meeting. The RUC stated in their recommendations for 2X000 that the clinical nature of CPT codes 27279 and 27280 is extensively disparate from 2X000 for both the surgical approach and the specialties that perform the procedures. Additionally, they stated that no substantive changes were made to CPT codes 27279 and 27280 at the September 2022 CPT panel meeting and 27279 has been reviewed by the RUC as recently as 2018.

We are proposing the RUC-recommended work RVU of 7.86 for CPT code 2X000. We are also proposing the RUC-recommended direct PE inputs without refinement.

(2) Vertebral Body Tethering (CPT Codes 2X002, 2X003, and 2X004)

At the September 2022 CPT Panel meeting, two new Category I CPT codes, 2X002 (*Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments)* and 2X003 (*Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments)* were established for thoracic tethering. In addition, another new Category I CPT code, 2X004 (*Revision (eg, augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed*) was established for tether revision, replacement or removal. This code family was then surveyed for the January 2023 RUC meeting.

We are proposing the RUC-recommended work RVUs of 32.00 for CPT code 2X002, 35.50 for CPT code 2X003, and 36.00 for CPT code 2X004. We are also proposing the RUC-recommended direct PE inputs without refinement.

(3) Total Disc Arthroplasty (CPT Codes 22857 and 22860)

In September 2021, the CPT Editorial Panel created CPT Category I code 22860 to describe *Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)* and replace CPT Category III code 0163T (*Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (List separately in addition to code for primary procedure)*), which prompted CPT codes 22860 and 22857 (*Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar*) to be surveyed for the January 2022 RUC meeting. At the January 2022 RUC meeting, the specialty societies indicated, and the RUC agreed, that the survey results for both CPT codes 22857 and 22860 were erroneous and that the codes should be resurveyed for the April 2022 RUC meeting. Therefore, we proposed and finalized to maintain the RUC-recommended work RVU of 27.13 for CPT code 22857 and contractor pricing for CPT code 22860 for CY 2023.

For CY 2024, we are proposing the April 2022 RUC-recommended work RVU of 27.13 for CPT code 22857, which represents no change from the current work RVU. For CPT code 22860, we disagree with the April 2022 RUC-recommended survey median work RVU of 7.50 and are proposing the survey (with experience) 25th percentile work RVU of 6.88. We note that, of the 46 ZZZ-codes with an intraservice time of 60 minutes, only four have a work RVU higher than the RUC-recommended 7.50.

We note that our proposed work RVU of 6.88 will maintain relativity with CPT codes 22552 (*Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for primary procedure)*) (work RVU = 6.50, 45 minutes intra-service and 50 minutes total time), which is an anterior approach spine procedure that requires less time, and CPT code 22208 (*Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (eg, pedicle/vertebral body subtraction); each additional vertebral segment (List separately in addition to code for primary procedure)*) (work RVU = 9.66, 120 minutes intra-service and 135 minutes total time). As the RUC mentioned in their recommendations, these codes appropriately bracket CPT code 22860 and demonstrate relativity among similar surgical spine add-on codes. The RUC noted that their recommended work RVU of 7.50 reflects the increased intensity of spine procedures performed from an anterior approach, but we note that CPT code 22226 (*Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (List separately in addition to code for primary procedure)*), which represents an anterior approach, and CPT code 22216 (*Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (List separately in addition to primary procedure)*), which represents a posterior or posterolateral approach, are both valued at 6.03 work RVUs and have identical IWPUTs of 0.1005. CPT codes 22216 and 22226 are ZZZ codes and have identical times as CPT code

22860, therefore, we believe the proposed survey (with experience) 25th percentile work RVU of 6.88 for CPT 22860 is more appropriate than the RUC recommended work RVU.

We are proposing the RUC-recommended direct PE inputs for both codes without refinement.

(4) Phrenic Nerve Stimulation System (CPT Codes 3X008, 3X009, 3X010, 3X011, 3X012, 3X013, 3X014, 3X015, 9X045, 9X046, 9X047, and 9X048)

In September 2022, the CPT Editorial Panel created eight new Category I CPT codes to describe insertion, repositioning, removal, and removal and replacement of a phrenic nerve stimulator system, as well as adding four additional new Category I codes to describe activation, interrogation, and programming of a phrenic nerve stimulator system. These new codes will replace thirteen Category III codes, 0424T–0436T. The twelve new Category I codes were surveyed and then reviewed for the January 2023 RUC meeting.

We are proposing the RUC-recommended work RVU for all 12 codes in the Phrenic Nerve Stimulation System family. We are proposing a work RVU of 9.50 for CPT code 3X008 (*Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]) including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation when performed*), a work RVU of 5.43 for CPT code 3X009 (*Insertion of phrenic nerve stimulator transvenous sensing lead*), a work RVU of 9.55 for CPT code 3X010 (*Removal of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; system, including pulse generator and lead(s)*), a work RVU of 5.42 for CPT code 3X011 (*Removal of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s) only),* a work RVU of 3.04 for CPT code 3X012 (*Removal of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator only*), a work RVU of 6.00 for CPT code 3X013 (*Repositioning of phrenic nerve stimulator transvenous lead(s)*), a work RVU of 6.05 for CPT code 3X014 (*Removal and replacement of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming when performed; pulse generator*), a work RVU of 8.51 for CPT code 3X015 (*Removal and replacement of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming when performed; transvenous stimulation or sensing lead*), a work RVU of 0.85 for CPT code 9X045 (*Therapy activation of implanted phrenic nerve stimulator system including all interrogation and programming*), a work RVU of 0.80 for CPT code 9X046 (*Interrogation and programming (minimum one parameter) of implanted phrenic nerve stimulator system*), a work RVU of 1.82 for CPT code 9X047 (*Interrogation and programming of implanted phrenic nerve stimulator system during a polysomnography*), and a work RVU of 0.43 for CPT code 9X048 (*Interrogation, without programming of implanted phrenic nerve stimulator system*).

We are proposing to refine the CA039 Post-operative visits (total time) for CPT code 3X014 from 36 minutes to 53 minutes to reflect the fact that this code has a Level 4 office visit and not a Level 3 office visit included in its global period; we believe that this was an unintended technical error in the RUC recommendation. We are also proposing to refine the equipment time for the exam table (EF023) equipment from 36 minutes to 53 minutes for CPT code 3X014 to conform to this proposed change in clinical labor time. For all other codes, we are proposing the direct PE inputs as recommended by the RUC without refinement.

(5) Posterior Nasal Nerve Ablation (CPT Codes 30117, 30118, 3X016, and 3X017)

In September 2022, the CPT Editorial Panel created two new endoscopy codes for ablation of the posterior nasal nerve: CPT code 3X016 (*Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve*), and CPT code 3X017 (*Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve*). In preparation for the January 2023 RUC meeting, both new posterior nasal nerve codes, 3X016 and 3X017, as well as family CPT codes 30117 and 30118, were surveyed. For CY 2024, the RUC recommended a work RVU of 3.91 for CPT code 30117, a work RVU of 9.55 for CPT code 30118, and a work RVU of 2.70 for both CPT codes 3X016 and 3X017.

We are proposing the RUC-recommended work RVU of 3.91 for CPT code 30117. We are proposing to remove the clinical labor for the CA037 (*Conduct patient communications*) activity code for CPT code 30117. This clinical labor is associated with patient communications which already take place during the CA036 (*Discharge day management*) activity code for 10-day and 90-day global procedures. We are proposing to remove this clinical labor as it would be duplicative with the communications already taking place under the CA036 activity code. We are proposing to delete supply item SB027 (*gown, staff, impervious*) because supply items SA042 (*pack, cleaning and disinfecting, endoscope*) and SA043 (*pack, cleaning, surgical instruments*) each include this same item. Supply items SA042 and SA043 are both included in the direct PE inputs for CPT Code 30117.

We disagree with the RUC-recommended work RVU of 9.55 for CPT code 30118 and are proposing a work RVU of 7.75, based on a direct crosswalk from CPT code 28298 (*Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal phalanx osteotomy, any method*) which has the same 60 minutes of intra-service time and similar total time as CPT code 30118. We believe the work RVU should be lower than the RUC recommendation of 9.55 to reflect the decrease in intra-service time from 105 minutes to 60 minutes, and the decrease in total time from 288 minutes to 211 minutes. In the case of CPT code 30118, the intra-service work time is decreasing by 43 percent and the total work time is decreasing by 27 percent but the RUC-recommended work RVU is only decreasing by 4 percent. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in the surveyed work time should be reflected in commensurate decreases to work RVUs.

We also note that at the RUC-recommended work RVU of 9.55, the intensity of CPT code 30118 would be increasing by more than 50 percent. We disagree that there would be such a significant increase in the intensity for the procedure, as it is transitioning from inpatient to outpatient status which suggests that the intensity has remained the same or decreased over time. We also disagree that this would be the case since the intensity for CPT code 30117 is decreasing at the RUC-recommended work RVU of 3.91. Therefore, we are also proposing a work RVU of 7.75 because it maintains the current intensity of CPT code 30118 instead of resulting in an increase in intensity. The proposed work RVU of 7.75 is supported by the reference CPT codes

we compared to CPT code 30118 with the same 60 minutes of intra-service time and similar total time as CPT code 30118; reference CPT code 11970 (*Replacement of tissue expander with permanent implant*) has a work RVU of 7.49, and reference CPT code 19325 (*Breast augmentation with implant*) has a work RVU of 8.12. We believe the proposed RVU of 7.75 is a more appropriate value overall than 9.55 when compared to the range of codes with the same intra-service time and similar total time.

We are proposing to remove the clinical labor for the CA037 (*Conduct patient communications*) activity code for CPT code 30118. This clinical labor is associated with patient communications which already take place during the CA036 (*Discharge day management*) activity code for 10-day and 90-day global procedures. We are proposing to remove this clinical labor from CPT code 30118 as it would be duplicative with the communications already taking place under the CA036 activity code.

We are proposing the RUC-recommended work RVU of 2.70 for CPT codes 3X016 and 3X017. Both CPT codes 3X016 and 3X017 are endoscopic procedures; therefore, we are proposing CPT code 31231 (*Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)*) as the endoscopic base code for both of these codes because the description of these procedures includes what is described for CPT code 31231, with the additional component of the posterior nasal nerve ablation. Both of these procedures are performed with an endoscope. CPT codes 3X016 and 3X017 are not add-on codes, and both have a 0-day global period. The endoscopic base code that we are assigning to CPT codes 3X016 and 3X017 is used in a specific type of multiple procedure payment reduction that applies to some endoscopy codes.

We are proposing to refine the RUC-recommended direct PE inputs for both CPT codes 3X016 and 3X017. For CPT code 3X016, we are refining the equipment time for the ES031 equipment (*scope video system (monitor, processor, digital capture, cart, printer, LED light)*) from 39 minutes to 32 minutes. The RUC used the CA025 (*clean scope*) time of 10 minutes instead of the CA024 (*clean room/equipment by clinical staff*) time of 3 minutes in the Scope Systems formula, when the time for CA024 is the standard; we believe that this was an unintended technical error in the RUC recommendation. We are similarly refining the equipment time for ES031 from 39 minutes to 34 minutes for CPT code 3X017.

For CPT code 3X017, we are refining the equipment time for the ES040 equipment (*PROXY endoscope, rigid, sinoscopy (0 degrees)*) from 39 minutes to 41 minutes because the RUC used 18 minutes of intra-service time for CA018 (*Assist physician or other qualified healthcare professional—directly related to physician work time (100%)*) instead of 20 minutes in the standard Scope formula. Also, for both CPT codes 3X016 and 3X017, we propose to delete supply item SB027 (*gown, staff, impervious*) because SA042 (*pack, cleaning and disinfecting, endoscope*) and SA043 (*pack, cleaning, surgical instruments*) each include this same item. Supply items SA042 and SA043 are both included in the PE inputs for CPT codes 3X016 and 3X017.

(6) Cystourethroscopy With Urethral Therapeutic Drug Delivery (CPT Code 5X000)

In September 2022, the CPT Editorial Panel replaced Category III code 0499T (*Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed*) with the new Category I CPT code 5X000 (*Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed*) to describe cystourethroscopy with mechanical urethral dilation and urethral therapeutic drug delivery. For CY 2024, the RUC recommended a work RVU of 3.10 for CPT code 5X000.

We are proposing the RUC-recommended work RVU of 3.10 for CPT code 5X000. We are also proposing the RUC-recommended direct PE inputs for CPT code 5X000 without refinement.

Since this is an endoscopic procedure, we propose CPT code 52000 (*Cystourethroscopy (separate procedure)*) as the endoscopic base code for CPT code 5X000 because the description of this procedure includes what is described for CPT code 52000 with the additional component of the urethral therapeutic drug delivery. This procedure is performed with a cystoscope. CPT code 5X000 is not an add-on code, it has a 0-day global period. The endoscopic base code that we are assigning to CPT code 5X000 is a specific type of multiple procedure payment reduction that applies to some endoscopy codes.

(7) Transcervical RF Ablation of Uterine Fibroids (CPT Code 5X005)

In September 2022, the CPT Editorial Panel deleted Category III code 0404T (*Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency*) and created a new Category I CPT code 5X005 (*Transcervical ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency*) to report and describe transcervical radiofrequency ablation of uterine fibroid(s) which prompted CPT code 5X005 to be surveyed for the January 2023 RUC meeting. At the January 2023 RUC meeting, the specialty societies indicated, and the RUC agreed, that the survey results for CPT code 5X005 showed that the survey 25th percentile work RVU of 7.21 appropriately recognizes the work involved in this service.

We are proposing the RUC-recommended work RVU of 7.21 for CPT code 5X005. The RUC recommends that CPT code 5X005 be placed on the New Technology list to be re-reviewed by the RUC in 3 years to ensure correct valuation and utilization assumptions. We will revisit the valuations of CPT code 5X005 in future rulemaking as needed, based on our annual review process discussed in the background section of this proposed rule.

CPT code 5X005 includes a medium instrument pack (EQ138) as one of the practice expense inputs for this code. Since the medium instrument pack is classified as equipment, it should include time for cleaning the surgical instrument package. We noted a mistake in one of the equipment time formulas for the medium instrument pack (EQ138) which used the CA024 clean room/equipment by clinical staff time instead of the CA026 clean surgical instrument package time in the equipment formula. Therefore, we are proposing to refine the medium instrument pack equipment time from 65 minutes to 77 minutes to conform to our established policy for surgical instrument packs, otherwise we are proposing the RUC-recommended direct PE inputs without refinement.

(8) Suprachoroidal Injection (CPT Code 6X000)

In September 2022, the CPT Editorial Panel introduced category I CPT code 6X000 as a new code. CPT code 6X000 describes suprachoroidal injection, which is the injection of medication into the space between the choroid and the sclera of the eye with procedure-specific needles and an injection kit. CPT code 6X000 replaces temporary

category III CPT code 0465T (*Suprachoroidal injection of a pharmacologic agent (does not include supply of medication)*), which was contractor priced. While there are other existing general CPT codes for injections to the eye, the AMA RUC is adding CPT code 6X000 (*Suprachoroidal space injection of pharmacologic agent (separate procedure) (Report medication separately)*) to describe a more specific service to better distinguish this procedure from the rest of the codes for eye injections in this family. CPT code 6X000 is a 000-day global code and currently, there is only one FDA-approved medication to treat macular edema associated with uveitis which is reported separately with HCPCS J-code J3299 triamcinolone acetonide (Xipere®).

We are proposing the RUC-recommended work RVU of 1.53 for CPT code 6X000. We are also proposing the RUC-recommended direct PE inputs for the code without refinement.

(9) Skull Mounted Cranial Neurostimulator (CPT Codes 619X1, 619X2, and 619X3)

In February 2022, the CPT Editorial Panel created codes 619X1, 619X2, and 619X3 to describe Skull-Mounted Cranial Neurostimulator, and these codes were surveyed for the October 2022 RUC meeting.

We are proposing the RUC-recommended work RVU of 25.75 for CPT code 619X1 (*Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)*), the RUC-recommended work RVU of 11.25 for CPT code 619X2 (*Revision or replacement of skull-mounted cranial neurostimulator pulse generator or receiver with connection to depth and/or cortical strip electrode array(s)*), and the RUC-recommended work RVU of 15.00 for CPT code 619X3 (*Removal of skull-mounted cranial neurostimulator pulse generator or receiver with cranioplasty, when performed*).

We are proposing the RUC-recommended direct PE inputs for CPT codes 619X1, 619X2, and 619X3 without refinement.

(10) Spinal Neurostimulator Services (CPT Codes 63685, 63688, 64XX2, 64XX3, and 64XX4)

For CPT codes 63685 (*Insertion or replacement of spinal neurostimulator pulse generator or receiver requiring pocket creation and connection between electrode array and pulse generator or receiver*) and 63688 (*Revision or removal of implanted spinal neurostimulator pulse generator or receiver, with detachable connection to electrode array*) we are proposing the RUC-recommended work RVUs of 5.19 and 4.35, respectively. We are proposing the RUC-recommended direct PE inputs for CPT codes 63685 and 63688 without refinement.

We agree with the RUC recommended contractor pricing for CPT codes 64XX2 (*Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator including imaging guidance, when performed; initial electrode array*), 64XX3 (*Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator including imaging guidance, when performed; each additional electrode array*), and 64XX4 (*Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator*); and we are proposing contractor pricing for these three codes.

(11) Neurostimulator Services-Bladder Dysfunction (CPT Codes 64590 and 64595)

For CPT codes 64590 (*Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver*) and 64595 (*Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array*) we are proposing the RUC-recommended work RVUs of 5.10 and 3.79, respectively.

We are requesting clarification on the direct PE inputs for CPT code 64590 in the non-facility setting. Specifically, we believe the RUC inadvertently proposed 56 minutes of equipment time for the EQ114 equipment (electrosurgical generator), instead of 48 minutes using the default formula for calculating equipment time. We believe that 48 minutes of equipment time for EQ114 is appropriate and matches the clinical labor time; therefore, we are proposing 48 minutes for the EQ114 equipment for CPT code 64590. We also believe that the EQ209 equipment (*programmer, neurostimulator (w-printer)*) was intended to match the same 84 minutes of equipment time listed for the EF031 power table as both were indicated to be used during the follow-up office visit. Therefore, we are proposing 84 minutes of equipment time for EQ209 for CPT code 64590.

We are proposing the remaining RUC-recommended direct PE inputs for CPT code 64590 without refinement. We are also proposing the RUC-recommended direct PE inputs for CPT code 64595 without refinement.

(12) Ocular Surface Amniotic Membrane Placement/Reconstruction (CPT Codes 65778, 65779, and 65780)

CPT code 65778 (*Placement of amniotic membrane on the ocular surface; without sutures*) was identified by the Relativity Assessment Workgroup (RAW) via the high-volume growth screen for codes with Medicare utilization over 10,000 screen. During the September 2022 RAW meeting, the specialty societies stated that CPT codes 65778, 65779 (*Placement of amniotic membrane on the ocular surface; single layer, sutured*), and 65780 (*Ocular surface reconstruction; amniotic membrane transplantation, multiple layers*) would be surveyed for the January 2023 RUC meeting.

For CY 2024, we are proposing the RUC-recommended work RVUs for all three CPT codes. We are proposing a work RVU of 0.84 for CPT code 65778 (*Placement of amniotic membrane on the ocular surface; without sutures*), a work RVU of 1.75 for CPT code 65779 (*Placement of amniotic membrane on the ocular surface; single layer, sutured*), and a work RVU of 7.03 for CPT code 65780 (*Ocular surface reconstruction; amniotic membrane transplantation, multiple layers*). We are also proposing the RUC-recommended direct PE inputs for CPT codes 65778, 65779, and 65780 without refinement.

(13) Fractional Flow Reserve With CT (CPT Code 7X005)

For CY 2018, the CPT Editorial Panel established four new Category III CPT codes for fractional flow reserve derived from computed tomography (FFRCT): CPT codes 0501T–0504T. Medicare began payment for CPT code 0503T (*Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model*) in the hospital outpatient department setting under the Outpatient Prospective Payment System (OPPS) in CY 2018 (82 FR 59284). For the PFS, we typically assign contractor pricing for Category III codes since they are temporary codes assigned to emerging technology and services. However, we

made an exception for FFRCT services and we have since been trying to understand the costs of the PE resource inputs for CPT code 0503T in the physician office setting. In the CY 2021 PFS final rule (85 FR 84630), we stated that we found FFRCT to be similar to other technologies that use algorithms, artificial intelligence, or other innovative forms of analysis to determine a course of treatment, where the analysis portion of the service cannot adequately be reflected under the PE methodology; and that our recent reviews for the overall cost of CPT code 0503T had shown the costs in the physician office setting to be similar to costs reflected in payment under the OPPS (85 FR 84630). As such, we proposed to use the geometric mean costs under the OPPS as a proxy for CPT code 0503T and ultimately finalized national pricing for CPT code 0503T based on a valuation crosswalk to the technical component (TC) of CPT code 93457 in the CY 2022 PFS final rule (86 FR 65037–65042).

For CY 2024, the CPT Editorial Panel approved the replacement of Category III codes 0501T–0504T with a single new Category I code (7X005) to report non-invasive estimate of coronary fractional flow reserve derived from augmentative software analysis of the dataset from a coronary computed tomography angiography. CPT code 7X005 (*Noninvasive estimate of coronary fractional flow reserve derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional*) was reviewed at the January 2023 RUC meeting and valuation recommendations were submitted to CMS. These recommendations include a software analysis fee for FFRCT listed as a supply input which accounts for the overwhelming majority of the code's valuation.

We have long had concerns that the software algorithm in the analysis fee for CPT code 7X005 is not well accounted for in our PE methodology; however, we recognize that practitioners are incurring resource costs for purchasing the FFRCT software and its ongoing use. This was the rationale for our previous policy to use a crosswalk that reflected the overall relative resource costs for this service while we continued to consider potentially refining and updating our PE methodology. The RUC recommendations include the previously mentioned software analysis fee for FFRCT as a supply input. However, analysis fees are not well accounted for in our current PE methodology. Although we recognize that these fees are a type of cost for practitioners, we have not traditionally recognized these analysis fees as forms of direct PE in our methodology. We previously stated our belief that crosswalking the RVUs for CPT code 0503T to a code with similar resource costs (the TC for CPT code 93457) allowed CMS to recognize that practitioners are incurring resource costs for the purchase and ongoing use of the software employed in CPT code 0503T, which would not typically be considered direct PE under our current methodology (86 FR 65038 and 65039).

We are therefore proposing to maintain the previous valuation crosswalk to the technical component of CPT code 93457 for the new FFRCT code 7X005. This new Category I code is intended as a direct replacement for Category III code 0503T, and maintaining the current crosswalk will allow the geometric mean costs under the OPPS to continue to serve as a proxy for valuation. We are specifically crosswalking the technical component of CPT code 7X005 to the technical component of CPT code 93457; we are proposing the RUC-recommended work RVU of 0.75 for the professional component of CPT code 7X005, and the global component will be comprised of their sums as usual. We also note that there was an error in the RUC's recommended equipment time for the Professional PACS Workstation (ED053), which was listed at 14.5 minutes instead of the correct 13.5 minutes based on the sum of the intraservice work time (11 minutes) plus half of the preservice work time (5 divided by 2 = 2.5 minutes).

(14) Ultrasound Guidance for Vascular Access (CPT Code 76937)

In order to specify the insertion of a peripherally inserted central venous catheter (PICC), the CPT Editorial Panel decided to create two new codes: CPT 36572 and CPT 36573, and revised CPT codes 36568, 36569 and 36584 in September of 2017. This revision of these codes created a scenario where these bundled services could be performed by a clinician that performs the procedure without imaging guidance or a radiologist that performs the procedure with imaging guidance. When this code family was surveyed again in January 2018, CPT code 76937 *(Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting (List separately in addition to code for primary procedure)* was identified as part of this code family. Since it was expected that utilization of PICC procedures would decrease once CPT code 76937 was bundled with these services, the specialty societies that perform this service proposed to review CPT code 76937 after 2 years, once more data about these services became available. CPT code 76937 was reviewed at the October 2022 RUC meeting for CY 2024.

We are proposing the RUC-recommended work RVU of 0.30 for CPT 76937. We are also proposing the RUC-recommended direct PE inputs for CPT 76937.

(15) Neuromuscular Ultrasound (CPT Codes 76881, 76882, and 76883)

Since their creation in 2011, CPT codes 76881 (*Ultrasound, complete joint (i.e., joint space and peri-articular soft-tissue structures), real-time with image documentation*) and 76882 (*Ultrasound, limited, joint or other nonvascular extremity structure(s) (e.g., joint space, peri-articular tendon[s], muscle[s], nerve[s], other soft-tissue structure[s], or soft-tissue mass[es]), real-time with image documentation*) have been reviewed numerous times as New Technology/New Services by the Relativity Assessment Workgroup (RAW). In October 2016, the RAW reviewed these codes and agreed with the specialty societies that the dominant specialties providing the complete (CPT code 76881) versus the limited (CPT code 76882) ultrasound of extremity services were different than originally thought, causing variation in the typical PE inputs. The RAW recommended referral to the Practice Expense Subcommittee for review of the direct PE inputs and the CPT Editorial Panel to clarify the introductory language regarding the reference to one joint in the complete ultrasound. The PE Subcommittee reviewed the direct PE inputs for CPT codes 76881 and 76882 and adjusted the clinical staff time at the January 2017 RUC meeting, and the CPT Editorial Panel editorially revised CPT codes 76881 and 76882 to clarify the distinction between complete and limited studies and revised the introductory guidelines to clarify the reference to one joint in the complete ultrasound procedure in June 2017.

In October 2021, the CPT Editorial Panel approved the addition of CPT code 76883 (*Ultrasound, nerve(s) and accompanying structures throughout their entire anatomic course in one extremity, comprehensive, including real-time cine imaging with image*

documentation, per extremity) for reporting real-time, complete neuromuscular ultrasound of nerves and accompanying structures throughout their anatomic course, per extremity, and the revision of CPT code 76882 to add focal evaluation. CPT codes 76881 and 76882 were identified as part of the neuromuscular ultrasound code family with CPT code 76883 and surveyed for the January 2022 RUC meeting. We reviewed these recommendations for CY 2023 and discussed our concerns with the commenters' assertions regarding typical PE inputs for CPT code 76882 in the CY 2023 PFS final rule (87 FR 69506 through 69510). Specifically, given the changes in dominant specialty for these CPT codes from 2010 to 2017, and again from 2017 to 2022, we recommended that the RUC and interested parties reconsider the PE inputs for each code based on the dominant specialty for each CPT code, based on the most recent year's Medicare claims data, and consideration of survey responses submitted to CMS in response to the CY 2023 PFS proposed rule.

The PE inputs for CPT codes 76881, 76882, and 76883 were subsequently re-reviewed at the January 2023 RUC meeting and the RUC submitted refinements to the PE inputs for CPT code 76882 only. We are proposing the RUC-recommended PE refinements for CPT code 76882 with the exception of the RUC-recommended 13.5 minutes for ED053 (Professional PACS workstation) and 23 minutes for EQ250 (ultrasound unit, portable). We note that the old intraservice time of 11 minutes was used in error when calculating the standard equipment time for ED053. Therefore, we disagree with the RUC-recommended equipment time of 13.5 minutes and are proposing 17.5 minutes for ED053, which is calculated by using the standard equipment formula for ED053 established in the CY 2017 PFS final rule (81 FR 80182) with the updated intraservice time from the CY 2023 PFS final rule ((0.5 * 5) + 15 = 17.5).

We disagree with the RUC-recommended 23 minutes of equipment time for EQ250, which includes one minute of clinical labor time for CA014 (Confirm order, protocol exam) in the highly technical equipment formula, as discussed beginning in the CY 2013 PFS final rule (77 FR 69028), in error. Therefore, the correct equipment time for EQ250 using the highly technical equipment formula would be 22 minutes. However, because the Summary of Recommendations included in the RUC recommendations did not provide a rationale for the use of the highly technical equipment formula for EQ250, we are proposing to maintain the 15 minutes of equipment time for EQ250 for CPT code 78882, which corresponds to the interservice time for this code and maintains consistency with how equipment time is allotted for EQ250 across the three codes in this family. We refer readers to the classification of highly technical equipment in the CY 2014 PFS final rule (79 FR 67639).

The RUC did not make recommendations on and we are not proposing any changes to the work RVU for CPT codes 76881, 76882, and 76883.

(16) Intraoperative Ultrasound Services (CPT Codes 76998, 7X000, 7X001, 7X002, and 7X003)

In October 2018, the Relativity Assessment Workgroup (RAW) created a screen for CMS/Other codes with Medicare utilization of 20,000 or more, and CPT code 76998 (*Ultrasonic guidance, intraoperative*) was subsequently identified as part of that screen. When CPT code 76998 was identified in the CMS/Other screen, it was noted that many specialties were represented in the Medicare claims data. Specialties representing cardiothoracic surgery, general surgery, breast surgery, urology, interventional cardiology, interventional radiology and vascular surgery jointly submitted an action plan that the RAW reviewed in October 2019. Based on the variability of intraoperative ultrasound for each specialty with differences in the typical patient and physician work, it was decided that each society would submit applications for new code(s) as needed to carve out the work currently reported with 76998 until the code was no longer needed, or until it was clear what the final dominant use of 76998 was so that a survey could be conducted.

In October 2019, the RUC referred this issue to the CPT Editorial Panel to clarify correct coding and accurately differentiate physician work, as multiple specialties currently report CPT code 76998. The CPT Editorial Panel addressed CPT code 76998 in 2020 and 2021 by adding instructional parentheticals that restrict the use of imaging guidance with vein ablation procedures and adding new codes that bundled imaging guidance for urological procedures. In May 2022, the CPT Editorial Panel created four new codes to report intraoperative cardiac ultrasound services, thus carving out most of the prior reporting of code 76998 by cardiothoracic surgeons and cardiologists.

After utilization was removed from code 76998 for vein ablation procedures, most urological procedures, cardiac procedures and intra-abdominal procedures through instructions and/or new or revised codes, it was determined that the dominant use of the code would be related to breast surgery, allowing for code 76998 to be surveyed. CPT codes 7X000 (*Ultrasound, intraoperative thoracic aorta (e.g., epiaortic), diagnostic*), 7X001 (*Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; including placement and manipulation of transducer, image acquisition, interpretation and report*), 7X002 (*Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; placement, manipulation of transducer, and image acquisition only*), 7X003 (*Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; interpretation and report only*), and 76998 were surveyed by the specialty societies for the September 2022 RUC meeting.

We disagree with the RUC-recommended work RVU of 1.20 for CPT code 76998 and are proposing the total time ratio work RVU of 0.91. The RUC recommended a 7-minute total time decrease for CPT code 76998. We agree with the RUC that the intensity of CPT code 76998 (real-time during an operation) is greater than the identically-timed CPT code 76641 (*Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete*), which represents a single ultrasound session typically performed by a technician, whereas CPT code 76998 includes multiple, separate ultrasound maneuvers during a surgical procedure that require a more intense, immediate interpretation in order to direct resection of the breast tissue and ensure a thorough and complete surgical excision of the abnormal breast tissue. The proposed work RVU of 0.91 for CPT code 76998 adequately values the surgeon's 5 minutes of pre-service time, 12 minutes of intraservice time, and 5 minutes of immediate post-service time more than the same 5, 12, and 5 minutes of the technician's time for CPT code 76641, which has a work RVU of 0.73.

Additionally, the IWPUT of CPT code 76641 is appropriately less than the IWPUT of CPT code 76698, with IWPUTs of 0.0422 and 0.0572, respectively. We remind interested parties that 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, decreases in time should

be reflected in decreases to work RVUs. We disagree with the RUC-recommended maintenance of the current work RVU for CPT code 76998 for a few reasons: the RUC recommendations did not advocate for a change in intensity, and presumably some higher-intensity cardiac procedures will no longer be reported using CPT code 76998, as they can now be reported using CPT codes 7X000 through 7X003. Instead, we are proposing an appropriately lower work RVU and associated IWPUT to account for the 7-minute decrease in total time and removal of higher-intensity cardiac procedures previously reported by CPT code 76998. We note that the proposed work RVU of 0.91 for CPT code 76998 is supported by the upper brackets of CPT codes 72125 (*Computed tomography, cervical spine; without contrast material*), 72128 (*Computed tomography, thoracic spine; without contrast material*), and 72131 (*Computed tomography, lumbar spine; without contrast material*), and a lower bracket of CPT code 76641. CPT codes 72125, 72128, and 72131 represent spinal computed tomography (CT) of the cervical, thoracic, and lumbar spine, respectively.

We are proposing the RUC-recommended work RVU of 0.60 and work times of 5 minutes of pre-evaluation time, 10 minutes of intraservice time, and 3 minutes of immediate postservice time for total time of 18 minutes for CPT code 7X000. We are also proposing the RUC-recommended work times for CPT codes 7X001 and 7X002 of 10 minutes of pre-evaluation time and 20 minutes of intraservice time for both codes, and 5 and 10 minutes of immediate postservice time, for total times of 40 and 35 minutes, respectively. We are proposing the RUC-recommended work times for CPT code 7X003 with the exception of the intraservice time. We are proposing the survey median intraservice time of 15 minutes rather than the RUC-recommended 75th percentile based on the assertion in the RUC's Summary of Recommendations that the cardiologist is typically in the operating room intraoperatively with the cardiothoracic surgeon prior to and after the cardiac repair. Based on this assertion, we do not believe the cardiologist spends the same amount of time in the operating room as the cardiothoracic surgeon in CPT codes 7X001 and 7X002. Therefore, we are proposing 5 minutes of pre-evaluation time, 15 minutes of intraservice time, and 10 minutes of immediate postservice time for total time of 30 minutes for CPT code 7X003.

Due to the CPT code descriptor for CPT code 7X001, we believe that the appropriate work for this service is reflected in the combined work of CPT codes 7X002 and 7X003. We note that in the CY 2015 PFS final rule (79 FR 67669), we reviewed a similarly constructed family of codes representing interventional transesophageal echocardiography (TEE) for congenital cardiac anomalies in the same way by proposing and finalizing a work RVU for CPT code 93315 (*Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report*) equal to the combined work RVUs of CPT codes 93316 (*Transesophageal echocardiography for congenital cardiac anomalies; placement of transesophageal probe only*) and 93317 (*Transesophageal echocardiography for congenital cardiac anomalies; image acquisition, interpretation and report only*). We note that the Summary of Recommendations for 7X001 through 7X003 state that these intraoperative ultrasound services are expected to be very rare, as intraoperative TEE is considered the gold standard and can be performed for most patients instead, which could be reported using CPT codes 93315 through 93317. Because CPT codes 7X001 through 7X003 are an alternative to CPT codes 93315 through 93317 for congenital cardiac anomalies when intraoperative TEE is contraindicated, we believe we should maintain consistency and propose a work RVU for CPT code 7X001 that equals the combined work RVUs of CPT codes 7X002 and 7X003.

Therefore, we disagree with the RUC-recommended work RVUs of 1.90, 1.20, and 1.55 for CPT codes 7X001, 7X002, and 7X003, respectively. We are proposing a work RVU of 1.62 for CPT code 7X001 based on a crosswalk to CPT codes 73219 (*Magnetic resonance (e.g., proton) imaging, upper extremity, other than joint; with contrast material(s)*) and 78452 (*Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection*). We note that this crosswalk is strongly supported by total time ratios between CPT code 7X001 and reference CPT codes 93312 (*Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); including probe placement, image acquisition, interpretation and report*) and 93315, which equal 1.66 and 1.67 respectively. We also note that this is supported by a total time ratio to the current time and work RVU for the code that cardiothoracic surgeons currently use to report this service prior to the creation of CPT code 7X001, CPT code 76998 ((40/29) * 1.20 = 1.66). Lastly, this is also supported by a total time ratio to the same CPT code 76998 after factoring in the updated total time of 22 minutes and our proposed work RVU for CPT code 76998 of 0.91 ((40/22) * 0.91 = 1.65). We note that a work RVU of 1.62 for CPT code 7X001 yields an IWPUT of 0.059, which is slightly higher than the IWPUTs of the intraoperative TEE CPT codes 93315 and 93312 that represent the complete procedure, which are 0.0532 and 0.0580, respectively.

Similar to how CPT code 7X001 is broken down into service parts by CPT code 7X002 and 7X003 to allow for multiple providers to perform different parts of the whole service done by one provider (represented by 7X001), CPT codes 93312 through 93314 and 93315 through 93317 are broken down as well. According to the RUC Database, CPT code 93316 represents placement of transesophageal probe only, typically performed by a cardiac anesthesiologist. CPT code 93313 (*Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); placement of transesophageal probe only*) also represents placement of transesophageal probe only, when performed by a cardiac anesthesiologist. Similarly, CPT code 7X002 represents placement and manipulation of transducer and image acquisition only, which is typically performed by a cardiothoracic surgeon according to the Summary of Recommendations.

According to the RUC Database, CPT code 93317 represents image acquisition and interpretation and report only, typically done by the cardiologist after probe placement typically performed by the cardiac anesthesiologist, represented by CPT code 93316. CPT code 93314 (*Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); image acquisition, interpretation and report only*) also represents image acquisition and interpretation and report only, typically done by the cardiologist after probe placement typically performed by the anesthesiologist, represented by CPT code 93313. Similarly, CPT code 7X003 represents interpretation and report

only, which is typically performed by a cardiologist according to the Summary of Recommendations.

Because this family is broken down into service parts in the same way CPT codes 93312 through 93314 and 93315 through 93317 are, we disagree with the RUC's recommendation to assign work RVUs for CPT codes 7X002 and 7X003 that sum to more than the aggregate work RVU for CPT code 7X001. Therefore, we are proposing a work RVU of 1.08 for CPT code 7X002 and a work RVU of 0.54 for CPT code 7X003, which sum to the proposed aggregate work RVU of 1.62 for CPT code 7X001. The proposed work RVUs for CPT code 7X002 and 7X003 were calculated by taking the aggregate work RVU of the whole service, represented by CPT code 7X001, and dividing by three based on the number of discernable service parts: probe placement and manipulation, image acquisition, and interpretation and report. Because CPT code 7X002 represents two of the three service parts performed by a cardiothoracic surgeon, we allotted ⅔ rds of the aggregated work RVU for CPT code 7X001, equaling 1.08 (1.62 * ⅔ = 1.08). Because CPT code 7X003 represents one of the three service parts performed by a cardiologist, we allotted ⅓ rd of the aggregated work RVU for CPT code 7X001, equaling 0.54 (1.62 * ⅓ = 0.54). Because the Summary of Recommendations was unclear regarding the intensity of each part of the service as broken out, we invite comments on additional ways to break down the aggregate work RVU of CPT code 7X001 to adequately account for the cardiothoracic surgeon and cardiologist's time and intensity to perform CPT codes 7X002 and 7X003, but we believe that the work RVUs should sum to no more than the aggregate work RVU for CPT code 7X001 based on similarly broken down code families that represent the more widely used intraoperative TEE procedures. The RUC did not recommend and we are not proposing any direct PE inputs for the five codes in the Intraoperative Ultrasound family.

(17) Percutaneous Coronary Interventions (CPT Code 9X070)

In September 2022, the CPT Editorial Panel created one new Category I CPT code for percutaneous coronary lithotripsy. Sixteen other percutaneous coronary intervention (PCI) codes were considered part of the code family but were ultimately not reviewed by the RUC. New add-on CPT code 9X070 was reviewed by the RUC on an interim basis for CY 2024 while the entire percutaneous coronary intervention code family was referred to the CPT Editorial Panel for restructuring for the CY 2025 cycle.

We are proposing the RUC-recommended work RVU of 2.97 for CPT code 9X070 (*Percutaneous transluminal coronary lithotripsy*). The RUC did not recommend and we are not proposing any direct PE inputs for this facility-based add-on service.

(18) Auditory Osseointegrated Device Services (CPT Codes 926X1 and 926X2)

In February 2022, the CPT Editorial Panel created CPT code 926X1 (*Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; first 60 minutes*) and 926X2 (*Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; each additional 15 minutes (list separately in addition to code for primary procedure*) for CY 2024. CPT code 926X2 serves as the add-on code for base CPT code 926X1.

We are proposing the RUC-recommended work RVU of 1.25 for CPT code 926X1 and 0.33 for CPT 926X2. We are also proposing the RUC-recommended direct PE inputs for both codes. Additionally, because audiologists provide these services, we are proposing to add CPT codes 926X1 and 926X2 to the list of audiology services that can be billed with the AB modifier, that is personally provided by audiologists without a physician/NPP referral for non-acute hearing conditions—the list for CY 2023 is available at *https://www.cms.gov/audiology-services*.

(19) Venography Services (CPT Codes 9X000, 9X002, 9X003, 9X004, and 9X005)

In February 2022, the CPT Editorial Panel created six new CPT add-on codes to describe Venography services that are performed during cardiac catheterization for congenital heart defects in the superior vena cava (SVC), the inferior vena cava (IVC), and in other congenital veins, that will be reported in conjunction with the main cardiac catheterization procedure codes (CPT codes 93593–93598). CPT codes 9X000 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; anomalous or persistent superior vena cava when it exists as a second contralateral superior vena cava, with native drainage to heart (List separately in addition to code for primary procedure)*) and CPT codes 9X001 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; inferior vena cava (List separately in addition to code for primary procedure)*) were to replace the two more general CPT codes 75827 (*Venography, caval, superior, with serialography, radiological supervision and interpretation*) and 75825 (*Venography, caval, inferior, with serialography, radiological supervision and interpretation*). CPT code 9X001 has since been rescinded, and all the remaining new add-on codes have been clarified to state in their descriptors that they are specifically for congenital heart defects.

For CPT code 9X000 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; anomalous or persistent superior vena cava when it exists as a second contralateral superior vena cava, with native drainage to heart (List separately in addition to code for primary procedure*)), the AMA RUC proposes a work RVU of 1.20 for 10 minutes of intra-service time and total time. We are proposing the AMA RUC recommended work RVU of 1.20 with 10 minutes of intra-service time and total time for CPT code 9X000.

For CPT code 9X002 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; azygos/hemi-azygos venous system (List separately in addition to code for primary procedure*)), the AMA RUC proposes a work RVU of 1.13 for 10 minutes of intra-service time and total time. We note that this code has the same number of minutes as CPT code 9X000, but with a lower recommended work RVU. We are proposing the AMA RUC recommended work RVU of 1.13 with 10 minutes of intra-service time and total time for CPT code 9X002.

For CPT code 9X003 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; coronary sinus (List separately in addition to code for primary procedure*)) the AMA RUC proposes a work RVU of 1.43 for 12 minutes of intra-service time and total time. We note that this code has two additional minutes than CPT code 9X000 which is 20 percent more in physician time than the 10 minutes from CPT code 9X000. We are proposing the AMA RUC recommended work RVU of 1.43 with 12 minutes of intra-service time and total time for CPT code 9X003.

For CPT code 9X004 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating at or*

above the heart (e.g., from innominate vein) (List separately in addition to code for primary procedure)), the AMA RUC proposes a work RVU of 2.11 for 16 minutes of intra-service time and total time. We note that this code has six additional minutes more than CPT code 9X000 (10 minutes), which is 60 percent more physician time. Although we do not imply that increases in time as reflected in survey values must equate to a one-to-one or linear increase in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant increases in time within the same code family should typically be reflected in increases to work RVUs. In the case of CPT code 9X004, we believe that it would be more accurate to propose a work RVU of 1.92 to account for this increase in the surveyed work time as compared with CPT code 9X000. Therefore, we are proposing a work RVU of 1.92 along with 16 minutes of intra-service time and total time for CPT code 9X004.

For CPT code 9X005 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating below the heart (e.g., from the inferior vena cava) (List separately in addition to code for primary procedure*)), the AMA RUC proposes a work RVU of 2.13 for 17 minutes of intra-service time and total time. We note that this code has seven additional minutes more than CPT code 9X000 (10 minutes), which is 70 percent more physician time than CPT code 9X000. Although we do not imply that increases in time as reflected in survey values must equate to a one-to-one or linear increase in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant increases in time within the same code family should typically be reflected in increases to work RVUs. In the case of CPT code 9X005, we believe that it would be more accurate to propose a work RVU of 2.04 to account for this increase in the surveyed work time as compared with CPT code 9X000. Therefore, we are proposing a work RVU of 2.04 along with 17 minutes of intra-service time and total time for CPT code 9X005.

The RUC did not recommend and we are not proposing any direct PE inputs for the five codes in the Venography Services family.

(20) General Behavioral Health Integration Care Management (CPT Code 99484, and HCPCS Code G0323)

We are proposing to refine the work RVU of both CPT code 99484 and HCPCS code G0323, as proposed (see section II.J.1.c of this proposed rule), by increasing the work RVU to 0.93 from the current 0.61 and increasing the work time to 21 minutes to match the results of the surveyed work time. For CPT code 99484 we are proposing the direct PE inputs as recommended by the RUC without refinement. We are also proposing the same PE inputs for HCPCS code G0323.

CMS created four behavioral health integration (BHI) HCPCS G-codes for CY 2017. In 2018 the codes were replaced by new CPT codes. At that time RUC specialty societies undertook a survey but the RUC did not use the survey results to establish work RVUs, and instead adopted the valuations we had finalized in 2017. For CY 2017 we finalized a work RVU of 0.61 based on a direct crosswalk from CPT code 99490 (chronic care management services) (81 FR 80351). We recognized that the services described by CPT code 99490 are distinct from those furnished under BHI, but we stated that until we have more information about how the services described by G0507 (replaced in 2018 by CPT 99484) are typically furnished, we believed valuation based on an estimate of the typical resources would be most appropriate (81 FR 80351). For CY 2022 we increased the value of CPT code 99490 from 0.61 to 1.00 (86 FR 65118).

In the CY 2023 PFS final rule (87 FR 69549) we finalized a new HCPCS code, G0323 (care management services for behavioral health conditions, at least 20 minutes of clinical psychologist or clinical social worker time, per calendar month. (*These services include the following required elements: Initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, coordination with and/or referral to physicians and practitioners who are authorized by Medicare to prescribe medications and furnish E/M services, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.*)) (See section II.J.1.c. of this proposed rule, for proposed code descriptor refinement.) We valued HCPCS code G0323 based on a direct crosswalk to the work values and direct PE inputs for CPT code 99484, because we believed the services described by G0323 mirrored those described by CPT code 99484. We noted that we may consider changes in how this code is valued for future rulemaking.

We continue to be concerned about undervaluing care management services under the PFS given the variability of costs involved with these evolving models of care. The RUC has recommended revaluing CPT code 99484, following a survey of 63 respondents. The median survey work RVU was 1.30, and the median time was 21 minutes (all intra-service). The specialty societies recommend a value of 0.93 based on a crosswalk to code 99202. We believe the specialty societies are in a good position to understand the evolving practice models. The RUC has recommended the 25th percentile survey work RVU of 0.85. Consistent with our goals of ensuring continued and consistent access to these crucial care management services we are proposing to increase the work RVU of CPT code 99484 to 0.93. This value reflects the work RVU of CPT code 99202, which has a similar work time.

We continue to believe that the services described by HCPCS code G0323 as proposed (section II.J.1.c. of this proposed rule) closely mirror those described by CPT code 99484. As we are proposing to update the work RVU and one of the PE inputs for CPT code 99484, we continue to believe that a direct crosswalk to the work values and direct PE inputs for CPT code 99484, is an appropriate valuation of the level, time, and intensity of the services under G0323 as proposed (section II.J.1.c. of this proposed rule). As such we propose to value HCPCS code G0323, as proposed (section II.J.1.c. of this proposed rule), based on a direct crosswalk to the work values and direct PE inputs for CPT code 99484, as proposed, previously in this section.

We continue to believe that there is a systemic undervaluation of work estimates for behavioral health services. We are proposing values for CY 2024 that we believe will more accurately value the work involved in delivering behavioral health services.

(21) Advance Care Planning (CPT Codes 99497 and 99498)

In January 2022, the Relativity Assessment Workgroup reviewed CPT codes 99497 and 99498. The Workgroup determined these advance care planning services should be examined given the recent changes in evaluation and management services. The RUC recommended that CPT codes 99497 and 99498 be surveyed for physician work and practice expense for the April 2022 RUC meeting. The RUC recommended no changes in physician

time, work RVUs, or direct PE inputs for these services for CY 2024.

We are proposing the RUC-recommended work RVU of 1.50 for CPT code 99497 and 1.40 for CPT code 99498, which are the current values for these codes. We are proposing the RUC-recommended direct PE inputs for these codes without refinement.

(22) Pelvic Exam (CPT Code 9X036)

In September 2022, the CPT Editorial Panel created a new CPT code for reporting a pelvic exam—CPT code 9X036. The specialty societies noted that reimbursement for the work would be captured with the problem-oriented E/M code billed for the visit. The CPT Editorial Panel agreed, thus the new code is a practice expense only code that captures the direct practice expenses associated with performing a pelvic exam in the non-facility setting. CPT code 9X036 (*Pelvic Exam*) captures the 4 minutes of clinical staff time associated with chaperoning a pelvic exam.

We are proposing the RUC-recommended direct-PE inputs for CPT code 9X036 without refinement. As a PE-only service, the RUC did not recommend and we are not proposing a work RVU for this code.

(23) Hyperthermic Intraperitoneal Chemotherapy (HIPEC) (CPT Codes 9X034 and 9X035)

In September 2022, the CPT Editorial Panel created two time-based add-on Category I CPT codes 9X034 (*Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; first 60 minutes*) and 9X035 (*Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; each additional 30 minutes*). CPT codes 9X034 and 9X035 were surveyed for the January 2023 RUC meeting. While reviewing the survey data, it was noted by specialty societies that the instructions were not sufficient as the survey data reflected time estimates that exceeded the time specified in the new time-based code descriptors. The RUC has stated that the survey results for both CPT codes 9X034 and 9X035 are inaccurate and that the codes should be resurveyed for 2025. Therefore, the RUC recommended contractor pricing for CPT codes 9X034 and 9X035 and that they be referred to the CPT Editorial Panel for revision.

We are proposing to contractor price CPT codes 9X034 and 9X035 for CY 2024.

(24) Hyperbaric Oxygen Under Pressure (HCPCS Code G0277)

In 2015, CMS created HCPCS code G0277 (*Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval*) to describe direct practice expense inputs associated with CPT code 99183 (*Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session*) (consistent with the Medicare Hospital Outpatient Prospective Payment System coding mechanism). At the September 2022 Relativity Assessment Workgroup meeting, HCPCS code G0277 was identified as a high-volume growth code with Medicare utilization of 10,000 or more that have increased by at least 100 percent from 2015 through 2022, and was reviewed at the January 2023 RUC meeting. Hyperbaric oxygen therapy is typically administered to one patient in one hyperbaric chamber for two hours. Two hours is typical, and all inputs are prorated for four units being performed (each 30 minutes, totaling 2 hours). All medical supply and time inputs have been divided into quarters.

There has been a change in the dominant specialty providing this service, which is now primarily performed by family medicine. There has also been a change in clinical staff type, and it is now typical for a single staff person to perform all activities (RN/Respiratory Therapist) as opposed to two staff (an RN/LPN/MA and an RN/respiratory therapist). This is primarily due to a 2016 change by the National Board of Diving and Hyperbaric Medical Technology to no longer allow certified nursing assistants and certified medical assistants to be eligible to take the certified hyperbaric technologist examination. The PE Subcommittee agreed with the specialty societies to update the clinical staff type to reflect solely L047C *RN/Respiratory Therapist.* We agree with the specialties that the intra-service time is now more appropriately labeled as clinical activity CA021 (*Perform procedure/service—NOT directly related to physician work time*) as opposed to CA018 due to the change in clinical staff type.

We are proposing to refine the clinical labor time for the CA013 activity (*Prepare room, equipment, and supplies*) from 1.5 minutes to 0.5 minutes, as well as the clinical labor time for the CA016 activity (*Prepare, set-up and start IV, initial positioning and monitoring of patient*) from 1 minute to 0.5 minutes to align with the 2-minute standard for these clinical activities. We arrived at these refinements by dividing the standard 2-minutes of clinical labor times for CA013 and CA016 by four to account for all inputs being prorated for four units being performed for one typical two-hour session. CA013 and CA016 would each be 0.5 minutes per 30-minute interval, which amounts to the standard 2 minutes for these clinical activities when four units are billed for the typical two-hour session. The RUC recommends 30 minutes for clinical labor activity CA021 (*Perform procedure/service—Not directly related to physician work time (intra-service time)* based on a flawed assumption that the current 15 minutes for CA021 accounts for two patients receiving treatment at the same time. We note that it has been standard for one patient to receive treatment at a time and the current 15 minutes for CA021 is based on a time ratio to the CY 2015 RUC-recommended direct PE inputs for CPT code 99183; therefore, we disagree with this RUC recommendation and are proposing to refine the recommended intra-service CA021 clinical labor time to maintain the current 15 minutes. This is to reflect the 2015 PFS final rule where ''we used the RUC recommended direct PE inputs for 99183 and adjusted them to align with the 30 minute treatment interval'' (79 FR 67677). Each PE input is prorated for four units of G0277 being provided in one typical two-hour session. Since CPT code 99183 (*Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session*) is a 120-minute code with 60-minute intra-service time, all PE inputs in HCPCS code G0277 are prorated for four units being performed.

To conform to these changes in clinical labor time, we are also proposing to refine the equipment time for the EQ362 (*HBOT air break breathing apparatus demand system (hoses, masks, penetrator, and demand valve*)) and EQ131 (*hyperbaric chamber*) equipment items from the recommended 39.75 minutes to 23.25 minutes. This is a result of the 15-minute intra-service time, as opposed to the RUC recommendation of 30 minutes of intra-service time.

(25) Remote Interrogation Device Evaluation—Cardiovascular (HCPCS Code G2066, and CPT Codes 93297, and 93298)

CPT code 93299 (*Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system or subcutaneous cardiac rhythm monitor system, remote data acquisitions(s),* receipt of transmissions and technician review, technical support and distribution of results) was

meant to serve as a catch-all for both base CPT codes 93297 and 93298, which are work-only codes. However, the CPT Editorial Panel determined that CPT code 93299 was no longer necessary if CPT codes 93297 and 93298 were assigned direct PE inputs and therefore recommended CMS to delete CPT code 93299 at the beginning of CY 2020 under the assumption that CPT codes 93297 and 93298 would be assigned direct PE inputs. Since CMS did not agree with the recommended values, CMS decided to not allocate direct PE inputs for CPT codes 93297 or 93298 and instead created contractor priced HCPCS code G2066 for CY 2020 to ensure these services could still be furnished that were previously described under 93299 (84 FR 62777–62778). Since the publication of the CY 2020 PFS Final Rule, HCPCS code G2066 has remained contractor priced and CPT codes 93297 and 93298 remain as work-only codes. CMS continues to work with MACs and interested parties to address a lot of the payment concerns surrounding G2066 such as discrepancies in payment between jurisdictions. However, interested parties have indicated that a long-term solution is needed from CMS in order to help establish payment stability for these services.

Therefore, for CY 2024, we are proposing to delete HCPCS code G2066 and propose the RUC-recommended direct PE inputs for CPT codes 93297 and 93298. Since CPT code 93298 is most commonly billed with G2066, the RUC recommended the same inputs for CPT code 93298 and HCPCS code G2066 in the event that no change would be made for HCPCS code G2066. Since CMS does agree with the RUC recommended values, we are proposing to delete HCPCS code G2066 altogether and establish direct PE-inputs for CPT codes 93297 and 93298 based on the RUC recommendations.

The RUC did not make recommendations on and we are not proposing any changes to the work RVUs for CPT codes 93297 and 93298.

(26) Payment for Caregiver Training Services

a. Background

In CY 2022, we received AMA RUC recommendations for a new code family of two codes (CPT code 96202 (*Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); initial 60 minutes*) and CPT code 96203 (*Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); each additional 15 minutes (List separately in addition to code for primary service*)) that describe group caregiver training services for patient behavior management/modification (without the patient in attendance). In CY 2023 we received AMA RUC recommendations for a family of three new caregiver training codes (CPT codes 9X015 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face; initial 30 minutes*), and add-on code, CPT code 9X016 (*each additional 15 minutes (List separately in addition to code for primary service) (Use 9X016 in conjunction with 9X015)*), and 9X017 (*Group caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face with multiple sets of caregivers*).

Historically, we have taken the position that codes describing services furnished to other individuals without the patient's presence are not covered services. As we noted in the CY 2023 PFS final rule (87 FR 69521), we have explained in previous rulemaking that we read section 1862(a)(1)(A) of the Act to limit Medicare coverage and payment to items and services that are reasonable and necessary for the diagnosis and treatment of an individual Medicare patient's illness or injury or that improve the functioning of an individual Medicare patient's malformed body member. For example, in the CY 2013 PFS final rule (77 FR 68979), when discussing payment for the non-face-to-face care management services that are part of E/M services, we stated that Medicare does not pay for services furnished to parties other than the patient. We listed, as an example, communication with caregivers. Because the codes for caregiver behavior management training describe services furnished exclusively to caregivers rather than to the individual Medicare patient, we indicated that we did not review the RUC-recommended valuation of these codes or propose to establish RVUs for these codes for purposes of PFS payment. While we did not establish payment for the new caregiver behavior management training codes in the CY 2023 PFS final rule, we indicated that we believed there could be circumstances where separate payment for such services may be appropriate. We stated that we would continue to consider the status of these and similar services in rulemaking for CY 2024 (87 FR 69522 through 69523). We specifically requested public comment on how a patient may benefit in medical circumstances when a caregiver is trained to effectively modify the patient's behavior, how current Medicare policies regarding these caregiver training services (CTS) can impact a patient's health, and how the services described by these codes might currently be bundled into existing Medicare-covered services. (87 FR 69521). Public comments were generally in favor of CMS making payment for these codes, stating that there is extensive empirical support for training parents/guardians/caregivers in behavior management/modification as a component of the standard of care for the treatment of certain health-related behavior issues and that this training promotes improved outcomes. Commenters also noted that there are several CPT codes paid under the PFS that describe services that do not include direct contact with the patient but are still considered integral to the patient's care, including, for example, separately billable care management services, interprofessional consultations, and caregiver-focused health risk assessment instrument (*e.g.,* depression inventory) for the benefit of the patient. In response to public comments, we acknowledged the important role caregivers could have in a patient's overall care.

As indicated in the CY 2023 PFS final rule, we have continued to consider whether the caregiver behavior management training and similar caregiver training services could be considered to fall within the scope of services that are reasonable and necessary under section 1862(a)(1)(A) of the Act, in alignment with the principles of the recent Executive Order on Increasing Access to High-Quality Care and Supporting Caregivers (*https://*

www.whitehouse.gov/briefing-room/presidential-actions/2023/04/18/executive-order-on-increasing-access-to-high-quality-care-and-supporting-caregivers/) and as part of a HHS level review of our payment policies to identify opportunities to better account for patient-centered care (*https://acl.gov/programs/support-caregivers/raise-family-caregiving-advisory-council*), changes in medical practice that have led to more care coordination and team-based care, and to promote equitable access to reasonable and necessary medical services. We also believe it is important for practitioners furnishing patient centered care to use various effective communication techniques when providing patient centered care, in alignment with requirements under section 1557 of the Affordable Care Act. We believe that, in certain circumstances, caregivers can play a key role in developing and carrying out the treatment plan or, as applicable to physical, occupational, or speech-language therapy, the therapy plan of care (collectively referred to in this discussion as the ''treatment plan'') established for the patient by the treating practitioner (which for purposes of this discussion could include a physician; nonphysician practitioner such as a nurse practitioner, physician assistant, clinical nurse specialist, clinical psychologist; or a physical therapist, occupational therapist, or speech-language pathologist). In this context, we believe Caregiver Training Services (CTS) could be reasonable and necessary to treat the patient's illness or injury as required under section 1862(a)(1)(A) of the Act. We have had the opportunity to consider the best approach to establishing separate payment for the services described by the caregiver training codes, especially as it relates to a practitioner who is treating a patient and expending resources to train a caregiver who is assisting or acting as a proxy for the patient. However, we continue to explore these issues and would appreciate public comments on all aspects of the CTS proposals.

In this proposed rule for CY 2024, we include a proposed definition of ''caregiver'' for purposes of CTS, discuss the circumstances under which patients may benefit from care involving caregivers, and propose that CTS may meet the conditions for Medicare payment when treating practitioners identify a need to involve and train caregivers to assist the patient in carrying out a treatment plan. We also propose values for each of the CTS codes.

(1) Definition of a Caregiver

In our ongoing education and outreach work on the use of caregivers in assisting patients, we have broadly defined a caregiver as a family member, friend, or neighbor who provides unpaid assistance to a person with a chronic illness or disabling condition (*https://www.cms.gov/outreach-and-education/outreach/partnerships/caregiver#:~:text=Caregivers%20are%20broadly%20defined%20as,chronic%20illness%20or%20disabling%20condition*). Further, in the context of our proposals for CTS services, we believe a caregiver is an individual who is assisting or acting as a proxy for a patient with an illness or condition of short or long-term duration (not necessarily chronic or disabling); involved on an episodic, daily, or occasional basis in managing a patient's complex health care and assistive technology activities at home; and helping to navigate the patient's transitions between care settings. For purposes of CTS, we also are including a guardian in this definition when warranted. For CTS, when we say ''caregiver'' we are also referring to guardians who for purposes of CTS, are the caregiver for minor children or other individuals who are not legally independent. In these circumstances, a caregiver is a layperson assisting the patient in carrying out a treatment plan that is established for the patient by the treating physician or practitioner and assists the patient with aspects of their care, including interventions or other activities directly related to a treatment plan established for the patient to address a diagnosed illness or injury. In this context, caregivers would be trained by the treating practitioner in strategies and specific activities that improve symptoms, functioning, and adherence to treatment related to the patient's primary clinical diagnoses. Caregiver understanding and competence in assisting and implementing these interventions and activities from the treating practitioner is critical for patients with functional limitations resulting from various conditions.

(2) Patients Who Benefit From Care Involving Caregivers

We believe that a patient-centered treatment plan should appropriately account for clinical circumstances where the treating practitioner believes the involvement of a caregiver is necessary to ensure a successful outcome for the patient and where, as appropriate, the patient agrees to caregiver involvement. There may be clinical circumstances when it might be appropriate for the physician or practitioner to directly involve the caregiver in developing and carrying out a treatment plan. Such clinical circumstances could include various physical and behavioral health conditions and circumstances under which CTS may be reasonable and necessary to train a caregiver who assists in carrying out a treatment plan. Conditions include but are not limited to, stroke, traumatic brain injury (TBI), various forms of dementia, autism spectrum disorders, individuals with other intellectual or cognitive disabilities, physical mobility limitations, or necessary use of assisted devices or mobility aids. The previously mentioned clinical scenarios are examples of circumstances under which CTS may be reasonable and necessary to train a caregiver who assists in carrying out a treatment plan. For example, patients with dementia, autism spectrum disorder, or individuals with other intellectual or cognitive disabilities, may require assistance with challenging behaviors in order to carry out a treatment plan, patients with mobility issues may need help with safe transfers in the home to avoid post-operative complications, patients with persistent delirium may require guidance with medication management, patients with certain degenerative conditions or those recovering from stroke may need assistance with feeding or swallowing. Separate from medical circumstances noted previously in this section above, we also seek to avoid potentially duplicative payment. We would not expect the caregiver population receiving these services on behalf of the patient to also receive CTS on behalf of the patient under another Medicare benefit category or Federal program. Also, we note that when Medicare and Medicaid cover the same services for patients eligible for both programs, Medicare generally is the primary payer in accordance with section 1902(a)(25) of the Act. Based on the specificity of the coding for our proposal, we do not expect that CTS will neatly overlap with any other coverage for patients who are dually eligible for Medicare and Medicaid. However, we are seeking public comment regarding whether States typically cover services similar to CTS under their Medicaid programs, and whether such coverage would be duplicative of the CTS service codes. We are seeking comment on this issue and whether payment is currently available for CTS through other Federal or other programs.

(3) Reasonable and Necessary CTS

We believe CTS could be reasonable and necessary when furnished based on an established individualized, patient-centered treatment plan or therapy plan of care accounting for the patient's specific medical needs, including, but not limited to, the examples specified previously in this proposed rule.

As provided in the code descriptors, treating practitioners may train caregivers in a group setting with other caregivers who are involved in care for patients with similar needs for assistance to carry out a treatment plan. Training for all of the caregivers for the patient could occur simultaneously, and the applicable CTS codes (CPT code 96202, 96203, and 9X017) would be billed once per beneficiary. We are seeking comment on this issue. We also seek comment on whether payment is currently available for CTS through other Federal or other programs. We are considering whether CTS would be reasonable and necessary when furnished to caregivers in more than one single session, or to (presumably the same) caregivers by the same practitioner for the same patient more than once per year and are seeking comment on this. We want to note that the treating physician or NPP may provide training to more than one caregiver for a single patient.

(4) Proposals

For CY 2024, we propose to establish an active payment status for CPT codes 96202 and 96203 (caregiver behavior management/modification training services) and CPT codes 9X015, 9X016, and 9X017 (caregiver training services under a therapy plan of care established by a PT, OT, SLP). These codes allow treating practitioners to report the training furnished to a caregiver, in tandem with the diagnostic and treatment services furnished directly to the patient, in strategies and specific activities to assist the patient to carry out the treatment plan. As discussed previously in this section, we believe that CTS may be reasonable and necessary when they are integral to a patient's overall treatment and furnished after the treatment plan (or therapy plan of care) is established. The CTS themselves need to be congruent with the treatment plan and designed to effectuate the desired patient outcomes. We believe this is especially the case in medical treatment scenarios where assistance by the caregiver receiving the CTS is necessary to ensure a successful treatment outcome for the patient—for example, when the patient cannot follow through with the treatment plan for themselves (see examples previously mentioned in this section under ''Patients Who Benefit from Care Involving Caregivers'').

We are seeking public comment on this definition of 'caregiver' for purposes of CTS and are interested if there are any additional elements of a caregiver that we should consider incorporating in this proposed CTS caregiver definition. We think that our proposed definition would allow for holistic care of the patient with those who know and understand the patient, their condition, and their environment.

We propose that payment may be made for CTS services when the treating practitioner identifies a need to involve and train one or more caregivers to assist the patient in carrying out a patient-centered treatment plan. We further propose that because CTS services are furnished outside the patient's presence, the treating practitioner must obtain the patient's (or representative's) consent for the caregiver to receive the CTS. We further propose that the identified need for CTS and the patient's (or representative's) consent for one or more specific caregivers to receive CTS must be documented in the patient's medical record.

We are proposing to require the full 60 minutes of time to be performed in order to report CPT code 96202. The add on code, CPT code 96203, may be reported once 75 minutes of total time is performed. We are interested in and seeking comment on how the clinician and caregiver interactions would typically occur, including when the practitioner is dealing with multiple caregivers and how often these services would be billed considering the established treatment plan involving caregivers for the typical patient.

We are soliciting public comment on each of our proposals for CTS.

b. Coding

(1) Behavior Management/Modification Training for Guardians/Caregivers of Patients With a Mental or Physical Health Diagnosis (CPT Codes 96202 and 96203)

CPT code 96202 (*Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); initial 60 minutes*) and its add-on code, CPT code 96203 (*Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); each additional 15 minutes (List separately in addition to code for primary service*)), were two new codes created by the CPT Editorial Panel during its February 2021 meeting. The two codes are to be used to report the total duration of face-to-face time spent by the physician or other qualified health professional providing group behavior management/modification training to guardians or caregivers of patients. Although the patient does not attend the group trainings, the goals and outcomes of the sessions focus on interventions aimed at effectuating the practitioner's treatment plan through addressing challenging behaviors and other behaviors that may pose a risk to the person, and/or others. According to the Summary of Recommendations (which was submitted by the AMA RUC with the valuation of this code), during the face-to-face service time, caregivers are taught how to structure the patient's environment to support and reinforce desired patient behaviors, to reduce the negative impacts of the patient's diagnosis on patient's daily life, and to develop highly structured technical skills to manage the patient's challenging behavior.

Behavior management/modification training for guardians/caregivers of patients with a mental or physical health diagnosis should be directly relevant to the person-centered treatment plan for the patient in order for the services to be considered reasonable and necessary under the Medicare program. Each behavior should be clearly identified and documented in the treatment plan, and the caregiver should be trained in positive behavior management strategies.

(a) Valuation

The RUC recommended the survey median work value for both CPT codes 96202 and 96203. Three specialty societies sent surveys to a random sample of a subset of their members. Based on survey results and after discussion, the RUC recommended a work RVU of 0.43 for a specific patient who is represented in the group session being billed for CPT code 96202. The RUC noted that this recommendation is based upon a median group size of six caregivers and includes 10 minutes pre-time, 60 minutes intra-time, and 20

minutes post-time for a total time of 90 minutes. For CPT code 96203, the 15-minute add on code, the RUC recommended a work RVU of 0.12, which is also based upon a median group size of six. We are proposing the RUC-recommended work RVU of 0.43 for CPT code 96202 and the RUC-recommended work RVU of 0.12 for CPT code 96203. We are also proposing the RUC-recommended direct PE inputs for these codes.

Finally, we note that the RUC recommendation included information suggesting that the RUC intends to review the valuation of these services again soon.

(2) Caregiver Training in Strategies and Techniques To Facilitate the Patient's Functional Performance (CPT Codes 9X015, 9X016, and 9X017)

CPT codes 9X015 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face; initial 30 minutes*), and add-on code, CPT code 9X016 (*each additional 15 minutes (List separately in addition to code for primary service) (Use 9X016 in conjunction with 9X015)*), and 9X017 (*Group caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face with multiple sets of caregivers*) are new codes created by the CPT Editorial Panel during its October 2022 meeting. The three codes are to be used to report the total duration of face-to-face time spent by the physician or other qualified health professional providing individual or group training to caregivers of patients. Although the patient does not attend the trainings, the goals and outcomes of the sessions focus on interventions aimed at improving the patient's ability to successfully perform activities of daily living (ADL's). Activities of daily living generally include ambulating, feeding, dressing, personal hygiene, continence, and toileting.

During the face-to-face service time, caregivers are taught by the treating practitioner how to facilitate the patient's activities of daily living, transfers, mobility, communication, and problem-solving to reduce the negative impacts of the patient's diagnosis on the patient's daily life and assist the patient in carrying out a treatment plan. These specific services are reasonable and necessary when treating practitioners identify a need to involve and train caregivers to assist the patient in carrying out a treatment plan. As part of an individualized plan of care, the caregiver is trained in skills to assist the patient in completing daily life activities. These trainings to the caregiver include the development of skills such as safe activity completion, problem solving, environmental adaptation, training in use of equipment or assistive devices, or interventions focusing on motor, process, and communication skills.

(a) Valuation

The RUC recommended work values for CPT codes 9X015, 9X016, and 9X017 based on the survey median values and the key reference CPT codes 97535 and 97130. The surveyed codes fall appropriately between these key reference services compared to the work RVU, total time, and related intensity of each service. Three specialty societies sent surveys to a random sample of a subset of their members. Based upon survey results and after discussion, the RUC recommended a work RVU 1.00 for CPT code 9X015, a work RVU of 0.54 for 9X016, and a work RVU of 0.23 per specific patient represented in the group service being billed for CPT code 9X017.

We are proposing the RUC-recommended work RVU 1.00 for CPT code 9X015, the RUC-recommended work RVU of 0.54 for 9X016, and the RUC-recommended work RVU of 0.23 per identified patient service for CPT code 9X017. The RUC noted that the recommendation for 9X017 is based on a median group size of five caregivers. We are also proposing the RUC-recommended direct PE inputs for these codes.

Finally, we note that the RUC recommendation included information suggesting that the RUC intends to review the valuation of these services again soon. We are proposing to designate 9X015, 9X016, and 9X017 as ''sometimes therapy''. This means that the services of these codes are always furnished under a therapy plan of care when provided by PTs, OTs, and SLPs; but, in cases where they are appropriately furnished by physicians and NPPs outside a therapy plan of care, that is where the services are not integral to a therapy plan of care, they can be furnished under a treatment plan by physicians and NPPs.

We are proposing to accept RUC recommendations as stated previously in this section for these codes.

(27) Services Addressing Health-Related Social Needs (Community Health Integration Services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services)

a. Background

In recent years, we have sought to recognize significant changes in health care practice and been engaged in an ongoing, incremental effort to identify gaps in appropriate coding and payment for care management/coordination and primary care services under the PFS. See, for example, our CY 2013, 2015, and 2017 PFS final rules, where we finalized new coding to provide separate payment for transitional care management services, chronic care management services, and behavioral health care management services to improve payment accuracy to better recognize resources involved in care management and coordination for certain patient populations (77 FR 68978, 79 FR 67715 and 82 FR 53163, respectively). To improve payment accuracy, we are exploring ways to better identify and value practitioners' work when they incur additional time and resources helping patients with serious illnesses navigate the healthcare system or removing health-related social barriers that are interfering with the practitioner's ability to execute a medically necessary plan of care. Practitioners and their staff of auxiliary personnel sometimes obtain information about and help address, social determinants of health (SDOH) that significantly impact the practitioner's ability to diagnose or treat a patient. Additionally, practitioners and their staff of auxiliary personnel sometimes help newly diagnosed cancer patients and other patients with similarly serious, high-risk illnesses navigate their care, such as helping them understand and implement the plan of care, and locate and reach the right practitioners and providers to access recommended treatments and diagnostic services, taking into account the personal circumstances of each patient. Payment for these activities, to the extent they are reasonable and necessary for the diagnosis and treatment of the patient's illness or injury, is currently included in payment for other services such as evaluation and management (E/M) visits and some care management services. Medical practice has evolved to increasingly recognize the importance of these activities, and we believe practitioners are performing them more often. However, this work is not explicitly identified in current coding, and as such, we believe it is

underutilized and undervalued. Accordingly, we are proposing to create new coding to expressly identify and value these services for PFS payment, and distinguish them from current care management services. We expect that our proposed new codes would also support the CMS pillars [4] for equity, inclusion, and access to care for the Medicare population and improve patient outcomes, including for underserved and low-income populations where there is a disparity in access to quality care. They would also support the White House's National Strategy on Hunger, Nutrition and Health, and the White House's Cancer Moonshot Initiative.[5]

As part of this effort, in the CY 2023 PFS final rule (87 FR 69551 through 69551), we issued a Request for Information (RFI) related to Medicare Part B Payment for services involving Community Health Workers (CHWs). For CY 2024, we are considering how we could better recognize, through coding and payment policies, when members of an interdisciplinary team, including CHWs, are involved in treatment of Medicare beneficiaries. Currently, there is no separately enumerated statutory Medicare benefit category that provides direct payment to CHWs for their services. Additionally, current HCPCS coding does not specifically identify services provided by CHWs, even though CHWs may facilitate access to healthcare through community-based services that are necessary to alleviate barriers to care that are interfering with a practitioner's ability to diagnosis or treat an illness or injury. In rulemaking for the CY 2023 PFS, to gain a broader perspective on CHWs and how we could refine our coding and payment policies to better recognize their role in furnishing Medicare-covered services, we solicited comment through an RFI on how services involving CHWs are furnished in association with the specific Medicare benefits established by the statute.

Commenters were supportive overall of potential, separate coding and payment for services involving CHWs. The public comments indicated that a number of physicians, practitioners, group practices, and other entities currently utilize the services of CHWs to bridge gaps in the continuum of their medical and behavioral healthcare furnished to Medicare patients. In public comments on our RFI, interested parties provided testimonials and evidence about the effectiveness of CHWs and the services that they provide to patients in the community by monitoring, interpreting, clarifying, and supporting the plans of care that physicians and practitioners establish for delivering care to patients.

In addition, in 2021, the AMA CPT Editorial Panel recognized in the CPT E/M Guidelines that SDOH needs can increase complexity of a practitioner's medical decision making (MDM) for an E/M visit and increase risk to the patient, when diagnosis or treatment is significantly limited by SDOH.[6] Specifically, the CPT Editorial Panel included as an example of moderate level MDM for E/M visit coding and level selection, a situation where diagnosis or treatment is significantly limited by SDOH. This situation is listed as an example of moderate risk of morbidity from additional diagnostic testing or treatment. The CPT E/M Guidelines defined SDOH as, ''Economic and social conditions that influence the health of people and communities. Examples may include food or housing insecurity.'' [7] We adopted these revised CPT guidelines for MDM in E/M visits through notice and comment rulemaking, effective January 1, 2021 (84 FR 62844 through 62860, 87 FR 69587 through 69614).

Physicians and NPPs are generally trained to obtain a patient's social and family history, in support of patient-centered care, to aid in diagnosis, and to better understand and help address problem(s) addressed in a medical visit and associated risk factors.[8] For example, a practitioner who discovers that a patient's living situation does not permit reliable access to electricity may need to prescribe an inhaler rather than a power-operated nebulizer to treat asthma. Some practices and facilities employ social workers or other ancillary staff to help address SDOH needs that are impacting the ability to provide medically necessary care, such as appropriate treatment or diagnostic services after an office visit or following discharge from a facility.

Practitioners are increasingly expending resources to obtain information from the patient about health-related social needs and risks, and formulate diagnosis and treatment plans that take these needs into account. We believe that social workers, CHWs and other auxiliary personnel are currently performing some of these activities, and that the resources involved in these activities are not consistently appropriately reflected in current coding and payment policies. As such, we believe it would be appropriate to create codes to separately identify and more accurately value this work. Accordingly, we are proposing new coding to describe and separately value three types of services that may be provided by auxiliary personnel incident to the billing physician or practitioner's professional services, and under the billing practitioner's supervision, when reasonable and necessary to diagnose and treat the patient: community health integration services, SDOH risk assessment, and principal illness navigation. This section of our proposed rule lays out the proposed codes and their proposed valuation, and describes the circumstances under which we believe these services may be reasonable and necessary for the diagnosis or treatment of illness or injury such that Medicare payment may be made for them.

b. Community Heath Integration (CHI) Services

In light of the feedback we have received from our RFI regarding CHWs, and increased recognition within the medical community of the role that social needs can play in patients' health (specifically, interfering with ability to diagnose and treat patients), we are proposing to establish separate coding and payment for community health integration (CHI) services. We are proposing to create two new G codes describing CHI services performed by certified or trained auxiliary personnel, which may include a CHW, incident to the professional services and under the general supervision of the billing practitioner. We are proposing that CHI services could be furnished monthly, as medically necessary, following an initiating E/M visit (CHI initiating visit) in which the practitioner identifies the presence of SDOH need(s) that significantly limit the practitioner's ability to diagnose or treat the problem(s) addressed in the visit.

[4] CMS Strategic Plan | CMS.

[5] White-House-National-Strategy-on-Hunger-Nutrition-and-Health-FINAL.pdf (*whitehouse.gov*); Fact Sheet: President Biden Reignites Cancer Moonshot to End Cancer as We Know It | The White House *https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/02/fact-sheet-president-biden-reignites-cancer-moonshot-to-end-cancer-as-we-know-it/.*

[6] 2021 CPT Codebook, p. 16.

[7] 2021 CPT Codebook, p. 14.

[8] See for example Patient-Centered Communication: Basic Skills | AAFP; *https://www.aafp.org/about/policies/all/social-determinants-health-family-medicine-position-paper.html*; *https://doi.org/10.7326/M17-2441; https://nam.edu/social-determinants-of-health-201-for-health-care-plan-do-study-act/*; *https://www.ama-assn.org/system/files/2021-05/ama-equity-strategic-plan.pdf*; *https://edhub.ama-assn.org/steps-forward/module/2702762.* The Origins of the History and Physical Examination—Clinical Methods—NCBI Bookshelf (*nih.gov*) *https://www.ncbi.nlm.nih.gov/books/NBK458/.*

We propose that the CHI initiating visit would be an E/M visit (other than a low-level E/M visit that can be performed by clinical staff) performed by the billing practitioner who will also be furnishing the CHI services during the subsequent calendar month(s). The CHI initiating visit would be separately billed (if all requirements to do so are met), and would be a pre-requisite to billing for CHI services. We believe that certain types of E/M visits, such as inpatient/observation visits, ED visits, and SNF visits would not typically serve as CHI initiating visits because the practitioners furnishing the E/M services in those settings would not typically be the ones to provide continuing care to the patient, including furnishing necessary CHI services in the subsequent month(s).

The CHI initiating visit would serve as a pre-requisite to billing for CHI services, during which the billing practitioner would assess and identify SDOH needs that significantly limit the practitioner's ability to diagnose or treat the patient's medical condition and establish an appropriate treatment plan. The subsequent CHI services would be performed by a CHW or other auxiliary personnel incident to the professional services of the practitioner who bills the CHI initiating visit. The same practitioner would furnish and bill for both the CHI initiating visit and the CHI services, and CHI services must be furnished in accordance with the ''incident to'' regulation at § 410.26. We would not require an initiating E/M visit every month that CHI services are billed, but only prior to commencing CHI services, to establish the treatment plan, specify how addressing the unmet SDOH need(s) would help accomplish that plan, and establish the CHI services as incident to the billing practitioner's service. This framework is similar to our current requirements for billing care management services, such as chronic care management services. It also comports with our longstanding policy in the Medicare Benefit Policy Manual which provides, ''where a physician supervises auxiliary personnel to assist him/her in rendering services to patients and includes the charges for their services in his/her own bills, the services of such personnel are considered incident to the physician's service if there is a physician's service rendered to which the services of such personnel are an incidental part. This does not mean, however, that to be considered incident to, each occasion of service by auxiliary personnel (or the furnishing of a supply) need also always be the occasion of the actual rendition of a personal professional service by the physician. Such a service or supply could be considered to be incident to when furnished during a course of treatment where the physician performs an initial service and subsequent services of a frequency which reflect his/her active participation in and management of the course of treatment'' (Chapter 15, Section 60.1.B of the Medicare Benefit Policy Manual (Pub. 100–02), available on our website at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf* (*cms.gov*)).

We are also seeking comment on whether we should consider any professional services other than an E/M visit performed by the billing practitioner as the prerequisite initiating visit for CHI services, including, for example, an annual wellness visit (AWV) that may or may not include the optional SDOH risk assessment also proposed in this rule. Under section 1861(hhh)(3)(C) of the Act, the AWV can be furnished by a physician or practitioner, or by other types of health professionals whose scope of practice does not include the diagnosis and treatment involved in E/M services, for example a health educator. When the AWV is furnished by other types of health professionals, it is not necessarily furnished incident to the professional services of a physician or other practitioner. Therefore, if we were to allow an AWV furnished by a health care practitioner other than a physician or practitioner to serve as the initiating visit for CHI services, the CHI services would not necessarily be furnished consistent with our proposed application of the ''incident to'' regulations as a condition of payment. Further, we believe that practitioners would normally bill an E/M visit in addition to the AWV when medical problems are addressed in the course of an AWV encounter, in accordance with our manual policy providing that a medically necessary E/M visit may be billed when furnished on the same occasion as an AWV in those circumstances (Chapter 12, Section 30.6.1.1.H of the Medicare Claims Processing Manual (Pub. 100–04).

For purposes of assigning a supervision level for these ''incident to'' services, we are proposing to designate CHI services as care management services that may be furnished under the general supervision of the billing practitioner in accordance with § 410.26(b)(5). General supervision means the service is furnished under the physician's (or other practitioner's) overall direction and control, but the physician's (or other practitioner's) presence is not required during the performance of the service (§ 410.26(a)(3)).

In this proposal, the phrase or term ''problem addressed'' refers to the definition in the CPT E/M Guidelines that we have adopted for E/M visits. Specifically, ''[a] problem is a disease, condition, illness, injury, symptom, finding, complaint, or other matter addressed at the encounter, with or without a diagnosis being established at the time of the encounter. Problem addressed [means the following]: A problem is addressed or managed when it is evaluated or treated at the encounter by the physician or other qualified healthcare professional reporting the service. This includes consideration of further testing or treatment that may not be elected by virtue of risk/benefit analysis or patient/parent/guardian/surrogate choice. Notation in patient's medical record that another professional is managing the problem without additional assessment or care coordination documented does not qualify as being addressed or managed by the physician or other qualified healthcare professional reporting the service. Referral without evaluation (by history, examination, or diagnostic study[ies]) or consideration of treatment does not qualify as being addressed or managed by the physician or other qualified healthcare professional reporting the service. For hospital inpatient and observation care services, the problem addressed is the problem status on the date of the encounter, which may be significantly different than on admission. It is the problem being managed or co-managed by the reporting physician or other qualified healthcare professional and may not be the cause of admission or continued stay'' (2023 CPT Codebook, p. 6–8).

For purposes of CHI services (and PIN services discussed later in this section), we propose that SDOH means economic and social condition(s) that influence the health of people and communities, as indicated in these same CPT E/M Guidelines (2023 CPT codebook, page 11). We are proposing to adopt CPT's examples of SDOH, with additional examples. Specifically, we are proposing that SDOH(s) may include but are not limited to food insecurity, transportation insecurity, housing insecurity, and unreliable access to public utilities, when they significantly limit the practitioner's ability to diagnose or treat the problem(s) addressed in the CHI initiating visit. Since Medicare payment generally is limited to items and services that are reasonable and necessary for the

diagnosis or treatment of illness or injury, the focus of CHI services would need to be on addressing the particular SDOH need(s) that are interfering with, or presenting a barrier to, diagnosis or treatment of the patient's problem(s) addressed in the CHI initiating visit.

We propose the following specific codes and descriptors:

GXXX1 *Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit:*

- *Person-centered assessment, performed to better understand the individualized context of the intersection between the SDOH need(s) and the problem(s) addressed in the initiating E/M visit.*

++ Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors.

++ Facilitating patient-driven goal-setting and establishing an action plan.

++ Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.

- *Practitioner, Home-, and Community-Based Care Coordination.*

++ Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable).

++ Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.

++ Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.

++ Facilitating access to community-based social services (*e.g.,* housing, utilities, transportation, food assistance) to address the SDOH need(s).

- *Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the SDOH need(s), and educating the patient on how to best participate in medical decision-making.*
- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the SDOH need(s), in ways that are more likely to promote personalized and effective diagnosis or treatment.*
- *Health care access/health system navigation*

++ Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.

- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*
- *Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*
- *Leveraging lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

GXXX2—Community health integration services, each additional 30 minutes per calendar month (List separately in addition to GXXX1).

By way of example, tailored support could be provided through CHI services to a patient experiencing homelessness with signs of potential cognitive impairment and a history of frequent ED admissions for uncontrolled diabetes. The patient's primary care practitioner (PCP) learns during a clinic visit after discharge from the ED, that the patient has been able to reliably fill their prescriptions for diabetes medication, but frequently loses the medication (or access to it) while transitioning between homeless shelters and a local friend's home. In the medical record, the PCP documents SDOH need(s) of housing insecurity and transportation insecurity contributing to medication noncompliance, resulting in inadequate insulin control and a recent ED visit for hypoglycemia. The PCP's treatment plan is daily diabetes medication, with the goal of maintaining hemoglobin A1c within appropriate levels. To accomplish the treatment plan, the PCP orders CHI services to develop an individualized plan for daily medication adherence/access while applying for local housing assistance, and also orders a follow up visit for cognitive impairment assessment and care planning to further evaluate the potential contribution of cognitive impairment. The PCP's auxiliary personnel provide tailored support, comprised of facilitating communication between the patient, local shelters, and the friend, to help the patient identify a single location to reliably store their medication while applying for local housing assistance. The auxiliary personnel also help the patient identify a reliable means of transportation daily to that location for their medication, and show the patient how to create a daily automated phone reminder to take the diabetes medication. The auxiliary personnel document these activities (including amount of time spent) in the medical record at the PCP's office, along with periodic updates regarding the status of the patient's housing assistance application.

To help inform whether our proposed descriptor times are appropriate and reflect typical service times, and whether a frequency limit is relevant for the add-on code, we are seeking comment on the typical amount of time practitioners spend per month furnishing CHI services to address SDOH needs that pose barriers to diagnosis and treatment of problem(s) addressed in an E/M visit. We are also seeking comment to better understand the typical duration of CHI services, in terms of the number of months for which practitioners furnish the services.

We are proposing that all auxiliary personnel who provide CHI services must be certified or trained to perform all included service elements, and authorized to perform them under applicable State laws and regulations. Under § 410.26(a)(1) of our regulations, auxiliary personnel must meet any applicable requirements to provide the services performed incident to the billing practitioner's professional services, including licensure, that are imposed by the State in which the services are being furnished. In States where there are no applicable licensure or other laws or regulations relating to individuals performing CHI services, we are proposing to require auxiliary personnel providing CHI services to be trained to provide them. Training must include the competencies of patient and family communication, interpersonal and relationship-building, patient and family capacity-building, service coordination and system navigation,

patient advocacy, facilitation, individual and community assessment, professionalism and ethical conduct, and the development of an appropriate knowledge base, including of local community-based resources. We are proposing these competencies because they reflect professional consensus regarding appropriate core competencies for CHWs, applied to this context.[9] We are seeking public comment on whether it would be appropriate to specify the number of hours of required training, as well as the training content and who should provide the training.

We are proposing to require that time spent furnishing CHI services for purposes of billing HCPCS codes GXXX1–2 must be documented in the patient's medical record in its relationship to the SDOH need(s) they are intended to address and the clinical problem(s) they are intended to help resolve. The activities performed by the auxiliary personnel would be described in the medical record, just as all clinical care is documented in the medical record. We are proposing to require the SDOH need(s) to be recorded in the patient's medical record, and for data standardization, practitioners would be encouraged to record the associated ICD–10 Z–code (Z55–Z65) in the medical record and on the claim.

Since CHI services are community-based and involve connecting the patient with local resources in their community, and are highly personalized, *e.g.,* hearing and understanding a patient's life story and culture, we believe that most of the elements of CHI services would involve direct contact between the auxiliary personnel and the patient, and that a substantial portion would be in-person but a portion might be performed via two-way audio. We are seeking to confirm our understanding of where and how these services would be typically provided (*e.g.,* in-person, audio-video, two-way audio).

We are seeking public comment, in particular, regarding whether we should require patient consent for CHI services. For care management services that could generally be performed without any direct patient contact, we require advance patient consent to receive the services as a prerequisite to furnishing and billing the services, to avoid patients receiving bills for cost sharing that they might not be expecting to receive. For example, a patient might receive chronic care management services comprised of practitioners coordinating care with each other and reviewing or exchanging medical records between visits in ways that do not require involving the patient directly. As we have frequently discussed in prior rulemaking for care management services (for example, at 81 FR 80240), we do not have statutory authority to waive cost sharing for care management or other services. Rather, cost sharing remains applicable except as specified by statute such as for certain preventive services. In recent years, we have required advance documented patient consent to receive most care management services as a condition of the practitioner billing those services, to avoid a situation where the patient is surprised to receive a bill for the associated cost sharing. These consent requirements include informing the patient about applicable cost sharing, the right to discontinue services, and, where applicable, the limitation that payment is made for the service to only one practitioner per month. We have heard from interested parties over time that requiring advance patient consent is an administrative burden and may pose a barrier to receipt of needed services. We are not proposing to require consent for CHI services, since we believe these services typically would involve direct patient contact, and largely be provided in-person. However, if we hear from public commenters that CHI services would frequently not involve direct contact with the patient, or could extend for periods of time for which the patient might not be expecting to incur cost sharing obligations (such as multiple months), we would consider requiring patient consent to receive CHI services in our final rule.

We are proposing that a billing practitioner may arrange to have CHI services provided by auxiliary personnel who are external to, and under contract with, the practitioner or their practice, such as through a community-based organization (CBO) that employs CHWs, if all of the ''incident to'' and other requirements and conditions for payment of CHI services are met. While we are proposing to allow CHI services to be performed by auxiliary personnel under a contract with a third party, we wish to be clear, as we have in our regulations for current care management services, that there must be sufficient clinical integration between the third party and the billing practitioner in order for the services to be fully provided, and the connection between the patient, auxiliary personnel, and the billing practitioner must be maintained. As we discussed in a similar context for care management services the CY 2017 PFS final rule, if there is little oversight by the billing practitioner or a lack of clinical integration between a third party providing the services and the billing practitioner, we do not believe CHI services, as we propose to define them, could be fully performed; and therefore, in such cases, CHI services should not be billed (see 81 FR 80249). We would expect the auxiliary personnel performing the CHI services to communicate regularly with the billing practitioner to ensure that CHI services are appropriately documented in the medical record, and to continue to involve the billing practitioner in evaluating the continuing need for CHI services to address the SDOH need(s) that limit the practitioner's ability to diagnose and treat the problem(s) addressed in the initiating visit.

As noted in the CY 2023 PFS final rule (87 FR 69790) and explained in the CY 2023 PFS proposed rule (87 FR 46102), when we refer to community-based organizations, we mean public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations. They may include community-action agencies, housing agencies, area agencies on aging, centers for independent living, aging and disability resource centers or other non-profits that apply for grants or contract with healthcare entities to perform social services. As described earlier, they may receive grants from other agencies in the U.S. Department of Health and Human Services, including Federal grants administered by the Administration for Children and Families (ACF), Administration for Community Living (ACL), the Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMHSA), or State-funded grants to provide social services. Generally, we believe such organizations know the populations and communities they serve, and may have the infrastructure or systems in place to assist practitioners to provide CHI services. We understand that many CBOs provide social services and do other work that is beyond the scope of CHI services, but we believe they are well-positioned to develop relationships with practitioners for providing reasonable and necessary CHI services.

Because we are concerned about potential fragmentation that could occur in addressing specific SDOH, we are proposing that only one practitioner per beneficiary per calendar month could bill for CHI services. This would allow

[9] *https://chwtraining.org/c3-project-chw-skills/.*

the patient to have a single point of contact for all their CHI services during a given month.

We are proposing that the practitioner could separately bill for other care management services during the same month as CHI services, if time and effort are not counted more than once, requirements to bill the other care management service are met, and the services are medically reasonable and necessary.

We propose that CHI services could not be billed while the patient is under a home health plan of care under Medicare Part B, since we believe there would be significant overlap between services furnished under a home health plan of care and CHI services, particularly in the home health services referred to as ''medical social services,'' and in comprehensive care coordination. For example, medical social services can be furnished to the patient's family member or caregiver on a short-term basis when the home health agency (HHAs) can demonstrate that a brief intervention by a medical social worker is necessary to remove a clear and direct impediment to the effective treatment of the patient's medical condition or to the patient's rate of recovery. Additionally, the home health agency (HHA) conditions of participation require that HHAs coordinate all aspects of the beneficiary's care while under a home health plan of care, such as integrating services, whether provided directly or under arrangement, to assure the identification of patient needs and factors that could affect patient safety and treatment effectiveness and the coordination of care provided by all disciplines; and involvement of the patient, representative (if any), and caregiver(s), as appropriate, in the coordination of care activities.

Also, we note that when Medicare and Medicaid cover the same services for patients eligible for both programs, Medicare generally is the primary payer in accordance with section 1902(a)(25) of the Act. Based on the specificity of the coding for our proposal, we do not expect that CHI services will neatly overlap with any other coverage for patients who are dually eligible for Medicare and Medicaid. However, we are seeking public comment regarding whether States typically cover services similar to CHI under their Medicaid programs, and whether such coverage would be duplicative of the CHI service codes. We also seek comment on whether there are other service elements not included in the proposed CHI service codes that should be included, or are important in addressing unmet SDOH need(s) that affect the diagnosis or treatment of medical problems, where CMS should consider coding and payment in the future.

c. Proposed CHI Services Valuation

For HCPCS code GXXX1, we are proposing a work RVU of 1.00 based on a crosswalk to CPT code 99490 (*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 that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; first 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month*) as we believe these values most accurately reflect the resource costs incurred when the billing practitioner furnishes CHI services. CPT code 99490 has an intraservice time of 25 minutes and the work is of similar intensity to our proposed HCPCS code GXXX1. We are, therefore, proposing a work time of 25 minutes for HCPCS code GXXX1, based on this same crosswalk to CPT code 99490. We are also proposing to use this crosswalk to establish the direct PE inputs for HCPCS code GXXX1.

For HCPCS code GXXX2, we are proposing a crosswalk to the work RVU and direct PE inputs associated with CPT code 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 that 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 (List separately in addition to code for primary procedure)*) as we believe these values reflect the resource costs incurred when the billing practitioner furnishes CHI services. Therefore, we are proposing a work RVU of 0.70 and a work time of 20 minutes for HCPCS code GXXX2.

d. Social Determinants of Health (SDOH)—Proposal To Establish a Stand-Alone G Code

i. Background

As previously discussed, there is increasing recognition within the health care system of the need to take SDOH into account when providing health care services, given that it is estimated [10] that around 50 percent of an individual's health is directly related to SDOH. Healthy People 2030 define the broad groups of SDOH as: economic stability, education access and quality, healthcare access and quality, neighborhood and built environment, and social and community context, which include factors like housing, food and nutrition access, and transportation needs. Many Federal agencies are also developing policies to better address the impact SDOH have on patients, in support of HHS's Strategic Approach to Addressing Social Determinants of Health to Advance Health Equity,[11] as well as the CMS Framework for Health Equity.[12]

ii. Proposed SDOH Risk Assessment Code

Over the past several years, we have worked to develop payment mechanisms under the PFS to improve the accuracy of valuation and payment for the services furnished by physicians and other health care professionals, especially in the context of evolving models of care. Section 1862(a)(1)(A) of the Act generally excludes from coverage services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Practitioners across specialties have opined and recognized the importance of SDOH on the health care provided to their patients, including by recommending the assessment of SDOH through position or discussion papers,[13] [14] [15] organizational strategic plans,[16] and provider training modules.[17] Previously in this section of our proposed rule, we discuss how the practice of medicine currently includes assessment of health-related social needs or SDOH in taking patient histories, assessing patient risk, and informing medical decision making, diagnosis, care and treatment. The taking of a social history is generally

[10] *https://aspe.hhs.gov/sites/default/files/documents/e2b650cd64cf84aae8ff0fae7474af82/SDOH-Evidence-Review.pdf.*

[11] *https://aspe.hhs.gov/sites/default/files/documents/aabf48cbd391be21e5186eeae728ccd7/SDOH-Action-Plan-At-a-Glance.pdf.*

[12] *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

[13] *https://www.aafp.org/about/policies/all/social-determinants-health-family-medicine-position-paper.html.*

[14] *https://doi.org/10.7326/M17-2441.*

[15] *https://nam.edu/social-determinants-of-health-201-for-health-care-plan-do-study-act/.*

[16] *https://www.ama-assn.org/system/files/2021-05/ama-equity-strategic-plan.pdf.*

[17] *https://edhub.ama-assn.org/steps-forward/module/2702762.*

performed by physicians and practitioners in support of patient-centered care to better understand and help address relevant problems that are impacting medically necessary care. We believe the resources involved in these activities are not appropriately reflected in current coding and payment policies. As such, we are proposing to establish a code to separately identify and value a SDOH risk assessment that is furnished in conjunction with an E/M visit.

We are proposing a new stand-alone G code, GXXX5, *Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5–15 minutes, not more often than every 6 months.* SDOH risk assessment refers to a review of the individual's SDOH or identified social risk factors that influence the diagnosis and treatment of medical conditions. We are proposing GXXX5 to identify and value the work involved in the administering a SDOH risk assessment as part of a comprehensive social history when medically reasonable and necessary in relation to an E/M visit. SDOH risk assessment through a standardized, evidence-based tool can more effectively and consistently identify unmet SDOH needs, and enable comparisons across populations. For example, through administration of the SDOH risk assessment for a patient presenting for diabetes management, a practitioner might discover that a patient's living situation does not permit reliable access to electricity, impacting the patient's ability to keep insulin refrigerated. The practitioner may then prescribe a type of insulin that remains stable at room temperature, or consider oral medication instead. In this example, the practitioner could furnish an SDOH risk assessment in conjunction with the E/M visit to gain a more thorough understanding of the patient's full social history and to determine whether other SDOH needs are also impacting medically necessary care.

We further propose that the SDOH risk assessment must be furnished by the practitioner on the same date they furnish an E/M visit, as the SDOH assessment would be reasonable and necessary when used to inform the patient's diagnosis, and treatment plan established during the visit. Required elements would include:

- Administration of a standardized, evidence-based [18] SDOH risk assessment tool that has been tested and validated through research, and includes the domains of food insecurity, housing insecurity, transportation needs, and utility difficulties.

++ Billing practitioners may choose to assess for additional domains beyond those listed above if there are other prevalent or culturally salient social determinants in the community being treated by the practitioner.

Possible evidence-based tools include the CMS Accountable Health Communities [19] tool, the Protocol for Responding to & Assessing Patients' Assets, Risks & Experiences (PRAPARE) [20] tool, and instruments identified for Medicare Advantage Special Needs Population Health Risk Assessment.[21]

Given the multifaceted nature of unmet SDOH needs, appropriate follow-up is critical for mitigating the effects of the identified, unmet SDOH needs on a person's health. An SDOH risk assessment without appropriate follow-up for identified needs would serve little purpose. As such, CMS is seeking comment on whether we should require as a condition of payment for SDOH risk assessment that the billing practitioner also have the capacity to furnish CHI, PIN, or other care management services, or have partnerships with community-based organizations (CBO) to address identified SDOH needs.

The SDOH needs identified through the risk assessment must be documented in the medical record, and may be documented using a set of ICD–10–CM codes known as ''Z codes'' [22] (Z55–Z65) which are used to document SDOH data to facilitate high-quality communication between providers. We are proposing GXXX5 have a duration of 5–15 minutes for the administration of an SDOH risk assessment tool, billed no more often than once every 6 months. We propose to limit the SDOH assessment service to once every six months, as we believe there are generally not significant, measurable changes to health outcomes impacted by a patient's SDOH in intervals shorter than 6 months.

iii. Proposed Valuation for SDOH Risk Assessment GXXX5

We propose a direct crosswalk to HCPCS code G0444 (*Screening for depression in adults, 5–15 minutes*), with a work RVU of 0.18, as we believe this service reflects the resource costs associated when the billing practitioner performs HCPCS code GXXX5. HCPCS code G0444 has an intraservice time of 15 minutes, and the physician work is of similar intensity to our proposed HCPCS code GXXX5. Therefore, we are proposing a work time of 15 minutes for HCPCS code GXXX5 based on this same crosswalk to G0444. We are also proposing to use this crosswalk to establish the direct PE inputs for HCPCS code GXXX5.

We believe these services would largely involve direct patient contact between the billing practitioner or billing practitioner's auxiliary personnel and the patient through in-person interactions, which could be conducted via telecommunications as appropriate. Therefore, we are proposing to add this code to the Medicare Telehealth Services List to accommodate a scenario in which the practitioner (or their auxiliary personnel incident to the practitioner's services) completes the risk assessment in an interview format, if appropriate. We believe it is important that when furnishing this service, all communication with the patient be appropriate for the patient's educational, developmental, and health literacy level, and be culturally and linguistically appropriate. We are seeking comment on where and how these services would be typically provided, along with other aspects of the proposed SDOH assessment service.

e. Principal Illness Navigation (PIN) Services

i. Background

Experts on navigation of treatment for cancer and other high-risk, serious illnesses have demonstrated the benefits of navigation services for patients experiencing these conditions.[23] Experts have noted the importance of these services for all affected patients, but especially those with socioeconomic disadvantages or barriers to care. Navigation generally means the process or activity of ascertaining one's position and planning and following a route; the act of directing from one place to another; the skill or process of plotting a route and directing; the act, activity, or process of finding the way to get to a place you are traveling. In the context of healthcare, it refers to providing individualized help to the patient (and caregiver, if applicable) to identify appropriate practitioners and providers for care needs and support, and access necessary care timely, especially when the landscape is complex and delaying care can be deadly. It is often referred

[18] *https://health.gov/healthypeople/tools-action/browse-evidence-based-resources/types-evidence-based-resources.*

[19] *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.*

[20] *https://www.nachc.org/research-and-data/prapare/.*

[21] CMS–10825.

[22] *https://www.cms.gov/files/document/z-codes-data-highlight.pdf.*

[23] See for example, *https://view.ons.org/3hjHjc* and *https://www.accc-cancer.org/docs/projects/pdf/patient-navigation-guide.*

to in the context of patients diagnosed with cancer or another severe, debilitating illness, and includes identifying or referring to appropriate supportive services. It is perhaps most critical when a patient is first undergoing treatment for such conditions, due to the extensive need to access and coordinate care from a number of different specialties or service-providers for different aspects of the diagnosis or treatment, and in some cases, related social services (for example, surgery, radiation, chemotherapy for cancer; psychiatry, psychology, vocational rehabilitation for severe mental illness; psychiatry, psychology, vocational rehabilitation, rehabilitation and recovery programs for substance use disorder; infectious disease, neurology and immunology for human immunodeficiency virus (HIV)-associated neurocognitive disorders). For some conditions, patients are best able to engage with the healthcare system and access care if they have assistance from a single, dedicated individual who has ''lived experience'' (meaning they have personally experienced the same illness or condition the patient is facing). While we currently make separate payment under the PFS for a number of care management and other services that may include aspects of navigation services, those care management services are focused heavily on clinical aspects of care rather than social aspects, and are generally performed by auxiliary personnel who may not have lived experience or training in the specific illness being addressed. We are seeking to better understand whether there are gaps in coding for patient navigation services for treatment of serious illness, that are not already included in current care management services such as advance care planning services (CPT codes 99497–99498), chronic care management services (CPT codes 99490, 99439, 99491, 99437, 99487 and 99489), general behavioral health integration care management services (CPT code 99484), home health and hospice supervision (HCPCS codes G0181–G0182), monthly ESRD-related services (CPT codes 90951–90970), principal care management services (CPT codes 99424–99427), psychiatric collaborative care management services (CPT codes 99492–99494), and transitional care management services (CPT codes 99495–99496). See additional information on our PFS Care Management Services web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.*

For CY 2024, we are proposing to better recognize through coding and payment policies when certified or trained auxiliary personnel under the direction of a billing practitioner, which may include a patient navigator or certified peer specialist, are involved in the patient's health care navigation as part of the treatment plan for a serious, high-risk disease expected to last at least 3 months, that places the patient at significant risk of hospitalization or nursing home placement, acute exacerbation/decompensation, functional decline, or death. Examples of serious, high-risk diseases for which patient navigation services could be reasonable and necessary could include cancer, chronic obstructive pulmonary disease, congestive heart failure, dementia, HIV/AIDS, severe mental illness, and substance use disorder. We are proposing new coding for Principal Illness Navigation (PIN) services. In considering the appropriate patient population, we considered the patient population eligible for principal care management service codes (CPT codes 99424 through 99427), as well as clinical definitions of ''serious illness.'' For example, one peer-review study defined ''serious illness'' as a health condition that carries a high risk of mortality and either negatively impacts a person's daily function or quality of life, or excessively strains their caregivers.[24] Another study describes a serious illness as a health condition that carries a high risk of mortality and commonly affects a patient for several years.[25] Some measure serious illness by the amount of urgent health care use (911 calls, emergency department visits, repeated hospitalizations) and polypharmacy.[26] The navigation services such patients need are similar to CHI services (as discussed previously in this section), but SDOH need(s) may be fewer or not present; and there are specific service elements that are more relevant for the subset of patients with serious illness. Accordingly, we are proposing for PIN services a parallel set of services to the proposed CHI services, but focused on patients with a serious, high-risk illness who may not necessarily have SDOH needs; and adding service elements to describe identifying or referring the patient to appropriate supportive services, providing information/resources to consider participation in clinical research/clinical trials, and inclusion of lived experience or training in the specific condition being addressed.

[24] *https://pubmed.ncbi.nlm.nih.gov/29125784/.*

[25] *https://www.ajmc.com/view/serious-illness-a-high-priority-for-accountable-care.*

[26] *https://www.ajmc.com/view/serious-illness-a-high-priority-for-accountable-care.*

ii. Proposed Principal Illness Navigation (PIN) Service Definition

PIN services could be furnished following an initiating E/M visit addressing a serious high-risk condition/illness/disease, with the following characteristics:

- One serious, high-risk condition expected to last at least 3 months and that places the patient at significant risk of hospitalization, nursing home placement, acute exacerbation/decompensation, functional decline, or death;
- The condition requires development, monitoring, or revision of a disease-specific care plan, and may require frequent adjustment in the medication or treatment regimen, or substantial assistance from a caregiver.

Examples of a serious, high-risk condition/illness/disease include, but are not limited to, cancer, chronic obstructive pulmonary disease, congestive heart failure, dementia, HIV/AIDS, severe mental illness, and substance use disorder.

We propose that the PIN initiating visit would be an E/M visit (other than a low-level E/M visit that can be performed by clinical staff) performed by the billing practitioner who will also be furnishing the PIN services during the subsequent calendar month(s). The PIN initiating visit would be separately billed (if all requirements to do so are met), and would be a pre-requisite to billing for PIN services. We believe that certain types of E/M visits, such as inpatient/observation visits, ED visits, and SNF visits would not typically serve as PIN initiating visits because the practitioners furnishing the E/M services in those settings would not typically be the ones to provide continuing care to the patient, including furnishing necessary PIN services in the subsequent month(s).

The PIN initiating visit would serve as a pre-requisite to billing for PIN services, during which the billing practitioner would identify the medical necessity of PIN services and establish an appropriate treatment plan. The subsequent PIN services would be performed by auxiliary personnel incident to the professional services of the practitioner who bills the PIN initiating visit. The same practitioner would furnish and bill for both the PIN initiating visit and the PIN services, and PIN services must be furnished in accordance with the ''incident to'' regulation at § 410.26. We would not require an initiating E/M visit every month that PIN services are billed, but

only prior to commencing PIN services, to establish the treatment plan, specify how PIN services would help accomplish that plan, and establish the PIN services as incident to the billing practitioner's service. This framework is similar to our current requirements for billing care management services, such as chronic care management services. It also comports with our longstanding policy in the Medicare Benefit Policy Manual which provides, ''where a physician supervises auxiliary personnel to assist him/her in rendering services to patients and includes the charges for their services in his/her own bills, the services of such personnel are considered incident to the physician's service if there is a physician's service rendered to which the services of such personnel are an incidental part. This does not mean, however, that to be considered incident to, each occasion of service by auxiliary personnel (or the furnishing of a supply) need also always be the occasion of the actual rendition of a personal professional service by the physician. Such a service or supply could be considered to be incident to when furnished during a course of treatment where the physician performs an initial service and subsequent services of a frequency which reflect his/her active participation in and management of the course of treatment'' (Chapter 15, Section 60.1.B of the Medicare Benefit Policy Manual (Pub. 100–02), available on our website at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf*.

We are also seeking comment on whether we should consider any professional services other than an E/M visit performed by the billing practitioner as the prerequisite initiating visit for PIN services, including, for example, an annual wellness visit (AWV) that may or may not include the optional SDOH risk assessment also proposed in this rule. Under section 1861(hhh)(3)(C) of the Act, the AWV can be furnished by a physician or practitioner, or by other types of health professionals whose scope of practice does not include the diagnosis and treatment involved in E/M services, for example a health educator.

When the AWV is furnished by other types of health professionals, it is not necessarily furnished incident to the professional services of a physician or other practitioner. Therefore, if we were to allow an AWV furnished by a health care practitioner other than a physician or practitioner to serve as the initiating visit for PIN services, the PIN services would not necessarily be furnished consistent with our proposed application of the ''incident to'' regulations as a condition of payment. Further, we believe that practitioners would normally bill an E/M visit in addition to the AWV when medical problems are addressed in the course of an AWV encounter, in accordance with our manual policy providing that a medically necessary E/M visit may be billed when furnished on the same occasion as an AWV in those circumstances (Chapter 12, Section 30.6.1.1.H of the Medicare Claims Processing Manual (Pub, 100–04).

For purposes of assigning a supervision level for payment, we are proposing to designate PIN services as care management services that may be furnished under general supervision under § 410.26(b)(5). General supervision means the service is furnished under the physician's (or other practitioner's) overall direction and control, but the physician's (or other practitioner's) presence is not required during the performance of the service (§ 410.26(a)(3)).

We propose the following codes for PIN services. As described previously, and in our proposed PIN code descriptors, the term ''SDOH need(s)'' means an SDOH need(s) that is identified by the billing practitioner as significantly limiting the practitioner's ability to diagnose or treat the serious, high-risk condition/illness/disease addressed in the initiating E/M visit. ''Addressed'' means the definition in the CPT E/M Guidelines that we have adopted for E/M visits. Specifically, ''[a] problem is a disease, condition, illness, injury, symptom, finding, complaint, or other matter addressed at the encounter, with or without a diagnosis being established at the time of the encounter. Problem addressed [means the following]: A problem is addressed or managed when it is evaluated or treated at the encounter by the physician or other qualified healthcare professional reporting the service. This includes consideration of further testing or treatment that may not be elected by virtue of risk/benefit analysis or patient/parent/guardian/surrogate choice. Notation in patient's medical record that another professional is managing the problem without additional assessment or care coordination documented does not qualify as being addressed or managed by the physician or other qualified healthcare professional reporting the service. Referral without evaluation (by history, examination, or diagnostic study[ies]) or consideration of treatment does not qualify as being addressed or managed by the physician or other qualified healthcare professional reporting the service. For hospital inpatient and observation care services, the problem addressed is the problem status on the date of the encounter, which may be significantly different than on admission. It is the problem being managed or co-managed by the reporting physician or other qualified healthcare professional and may not be the cause of admission or continued stay'' (2023 CPT Codebook, pages. 6 through 8).

For purposes of PIN services, we propose that SDOH means economic and social condition(s) that influence the health of people and communities, as indicated in these same CPT E/M Guidelines (2023 CPT codebook, page 11). We are proposing to adopt CPT's examples of SDOH, with additional examples. Specifically, we are proposing that SDOH(s) may include but are not limited to food insecurity, transportation insecurity, housing insecurity, and unreliable access to public utilities, when they significantly limit the practitioner's ability to diagnose or treat the serious, high-risk illness/condition/disease. Since Medicare payment is limited to items and services that are reasonable and necessary for the diagnosis or treatment of illness or injury, with respect to addressing SDOH need(s), the focus of PIN services would need to be on addressing particular SDOH need(s) that are interfering with, or presenting a barrier to, diagnosis or treatment of the serious, high-risk condition.

GXXX3 Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities:

- *Person-centered assessment, performed to better understand the individual context of the serious, high-risk condition.*

++ *Conducting a person-centered assessment to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors.*

++ *Facilitating patient-driven goal setting and establishing an action plan.*

++ *Providing tailored support as needed to accomplish the practitioner's treatment plan.*

- *Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.*
- *Practitioner, Home, and Community-Based Care Coordination*

++ *Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; home- and*

community-based service providers; and caregiver (if applicable).

++ Communication with practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.

++ Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.

++ Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s).

- *Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making.*
- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition.*
- *Health care access/health system navigation.*

++ Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care, and helping secure appointments with them.

++ Providing the patient with information/resources to consider participation in clinical trials or clinical research as applicable.

- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*
- *Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*
- *Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

GXXX4—Principal Illness Navigation services, additional 30 minutes per calendar month (List separately in addition to GXXX3).

To help inform whether our proposed descriptor times are appropriate and reflect typical service times, and whether a frequency limit is relevant for the add-on code, we are seeking comment on the typical amount of time practitioners spend per month furnishing PIN services. We are also seeking comment to better understand the typical duration of PIN services, in terms of the number of months for which practitioners furnish PIN services following an initiating visit.

We are proposing that all auxiliary personnel who provide PIN services must be certified or trained to provide all included PIN service elements, and be authorized to perform them under applicable State law and regulations. Under § 410.26(a)(1) of our regulations, auxiliary personnel must meet any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished. Many States have applicable rules and certifications, and there are existing certification programs for navigators working in certain settings of care or with specified conditions, such as cancer navigators, diabetes navigators, cardiovascular navigators, mental health navigators, geriatric care navigators, pediatric navigators, social worker navigators, primary care navigators, general patient advocate navigators, and nurse navigators in ambulatory settings.[27] Approximately 48 States have professional certification programs for peer support specialists providing services to patients with substance use or mental health conditions, which is required for billing peer support specialists' services to Medicaid. For substance use and mental health conditions, SAMHSA recently published National Model Standards for Peer Support Certification.[28]

In States that do not have applicable licensure, certification, or other laws or regulations, we are proposing to require auxiliary personnel providing PIN services to be trained to provide them. Training must include the competencies of patient and family communication, interpersonal and relationship-building, patient and family capacity building, service coordination and systems navigation, patient advocacy, facilitation, individual and community assessment, professionalism and ethical conduct, and the development of an appropriate knowledge base, including specific certification or training on the serious, high-risk condition/illness/disease addressed in the initiating visit. We are proposing these competencies because we believe they reflect professional consensus regarding appropriate core competencies, adjusted to this context.[29] We are seeking public comment on the number of hours of training to require, as well as the training content and who should provide the training.

We are proposing that time spent furnishing PIN services for purposes of billing HCPCS codes GXXX3–4 must be documented in the medical record in its relationship to the serious, high-risk illness. The activities performed by the auxiliary personnel, and how they are related to the treatment plan for the serious, high-risk condition, would be described in the medical record, just as all clinical care is documented in the medical record. We would require identified SDOH need(s), if present, to be recorded in the medical record, and for data standardization, practitioners would be encouraged to record the associated ICD–10 Z-code (Z55–Z65) in the medical record and on the claim.

Similar to CHI services (discussed previously in this proposed rule), we believe that many of the elements of PIN services would involve direct contact between the auxiliary personnel and the patient, but may not necessarily be in-person and a portion might be performed via two-way audio. We are seeking to confirm our understanding of where and how PIN services would be typically provided (for example, with or without direct patient contact, in-person, using audio-video, using two-way audio; and whether navigators are typically local to the patient).

We are seeking public comment in particular regarding whether we should require patient consent for PIN services. For care management services that could generally be performed without any direct patient contact, we require advance patient consent to receive the services as a prerequisite to furnishing and billing the services, to avoid patients receiving bills for cost sharing

[27] *https://resumecat.com/blog/patient-navigator-certifications.*

[28] *https://peerrecoverynow.org/product/comparative-analysis-of-state-requirements-for-peer-support-specialist-training-and-certification-in-the-us/* and *https://store.samhsa.gov/sites/default/files/pep23-10-01-001.pdf.*

[29] *https://view.ons.org/3hjHjc* and *https://www.accc-cancer.org/docs/projects/pdf/patient-navigation-guide*; *https://chwtraining.org/c3-project-chw-skills/*; and *https://peerrecoverynow.org/wp-content/uploads/Comparative-Analysis_Jan.31.2022-003.pdf*; *https://www.samhsa.gov/sites/default/files/national-model-standards-for-peer-support-certification.pdf?utm_source=SAMHSA&utm_campaign=4b88ba3e51-EMAIL_CAMPAIGN_2023_06_05_02_41&utm_medium=email&utm_term=0_-4b88ba3e51-%5BLIST_EMAIL_ID%5D.*

that they might not be expecting to receive. For example, a patient might receive chronic care management services comprised of practitioners coordinating care with each other and reviewing or exchanging medical records between visits, in ways that do not require involving the patient directly. As we have frequently discussed in prior rulemaking for care management services (for example, at 81 FR 80240), we do not have statutory authority to waive cost sharing for care management or other services. Rather, cost sharing remains applicable, except as specified by statute such as for certain preventive services. In recent years, we have required advance documented patient consent to receive most care management services as a condition of the practitioner billing those services, to avoid a situation where the patient is surprised to receive a bill for the associated cost sharing. These consent requirements include informing the patient about applicable cost sharing, the right to discontinue services, and, where applicable, the limitation that payment is made for the service to only one practitioner per month. We have heard from interested parties over time that requiring advance patient consent is an administrative burden and may unnecessarily prevent patient receipt of needed services. We are not proposing to require consent for PIN services, since we believe these services typically would involve direct patient contact, and largely be provided in-person. However, if we hear from public commenters that PIN services would frequently not involve direct contact with the patient, or could extend for periods of time for which the patient might not be expecting to incur cost sharing obligations (such as several months), we would consider requiring patient consent to receive PIN services in our final rule.

We are proposing that a billing practitioner may arrange to have PIN services provided by auxiliary personnel who are external to, and under contract with, the practitioner or their practice, such as through a community-based organization (CBO) that employs CHWs, if all of the ''incident to'' and other requirements and conditions for payment of PIN services are met. While we are proposing to allow PIN services to be performed by auxiliary personnel under a contract with a third party, we wish to be clear, as we have in our regulations for current care management services, that there must be sufficient clinical integration between the third party and the billing practitioner in order for the services to be fully provided, and the connection between the patient, auxiliary personnel, and the billing practitioner must be maintained. As we discussed in a similar context for care management services the CY 2017 PFS final rule, if there is little oversight by the billing practitioner or a lack of clinical integration between a third party providing the services and the billing practitioner, we do not believe PIN services, as we propose to define them, could be fully performed; and therefore, in such cases, PIN services should not be billed (81 FR 80249). We would expect the auxiliary personnel performing the PIN services to communicate regularly with the billing practitioner to ensure that PIN services are appropriately documented in the medical record, and to continue to involve the billing practitioner in evaluating the continuing need for PIN services to address the serious, high-risk condition.

In the CY 2023 final rule (87 FR 69790) and as explained in the CY 2023 PFS proposed rule (87 FR 46102), where we refer to community-based organizations, we mean public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations. They may include community-action agencies, housing agencies, area agencies on aging, centers for independent living, aging and disability resource centers or other non-profits that apply for grants or contract with healthcare entities to perform social services. As described earlier, they may receive grants from other agencies in the U.S. Department of Health and Human Services, including Federal grants administered by the Administration for Children and Families (ACF), Administration for Community Living (ACL), the Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMHSA), or State-funded grants to provide social services. Generally, we believe such organizations know the populations and communities they serve, and may have the infrastructure or systems in place to assist practitioners to provide PIN services. We understand that many CBOs provide social services and do other work that is beyond the scope of PIN services, but we believe they are well-positioned to develop relationships with practitioners for providing reasonable and necessary PIN services.

We are proposing that only one practitioner per beneficiary per calendar month could bill for PIN services for a given serious, high-risk condition, because we are concerned about potential care fragmentation if the patient has more than one navigator for their condition during a given month. Our proposal would allow the patient to have a single point of contact for navigation of their condition.

We are proposing that the practitioner could bill separately for other care management services during the same month as PIN, if time and effort are not counted more than once, requirements to bill the other care management services are met, and the services are medically reasonable and necessary.

Similar to CHI service (as discussed previously in this proposed rule), there are aspects of PIN services, or PIN services for certain conditions, that may be covered under a Medicaid program. When Medicare and Medicaid cover the same services for patients eligible for both programs, Medicare generally is the primary payer in accordance with section 1902(a)(25) of the Act. We are seeking public comment regarding whether States typically cover services similar to PIN under their Medicaid programs, and whether such coverage would be duplicative of the PIN service codes. We also seek comment on if there are other service elements not included in the PIN service codes that are part of associated care that should be included in the PIN service codes, or are important in navigation for high-risk conditions, where CMS should consider coding and payment in the future. For example, are there circumstances when clinical navigators, under the supervision of another professional, typically spend time face-to-face with patients that the PIN services codes, as currently described, may not fully account for?

iii. Proposed PIN Services Valuation

For HCPCS code GXXX3, we are proposing a work RVU of 1.00 based on a crosswalk to CPT code 99490 (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 that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; first 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month) as we believe these values most accurately reflect the resource costs associated when the billing practitioner performs PIN services. CPT code 99490 has an

intraservice time of 25 minutes and the physician work is of similar intensity to our proposed HCPCS code GXXX3. Therefore, we are proposing a work time of 25 minutes for HCPCS code GXXX3 based on this same crosswalk to CPT code 99490. We are proposing to use this crosswalk as well to establish the direct PE inputs for HCPCS code GXXX3.

For HCPCS code GXXX4, we are proposing a crosswalk to the work RVU and direct PE inputs associated with CPT code 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 that 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 (List separately in addition to code for primary procedure)*) as we believe these values reflect the resource costs associated with the clinician's direction of clinical staff who are performing the PIN services. Therefore, we are proposing a work RVU of 0.70 and a work time of 20 minutes for HCPCS code GXXX4.

(28) Maternity Services (CPT codes 59400, 59410, 59425, 59426, 59430, 59510, 59515, 59610, 59614, 59618, 59622)

In the CY 2021 PFS final rule with comment period (85 FR 84554–84555), we finalized our proposal to revalue the bundled maternity codes used to bill for delivery, antepartum, and postpartum maternity care services to account for increases in the values of office/outpatient E/M services. These codes are all designated with a unique global period indicator ''MMM.'' There are 11 MMM codes that include E/M visits as part of their valuation.

For CY 2024, we are proposing to update the work RVUs and work times of these MMM codes to reflect any relevant E/M updates associated with their global periods that were finalized in CY 2023. Table 11 contains a list of these codes and the proposed work RVUs for CY 2024. MMM codes are unique within the PFS in that they are the only global codes that provide a single payment for almost 12 months of services, which include a relatively large number of E/M visits performed along with delivery services and imaging; and were valued using a building-block methodology as opposed to the magnitude estimation method.

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TABLE 11: Current and Proposed Value for Each Maternity Services Code

CPT code	Current Work RVU value	2023 E/M adjustment value	New Work RVU Value
59400	36.58	0.42	**37.00**
59410	18.34	0.42	**18.76**
59425	7.80	0.00	**7.80**
59426	14.30	0.00	**14.30**
59430	3.22	0.00	**3.22**
59510	40.39	0.66	**41.05**
59515	22.13	0.66	**22.79**
59610	38.29	0.42	**38.71**
59614	20.06	0.42	**20.48**
59618	40.91	0.66	**41.57**
59622	22.66	0.66	**23.32**

TABLE 12: CY 2024 Work RVUs for New, Revised, and Potentially Misvalued Codes

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar	27.13	27.13	27.13	No
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)	C	7.50	6.88	No
2X000	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]), without placement of transfixation device	NEW	7.86	7.86	No
2X002	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments	NEW	32.00	32.00	No
2X003	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments	NEW	35.50	35.50	No
2X004	Revision (eg, augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed	NEW	36.00	36.00	No
30117	Excision or destruction (eg, laser), intranasal lesion; internal approach	3.26	3.91	3.91	No
30118	Excision or destruction (eg, laser), intranasal lesion; external approach (lateral rhinotomy)	9.92	9.55	7.75	No
3X008	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]) including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation when performed	NEW	9.50	9.50	No
3X009	Insertion of phrenic nerve stimulator transvenous sensing lead	NEW	5.43	5.43	No
3X010	Removal of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; system, including pulse generator and lead(s)	NEW	9.55	9.55	No
3X011	Removal of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s) only	NEW	5.42	5.42	No
3X012	Removal of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator only	NEW	3.04	3.04	No
3X013	Repositioning of phrenic nerve stimulator transvenous lead(s)	NEW	6.00	6.00	No
3X014	Removal and replacement of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming when performed; pulse generator	NEW	6.05	6.05	No
3X015	Removal and replacement of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming when performed; transvenous stimulation or sensing lead	NEW	8.51	8.51	No
3X016	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve	NEW	2.70	2.70	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
3X017	Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve	NEW	2.70	2.70	No
59400	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care	36.58	-	37.00	Yes
59410	Vaginal delivery only (with or without episiotomy and/or forceps); including postpartum care	18.34	-	18.76	Yes
59425	Antepartum care only; 4-6 visits	7.80	-	7.80	No
59426	Antepartum care only; 7 or more visits	14.30	-	14.30	No
59430	Postpartum care only (separate procedure)	3.22	-	3.22	No
59510	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care	40.39	-	41.05	Yes
59515	Cesarean delivery only; including postpartum care	22.13	-	22.79	Yes
59610	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery	38.29	-	38.71	Yes
59614	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps); including postpartum care	20.06	-	20.48	Yes
59618	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery	40.91	-	41.57	Yes
59622	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery; including postpartum care	22.66	-	23.32	Yes
5X000	Excision or destruction (eg, laser), intranasal lesion; internal approach	NEW	3.10	3.10	No
5X005	Transcervical ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency	NEW	7.21	7.21	No
619X1	Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)	NEW	25.75	25.75	No
619X2	Revision or replacement of skull-mounted cranial neurostimulator pulse generator or receiver with connection to depth and/or cortical strip electrode array(s)	NEW	11.25	11.25	No
619X3	Removal of skull-mounted cranial neurostimulator pulse generator or receiver with cranioplasty, when performed	NEW	15.00	15.00	No
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver requiring pocket creation and connection between electrode array and pulse generator or receiver	5.19	5.19	5.19	No
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver, with detachable connection to electrode array, with detachable connection to	5.30	4.35	4.35	No
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver direct or inductive coupling, requiring pocket creation and connection between electrode array and pulse generator or receiver	2.45	5.10	5.10	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array	1.78	3.79	3.79	No
64XX2	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator including imaging guidance, when performed; initial electrode array	NEW	C	C	No
64XX3	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator including imaging guidance, when performed; each additional electrode array	NEW	C	C	No
64XX4	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator	NEW	C	C	No
65778	Placement of amniotic membrane on the ocular surface; without sutures	1.00	0.84	0.84	No
65779	Placement of amniotic membrane on the ocular surface; single layer, sutured	2.50	1.75	1.75	No
65780	Ocular surface reconstruction; amniotic membrane transplantation, multiple layers	7.81	7.03	7.03	No
6X000	Suprachoroidal space injection of pharmacologic agent (separate procedure)	NEW	1.53	1.53	No
76881	Ultrasound, complete joint (ie, joint space and periarticular soft-tissue structures), real-time with image documentation	0.90	0.90	0.90	No
76882	Ultrasound, limited, joint or focal evaluation of other nonvascular extremity structure(s) (eg, joint space, peri-articular tendon[s], muscle[s], nerve[s], other soft-tissue structure[s], or soft tissue mass[es]), real-time with image documentation	0.69	0.69	0.69	No
76883	Ultrasound, nerve(s) and accompanying structures throughout their entire anatomic course in one extremity, comprehensive, including real-time cine imaging with image documentation, per extremity	1.21	1.21	1.21	No
76937	Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting	0.30	0.30	0.30	No
76998	Ultrasonic guidance, intraoperative	1.20	1.20	0.91	No
7X000	Ultrasound, intraoperative thoracic aorta (eg, epiaortic), diagnostic	NEW	0.60	0.60	No
7X001	Intraoperative epicardial cardiac (eg, echocardiography) ultrasound for congenital heart disease, diagnostic; including placement and manipulation of transducer, image acquisition, interpretation and report	NEW	1.90	1.62	No
7X002	Intraoperative epicardial cardiac (eg, echocardiography) ultrasound for congenital heart disease, diagnostic; placement, manipulation of transducer, and image acquisition only	NEW	1.20	1.08	No
7X003	Intraoperative epicardial cardiac (eg, echocardiography) ultrasound for congenital heart disease, diagnostic; interpretation and report only	NEW	1.55	0.54	Yes
7X005	Noninvasive estimate of coronary fractional flow reserve derived from augmentative software analysis of the data set from a coronary computed tomography angiography,	NEW	0.75	0.75	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	with interpretation and report by a physician or other qualified health care professional				
90832	Psychotherapy, 30 minutes with patient	1.70	-	1.78	No
90834	Psychotherapy, 45 minutes with patient	2.24	-	2.35	No
90837	Psychotherapy, 60 minutes with patient	3.31	-	3.47	No
90839	Psychotherapy for crisis; first 60 minutes	3.13	-	3.28	No
90840	Psychotherapy for crisis; each additional 30 minutes	1.50	-	1.57	No
90845	Psychoanalysis	2.10	-	2.20	No
90846	Family psychotherapy (without the patient present), 50 minutes	2.40	-	2.51	No
90847	Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes	2.50	-	2.62	No
90849	Multiple-family group psychotherapy	0.59	-	0.62	No
90853	Group psychotherapy (other than of a multiple-family group)	0.59	-	0.62	No
926X1	Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; first 60 minutes	NEW	1.25	1.25	No
926X2	Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; each additional 15 minutes	NEW	0.33	0.33	No
93297	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional	0.52	0.52	0.52	No
93298	Interrogation device evaluation(s), (remote) up to 30 days; subcutaneous cardiac rhythm monitor system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional	0.52	0.52	0.52	No
96202	Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); initial 60 minutes	B	-	0.43	No
96203	Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); each additional 15 minutes	B	-	0.12	No
99484	Care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated	0.61	0.85	0.93	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	rating scales, behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes, facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation, and continuity of care with a designated member of the care team.				
99497	Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate	1.50	1.50	1.50	No
99498	Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; each additional 30 minutes	1.40	1.40	1.40	No
9X000	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; anomalous or persistent superior vena cava when it exists as a second contralateral superior vena cava, with native drainage to heart	NEW	1.20	1.20	No
9X002	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; azygos/hemi-azygos venous system	NEW	1.13	1.13	No
9X003	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; coronary sinus	NEW	1.43	1.43	No
9X004	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating at or above the heart (eg, from innominate vein)	NEW	2.11	1.92	No
9X005	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating below the heart (eg, from the inferior vena cava)	NEW	2.13	2.04	No
9X015	Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [adls], instrumental adls [iadls], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face; initial 30 minutes	NEW	1.00	1.00	No
9X016	Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [adls], instrumental adls [iadls], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face; each additional 15 minutes	NEW	0.54	0.54	No
9X017	Group caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [adls], instrumental adls [iadls], transfers, mobility, communication, swallowing, feeding, problem solving,	NEW	0.23	0.23	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	safety practices) (without the patient present), face-to-face with multiple sets of caregivers				
9X034	Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; first 60 minutes	NEW	C	C	No
9X035	Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; each additional 30 minutes	NEW	C	C	No
9X036	Pelvic examination	NEW	0.00	0.00	No
9X045	Therapy activation of implanted phrenic nerve stimulator system including all interrogation and programming	NEW	0.85	0.85	No
9X046	Interrogation and programming (minimum one parameter) of implanted phrenic nerve stimulator system	NEW	0.80	0.80	No
9X047	Interrogation and programming of implanted phrenic nerve stimulator system during a polysomnography	NEW	1.82	1.82	No
9X048	Interrogation, without programming of implanted phrenic nerve stimulator system	NEW	0.43	0.43	No
9X070	Percutaneous transluminal coronary lithotripsy	NEW	2.97	2.97	No
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval	0.00	0.00	0.00	No
G0323	Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist, clinical social worker, mental health counselor, clinical professional counselor, professional counselor, or marriage and family therapist time, per calendar month.	0.61	-	0.93	Yes
G2066	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results	0.00	0.00	D	No
G2086	Office-based opioid treatment, monthly bundle including development of the treatment plan, care coordination, substance use counseling, individual therapy, and group therapy; initial month	7.06	-	8.14	Yes
G2087	Office-based opioid treatment, monthly bundle including care coordination, substance use counseling, individual therapy, and group therapy; subsequent month	6.89	-	7.97	Yes
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.	B	-	0.33	No
GPFC1	Psychotherapy for crisis furnished in an applicable site of service; first 60 minutes	NEW	-	4.70	No
GPFC2	Psychotherapy for crisis furnished in an applicable site of service; each additional 30 minutes	NEW	-	2.25	No
GXXX1	Community health integration services performed by certified or trained auxiliary personnel, which may include a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are	NEW	-	1.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit				
GXXX2	Community health integration services, each additional 30 minutes per calendar month	NEW	-	0.70	No
GXXX3	Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, which may include a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities	NEW	-	1.00	No
GXXX4	Principal Illness Navigation services, additional 30 minutes per calendar month	NEW	-	0.70	No
GXXX5	Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5-15 minutes	NEW	-	0.18	No

TABLE 13: CY 2024 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)
30117	Removal of intranasal lesion	L037D	RN/LPN/MTA	NF	Conduct patient communications	3	0	G1: See preamble text	-1.49
30117	Removal of intranasal lesion	L037D	RN/LPN/MTA	F	Conduct patient communications	3	0	G1: See preamble text	-1.49
30117	Removal of intranasal lesion	SB027	gown, staff, impervious	NF		2	0	S1: Duplicative; supply is included in SA042	-2.37
30118	Removal of intranasal lesion	L037D	RN/LPN/MTA	F	Conduct patient communications	3	0	G1: See preamble text	-1.49
3X014	Rmv&rplcmt phrnc nrv stim pg	L037D	RN/LPN/MTA	F	Post-operative visits (total time)	36	53	L9: Refined clinical labor to align with number of post-operative visits	8.47
3X016	Nsl/sinus ndsc rf abltj pnn	ES031	scope video system (monitor, processor, digital capture, cart, printer, LED light)	NF		39	32	E19: Refined equipment time to conform to established policies for scope accessories	-1.87
3X016	Nsl/sinus ndsc rf abltj pnn	SB027	gown, staff, impervious	NF		2	0	S1: Duplicative; supply is included in SA042	-2.37
3X017	Nsl/sinus ndsc cryoabltj pnn	ES031	scope video system (monitor, processor, digital capture, cart, printer, LED light)	NF		39	34	E19: Refined equipment time to conform to established policies for scope accessories	-1.34
3X017	Nsl/sinus ndsc cryoabltj pnn	ES040	PROXY endoscope, rigid, sinoscopy (0 degrees)	NF		39	41	E4: Refined equipment time to conform to established policies for scopes	0.02
3X017	Nsl/sinus ndsc cryoabltj pnn	SB027	gown, staff, impervious	NF		2	0	S1: Duplicative; supply is included in SA042	-2.37

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)
5X005	Transcrv abltj utrn fibrd rf	EQ138	instrument pack, medium ($1500 and up)	NF		65	77	E5: Refined equipment time to conform to established policies for surgical instrument packs	0.08
64590	Ins/rpl prph sac/gstr npgr	EQ114	electrosurgical generator, up to 120 watts	NF		56	48	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.14
64590	Ins/rpl prph sac/gstr npgr	EQ209	programmer, neurostimulator (w-printer)	NF		56	84	E7: Refined equipment time to conform to office visit duration	0.18
76882	Us lmtd jt/fcl evl nvasc xtr	ED053	Professional PACS Workstation	NF		14	17.5	E18: Refined equipment time to conform to established policies for PACS Workstations	0.21
76882	Us lmtd jt/fcl evl nvasc xtr	EQ250	ultrasound unit, portable	NF		23	15	E11: Refined equipment time to conform with other codes in the family	-1.29
7X005	N-invas est c ffr sw aly cta	ED053	Professional PACS Workstation	NF		14.5	13.5	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.06
G0277	Hbot, full body chamber, 30m	L047C	RN/Respiratory Therapist	NF	Prepare room, equipment and supplies	1.5	0.5	G1: See preamble text	-0.64
G0277	Hbot, full body chamber, 30m	L047C	RN/Respiratory Therapist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	1	0.5	G1: See preamble text	-0.32
G0277	Hbot, full body chamber, 30m	L047C	RN/Respiratory Therapist	NF	Perform procedure/service---NOT directly	30	15	G1: See preamble text	-9.65

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)
					related to physician work time				

TABLE 14: CY 2024 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)
3X014	Rmv&rplcmt phrnc nrv stim pg	EF023	table, exam	F		36	53	E15: Refined equipment time to conform to changes in clinical labor time	0.18
G0277	Hbot, full body chamber, 30m	EQ131	hyperbaric chamber	NF		40	23.25	E15: Refined equipment time to conform to changes in clinical labor time	-3.90
G0277	Hbot, full body chamber, 30m	EQ362	HBOT air break breathing apparatus demand system (hoses, masks, penetrator, and demand valve)	NF		40	23.25	E15: Refined equipment time to conform to changes in clinical labor time	-0.04

TABLE 15: CY 2024 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
36514	tubing set, plasma exchange	SC085	$186.12	$244.88	32%	2	328
36514, 36516	tubing set, blood warmer	SC084	$8.01	$15.33	91%	2	911
43754, 43755, 43756, 43757, 88120, 88121, 91065	biohazard specimen transport bag	SM008	$0.080	$0.087	9%	1	101,558
65778	human amniotic membrane allograft mounted on a non-absorbable self-retaining ring	SD248	$1,097.91	$872.50	-21%	2	48,005
65779	human amniotic membrane allograft	SD247	$771.33	$835.00	8%	1	106
88104, 88106, 88108, 88112, 88160, 88161, 88162	stain, PAP OG-6	SL491	$0.010	$0.020	100%	1	444,216
88302, 88304, 88305, 88307, 88309, 88312, 88313, 88319, 88323, 88325, 88355, 88358, G0416	slide dryer	EP034	$962.50	$1,785.49	86%	1	13,423,336
88302, 88304, 88305, 88307, 88309, 88341, 88342, 88344, 88360, 88361, G0416	Automated Casette Labeler	EP111	$26,700.26	$31,658.81	19%	1	14,100,742
88313	Congo Red kits	SA110	$6.16	$6.80	10%	1	799,406
88313, 88314	hematoxylin reagent	SL077	$0.0200	$0.0375	88%	1	815,572
88341	Anti CD45 Monoclonal Antibody	SL495	$4.48	$5.15	15%	3	982,692

88341, 88342, 88344, 88360, 88361	E-bar labels (Ventana 1358501)	SL475	$0.72	$1.104	53%	1	2,422,030
88341, 88342, 88344, 88360, 88361	UltraView Universal DAB Detection Kit	SL488	$9.70	$12.28	27%	3	2,422,030
88342	Confirm anti-CD15 Mouse Monoclonal Antibody (Ventana 760-2504)	SL474	$3.82	$4.90	28%	1	1,061,368
88344, 88360, 88361	250 Test Prep Kit # 78 (Ventana 786-3034)	SL486	$0.290	$0.309	7%	2	377,970
92230, 92235, 92242, 92287	fluorescein inj (5ml uou)	SH033	$49.13	$72.00	47%	7	305,201
95145, 95146, 95148, 95149	antigen, venom	SH009	$30.93	$35.58	15%	18	49,334
95147, 95148, 95149	antigen, venom, tri-vespid	SH010	$60.24	$69.21	15%	9	38,269

TABLE 16: CY 2024 New Invoices

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
2X000	Dorsal SI Joint Arthrodesis Implant	SD356	11,500.00	1	0
3X016	Radiofrequency Stylus / wand	SD357	1,950.00	4	3,728
3X016	Radiofrequency console	EQ407	4,972.50	4	3,728
3X017	Cryoablation handpiece and 2 canisters (one per side)	SD358	1,882.80	7	7,501
5X000	Optilume DCB, guidewire, and inflation device	SD359	2,245.00	22	0
5X005	Dispersive electrode (Sonata)	SD360	30.00	1	0
5X005	RFA Handpiece, sterile (Sonata)	SD361	2,500.00	1	0
5X005	RFA Generator System, including probe, cables and sterilization tray (Sonata)	EQ408	118,250.00	2	0
9X045, 9X046, 9X047, 9X048	phrenic nerve stimulator programmer with wand	EQ406	3,008.00	2	156

TABLE 17: CY 2024 No PE Refinements

HCPCS	Description
22857	Tot disc arthrp 1ntrspc lmbr
22860	Tot disc arthrp 2ntrspc lmbr
2X000	Arthrd si jt prq wo tfxj dev
2X002	Ant thrc vrt body tethrg <7
2X003	Ant thrc vrt body tethrg 8+
2X004	Rev rplc/rmv thrc vrt tethrg
3X008	Insj phrnc nrv stim sys
3X010	Rmvl phrnc nrv stim sys
3X011	Rmvl phrnc nrv stim transvns
3X012	Rmvl phrnc nrv stim pg only
3X013	Reposg phrnc nrv stim trnsvn
3X015	Rmv&rplcmt phrnc nrv stim ld
5X000	Cysto rx balo cath urtl strx
619X1	Ins sk-mnt crnl nstm pg/rcvr
619X2	Rev/rplcmt sk-mnt crnl nstm
619X3	Rmv sk-mnt crnl nstm pg/rcvr
63685	Ins/rplcmt spi npgr pocket
63688	Rev/rmv imp spi npgr dtch cn
64595	Rev/rmv prph sac/gstr npgr
64XX2	Ins/rplcmt prq eltrd ra pn 1
64XX3	Ins/rplcm prq eltrd ra pn ea
64XX4	Rev/rmvl nea pn w/intg nstim
65778	Cover eye w/membrane
65779	Cover eye w/membrane suture
65780	Ocular reconst transplant
6X000	Sprchoroidal spc njx rx agt
76881	Us xtr non-vasc complete
76883	Us nrv&acc strux 1xtr compre
76937	Us guide vascular access
7X001	Dx intraop epicar car us chd
926X1	Dx aly aud oi snd prcsr 1st
926X2	Dx aly aud oi snd prcsr each
93297	Icm device interrogat remote
93298	Ilr device interrogat remote
99484	Care mgmt svc bhvl hlth cond
99497	Advncd care plan 30 min
99498	Advncd care plan addl 30 min
9X015	Caregiver traing 1st 30 min
9X016	Caregiver traing ea addl 15
9X017	Group caregiver training
9X036	Pelvic examination
9X045	Therapy activation ipnss
9X046	Interrog&prgrmg ipnss
9X047	Interrog&prgrmg ipnss polysm
9X048	Interrog w/o prgrmg ipnss

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F. Evaluation and Management (E/M) Visits

1. Background

Over the past several years, we have engaged in a multi-year effort with the American Medical Association (AMA) and other interested parties to update coding and payment for evaluation and management (E/M) visits, so that they better reflect the current practice of medicine, are less administratively complex, and are paid more accurately under the PFS. This work is critical to improve payment accuracy and help reduce practitioner burnout.

E/M visits comprise approximately 40 percent of all allowed charges under the PFS. The office/outpatient (O/O) E/M visits comprise approximately half of these allowed charges (approximately 20 percent of total PFS allowed charges), and Other E/M visits (such as inpatient/observation visits, nursing facility visits and home/residence visits) comprise the other half (approximately 20 percent of total PFS allowed charges). As we have discussed in prior rules, within the E/M services represented in these percentages, there is wide variation in the volume and level of E/M visits billed by different specialties (84 FR 62844). According to Medicare claims data, E/M visits are furnished by nearly all specialties, but represent a greater share of total allowed services for physicians and other practitioners who do not routinely furnish procedural interventions or diagnostic tests. Accordingly, our policies for revaluation of E/M visits have a significant impact on relative resource valuation under the PFS, which could potentially impact patient care more broadly.

In this section of our proposed rule, we continue our work to address two outstanding issues in E/M visit payment: implementing separate payment for the O/O E/M visit complexity add-on code for separate payment, and our definition of split (or shared) visits which we delayed last year.

For CY 2018, we solicited public comment regarding how we could comprehensively reform the E/M documentation guidelines to reduce administrative and clinical burden, improve payment accuracy, and better align E/M coding and documentation with the current practice of medicine (82 FR 34078–34079, 82 FR 53163). We believed that the documentation requirements for history and physical exam were particularly outdated clinically and that medical decision making (MDM) and time were the more significant factors in distinguishing visit levels (82 FR 53164). Public commenters recommended a transparent, iterative, and perhaps transitional approach, and some commenters suggested that CMS and the AMA should also undertake revision and revaluation of the E/M visit code set itself, in addition to updating the documentation guidelines (82 FR 53165). Having reviewed the public comments, we noted they illustrated how difficult it is to utilize or rely upon such a relatively small set of codes to describe and pay for the work of a wide range of physicians and practitioners in many vastly different clinical contexts; that E/M documentation guidelines were not simply a matter of administrative burden, but were also clinically outdated and intimately related to the definition and description of E/M work as well as valuation; and that there were different opinions on potential redefinition and revaluation of the E/M code set depending on practitioner specialty, and the type of work dominating the specialty (for example, primary care, so-called ''cognitive'' specialty work, or global

procedures that have E/M visits bundled in rather than separately performed and documented) (82 FR 53165). We stated that we would continue working on these issues with interested parties in future years.

Because we agreed with commenters that we should take an incremental approach to these issues, the following year we proposed changes largely limited to the O/O E/M visit code family (83 FR 59628). In our CY 2019 PFS final rule, we finalized documentation changes, some of which took effect in CY 2019 (83 FR 59628–59535), while others (notably choice of MDM or time for supporting documentation) would be effective in CY 2021 in conjunction with finalized coding and payment changes for O/O E/M visits (83 FR 59636–59645). The coding and payment changes included a single payment rate for levels 2 through 4 O/O E/M visits (retaining separate payment for level 5 visits to account for the most complex patients and visits); two HCPCS add-on codes to provide separate, additional payments for the resource costs involved in furnishing certain types of O/O E/M visit care, specifically visit complexity inherently associated with primary care and non-procedural specialty care; and a third HCPCS code for O/O E/M visits taking extended amounts of time (83 FR 59638).

In January–February 2019, we held listening sessions, and we learned that the AMA was convening an E/M Workgroup to develop an alternative solution to some of these issues (84 FR 40673). The AMA proceeded to revise and resurvey the O/O E/M visit code family (see 84 FR 62844 through 62847). Effective January 1, 2021, the CPT Editorial Panel redefined the codes for O/O E/M visits such that the furnishing practitioner may select the level of visit to bill based either on the amount of practitioner time spent performing the visit or the level of medical decision-making (MDM) involved. The CPT Editorial Panel redefined MDM in the CPT E/M Guidelines, which are an accompanying set of CPT interpretive guidelines delineating different levels of MDM and various other reporting parameters. Additionally, history of present illness (History) and a physical exam were no longer used to select the O/O E/M visit level. These service elements were updated to remove reliance on clinically outdated parameters to contribute to selection of visit level, such as number of body systems reviewed, and to require instead that a medically appropriate history and exam are performed. Also, effective January 1, 2021, the CPT Editorial Panel revised the O/O E/M visit descriptor times. Previously, the CPT code descriptors included typical service times, but they were revised to specify new time ranges that must be furnished in order to select a given visit level using time. The AMA RUC resurveyed the O/O E/M visit CPT codes, and provided us with revaluation recommendations that we then addressed in our CY 2020 PFS proposed rule, a year in advance of when the revised codes would take effect in CY 2021 (84 FR 40675 through 40678).

In our CY 2020 PFS final rule, we generally adopted the revised O/O E/M code set and the related changes in the CPT E/M Guidelines, including the revised approach to visit level selection and documentation, for payment purposes under the PFS effective January 1, 2021 (84 FR 62844 through 62859). While we accepted the revised CPT codes and approach for the O/O E/M visits, we finalized Medicare-specific coding for prolonged O/O service codes, because we were concerned that the CPT codes were administratively complex, and their use would have impacted our ability to tell how much total time was spent with the patient and could have resulted in inappropriately inflated payment (84 FR 62849 through 62850, and 85 FR 84572 through 84575).

In our CY 2020 PFS final rule, we generally accepted the RUC recommendations, which reflected increased service times (84 FR 62851 through 62854). This resulted in increased values for the O/O E/M visit codes beginning in CY 2021. However, since we believed these increased valuations still did not account for the resources involved in furnishing certain kinds of care included in the O/O E/M visit code set, in the CY 2021 PFS final rule, we retained our add-on codes for visit complexity inherently associated with primary care and non-procedural specialty care, though we refined and consolidated them into a single code, a HCPCS add-on code G2211 (*O/O E/M visit complexity*) that can be reported in conjunction with O/O E/M visits to better account for additional resources associated with primary care, or similarly ongoing medical care related to a patient's single, serious condition, or complex condition (84 FR 62854 through 62856, 85 FR 84571). (Hereafter in this rule, we refer to this code as the O/O E/M visit complexity add-on).

After we issued the CY 2021 PFS final rule, section 113 of Division CC of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260, December 27, 2020) (CAA, 2021) imposed a moratorium on Medicare payment for this service by prohibiting CMS from making payment under the PFS for services described by HCPCS code G2211 (or any successor or substantially similar code) before January 1, 2024. Accordingly, the O/O E/M visit complexity add-on code can be reported, but it is currently assigned a bundled payment status indicator. See our fact sheet available at Physician Fee Schedule (PFS) Payment for Office/Outpatient Evaluation and Management (E/M) Visits—Fact Sheet [30] (*cms.gov*).

In the CY 2022 PFS final rule, we established revised payment rules for split (or shared) visits (86 FR 65150 through 65159). The following year the CPT Editorial Panel defined a split (or shared) visit for the first time in the CPT E/M Guidelines for 2023. However, we did not adopt the CPT definition as it did not conform with our established final policy or address which practitioner should report a shared visit.

For CY 2023, the CPT Editorial Panel also revised the rest of the E/M visit code families (except critical care services) to match the general framework of the O/O E/M visits, including inpatient and observation visits, emergency department (ED) visits, nursing facility visits, domiciliary or rest home visits, home visits, and cognitive impairment assessment. We refer to these other E/M visit code families as ''Other E/M'' visits or CPT codes, as relevant. Effective January 1, 2023, the CPT Editorial Panel redefined the Other E/M visits so that they parallel the O/O E/M visits, where visit level is selected based on the amount of practitioner time spent with the patient or the level of MDM as redefined in the CPT E/M Guidelines. As for the O/O E/M visits, a medically appropriate history and/or physical exam is a required element of the services, but no longer impacts the Other E/M visit level. The CPT Editorial Panel also revised the service times within the descriptors, the associated CPT prolonged service codes, and the CPT E/M Guidelines for the Other E/M CPT codes. The CPT Editorial Panel also consolidated a considerable number of the Other E/M CPT codes, with inpatient and observation visits being combined into a single code set, and home and domiciliary visits being combined into a single code set. The CPT Editorial Panel created one new CPT code for prolonged inpatient services by physicians and other qualified healthcare professionals on the date of the E/M visit. Finally, the RUC resurveyed the Other E/M visits and associated prolonged service codes,

[30] *https://www.cms.gov/files/document/physician-fee-schedule-pfs-payment-officeoutpatient-evaluation-and-management-em-visits-fact-sheet.pdf.*

and provided revaluation recommendations to CMS.

We addressed all of these changes to the Other E/M visit families in the CY 2023 PFS final rule (87 FR 69586 through 69616). In that final rule, we adopted the revised CPT codes and descriptors for Other E/M visits, except for prolonged services for which we finalized Medicare-specific coding. We also adopted the CPT E/M Guidelines for levels of MDM as revised for 2023. Regarding valuation, we adopted most of the RUC-recommended values for Other E/M visits, which increased their relative valuation in aggregate. However, we stated our belief that certain types of O/O E/M visits remain undervalued, given the moratorium on separate payment for the O/O E/M visit complexity add-on (87 FR 69588).We expressed concern about assumptions made in the RUC recommendations for Other E/M visits that patient needs were inherently more complex, or work was more intense for E/M visits furnished in non-office settings (for example, inpatient, ED, and home settings) when compared to the office settings (87 FR 69587 through 69588). We stated that this direct comparison between Other E/M visits and the O/O E/M visit codes may not be appropriate or accurate, and laid out reasons why practitioners in office settings may expend more resources than practitioners in institutional and other settings. We note that the survey times for O/O E/M visits increased significantly when resurveyed (85 FR 50123), while times for Other E/M visits generally decreased significantly or remained the same when resurveyed, despite the level of MDM remaining constant (87 FR 69598, 69605). To the extent we adopted the RUC-recommended values for Other E/M visits beginning in CY 2023, we expressed that we did not agree that the RUC-recommended relative values for E/M visits fully accounted for the complexity of certain kinds of visits, especially for those in the office setting, nor do they fully reflect appropriate relative values, since separate payment is not yet made for the O/O E/M visit complexity add-on (87 FR 69588).

During the CAA, 2021 moratorium on separate payment for the O/O E/M visit complexity add-on, interested parties have continued to engage CMS about the appropriate valuation of O/O E/M visits relative to other PFS services, including through public comments on the proposed revaluation of Other E/M visits (87 FR 70218), as well as in meetings and letters submitted to CMS outside of the rulemaking process. Anticipating the end of the CAA, 2021 moratorium, interested parties including the AMA, several medical associations, and others recently approached CMS outside of the rulemaking process with recommendations regarding implementation and potential refinements to the service beginning in 2024 to ensure the appropriate relative valuation of O/O E/M visits. Interested parties have also continued to approach CMS and the CPT Editorial Panel with questions and recommendations about payment rules for split (or shared) visits.

2. Office/Outpatient (O/O) E/M Visit Complexity Add-On Implementation

a. Background

As discussed above, in the CY 2021 PFS final rule, CMS refined the O/O E/M visit complexity add-on code, GPC1X (which was replaced by HCPCS code G2211), to describe intensity and complexity inherent to O/O E/M visits 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. (85 FR 84569–84571). While we adopted the AMA RUC recommendations for the revised O/O E/M CPT visit codes, those values did not fully account for the resource costs associated with primary care and other longitudinal care of complex patients. Under our final policy, which was delayed by the CAA, 2021 before it was implemented, the O/O E/M visit complexity add-on code could be reported with all O/O E/M visit levels. We disagreed with comments suggesting that billing of the O/O E/M visit complexity add-on code should be restricted to higher level office/outpatient E/M visits; and responded that, given the wide variety of visit types billable with the office/outpatient E/M visit code set, we did not believe that the value associated with the typical visit accounts for the additional resources associated with primary care or ongoing care related to a patient's single, serious, or complex chronic condition, regardless of the visit level. The full descriptor for the O/O E/M visit complexity add-on code, as refined in the CY 2021 PFS final rule, is HCPCS code 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))* (85 FR 84571) We also estimated that the O/O E/M visit complexity add-on service would be reported by specialties that rely on office/outpatient E/M visits to report the majority of their services and would be billed in addition to those E/M visits. While we did not explicitly prohibit billing the O/O E/M visit complexity add-on in conjunction with visits that are reported with various modifiers, and did not exclude those from our utilization estimates, we stated we did not expect the add-on service to be reported for visits billed with a payment modifier, for example, to identify a separately billable E/M visit in conjunction with a minor procedure (85 FR 84571 through 84572).We stated that visits reported with payment modifiers are likely to involve resources that are distinct from the stand-alone O/O E/M visits for primary care and other longitudinal care of complex patients, and that we may consider this issue in potential future rulemaking. We further stated that we do not expect the O/O E/M visit complexity add-on code to be reported when the O/O E/M visit is reported with payment modifiers such as modifier-25 which describes separately billed visits on the same day as another visit or procedure (see our fact sheet, identifying additional modifiers, available at Physician Fee Schedule (PFS) Payment for Office/Outpatient Evaluation and Management (E/M) Visits—Fact Sheet (*cms.gov*)).

Interested parties have continued to express uncertainty about when it would be appropriate to report the O/O E/M visit complexity add-on service. Some interested parties have expressed larger concerns about potential reductions to the PFS CF or redistributive impacts among specialties if we were to implement the O/O E/M visit complexity add-on code. In the CY 2021 PFS final rule, we clarified and refined the service definition to alleviate some of these concerns and revised our utilization estimates (85 FR 84572). Conversely, some interested parties, specifically practitioners that rely on office/outpatient E/M visits to report the majority of their services, who could use the add-on code to better reflect the resources they use to furnish complex longitudinal services expressed continued support for our policy. We reiterated our belief that the O/O E/M visit complexity add-on reflects the time, intensity, and PE resources involved when practitioners furnish the kinds of O/O E/M office visit 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. In response to comments, we also made further refinements to the HCPCS code descriptor to clarify that the code applies to a serious condition rather than any single condition. We also acknowledged concerns that, given the request by some medical societies for additional time to educate their members about appropriate use of the O/O E/M visit complexity add-on code, ongoing implementation of the revisions to the O/O E/M visit code set, electronic health records integration, and the persistence of the COVID–19 pandemic, practitioners that rely on O/O E/M visits to report the majority of their services are not likely to report the complexity add-on code with every office visit. However, we disagreed with commenters who thought the O/O E/M visit complexity add-on code would be billed with only 10 to 25 percent of O/O E/M services. Because we had not implemented any additional policies that restricted the billing of this code, we estimated that the add-on code would be billed with 90 percent of O/O E/M visits billed by certain physician specialties (roughly 58 percent of all office/outpatient E/M visits).

b. Proposal for O/O E/M Visit Complexity Add-On HCPCS Code G2211

Interested parties have continued to engage with us and provide recommendations for implementation of the O/O E/M visit complexity add-on. Some commenters recommended that CMS delay the implementation of HCPCS add-on code G2211, citing concerns about the expected budget neutrality adjustment necessitated by implementation of the O/O E/M visit complexity add-on and redistributive impact on PFS payment (85 FR 84572). Many commenters who rely upon O/O E/M visits to report the majority of their services continued to be supportive of HCPCS add-on code G2211 (85 FR 84570) and have recommended that we speedily implement it. Some of these commenters also recommended ways to clarify the intended use of the O/O E/M visit complexity add-on code, which could reduce redistributive impacts. Finally, as noted above, the values we established for the revised O/O E/M CPT codes in the CY 2021 PFS final rule were finalized in concert with a policy that would have provided separate payment for the new add-on code G2211 (87 FR 69588).To the extent we adopted the RUC-recommended values for Other E/M visits beginning in CY 2023, we expressed that we did not agree that the RUC-recommended relative values for E/M visits fully reflected appropriate relative values, since separate payment is not yet made for HCPCS code G2211.

The CAA, 2021 moratorium on Medicare payment under the PFS for HCPCS code G2211 will end on December 31, 2023. We are proposing to change the status of HCPCS code G2211 to make it separately payable by assigning the ''active'' status indicator, effective January 1, 2024. After considering feedback we have received from interested parties, both through the CY 2021 PFS rulemaking process and during the moratorium, we are also proposing several policy refinements (with respect to HCPCS code G2211). We stated in the CY 2021 PFS final rule that we would not expect HCPCS add-on code G2211 to be reported when the O/O E/M service is reported with a payment modifier, such as the modifier-25, which denotes a separately billable E/M service by the same practitioner furnished on the same day of a procedure or other service (85 FR 84572). We continue to believe that separately identifiable O/O E/M 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 O/O E/M visits to warrant different payment (85 FR 84572). As such we are proposing that the O/O E/M visit complexity add-on code, HCPCS code G2211, would not be payable when the O/O E/M visit is reported with payment modifier-25.

Interested parties have also requested that we reconsider our previous utilization assumptions. In the CY 2021 PFS final rule, we had assumed that specialties that rely on O/O E/M visit codes to report the majority of their services would be most likely to report the O/O E/M visit complexity add-on code, and that they would report the add-on code with every O/O E/M visit they report. We acknowledged commenters' concerns that, given the request by some medical societies to educate their members about appropriate use, and ongoing implementation of the revisions to the office/outpatient E/M visit code set, and electronic health records integration, practitioners that rely on office/outpatient E/M visits to report the majority of their services would not be likely to report HCPCS code G2211 with every O/O E/M visit they report (85 FR 84572).

Interested parties have presented reasons we find persuasive that such practitioners would not be likely to report HCPCS code G2211 with every O/O E/M visit they report. They reasoned that many practitioners delivering care in settings specifically designed to address acute health care needs, without coordination or follow-up, will regularly have encounters with patients that are not part of continuous care.

Furthermore, in contrast to situations, where the patient's overall, ongoing care is being managed, monitored, and/or observed by a specialist for a particular disease condition, we continue to believe that there are many visits with new or established patients where the O/O E/M visit complexity add-on code would not be appropriately reported, such as when the care furnished during the O/O E/M visit is provided by a professional whose relationship with the patient is of a discrete, routine, or time-limited nature; such as, but not limited to, 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 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 (85 FR 84570 and 84571).

These considerations taken together with our proposal that the O/O E/M visit complexity add-on code, HCPCS code G2211, would not be payable when the O/O E/M visit is reported with payment modifier-25 have informed our revised utilization assumptions. Taking into consideration the comments received by interested parties, and the reasons discussed above, we now estimate that HCPCS code G2211 will be billed with 38 percent of all O/O E/M visits initially. We calculated these revised utilization assumptions by considering the uptake of new codes in prior years, and the O/O E/M billing patterns of all specialties. Specifically, we took into account the likelihood that primary care specialties will have a higher utilization of the add-on code than other specialties, surgical specialties will have the lowest utilization since they are less likely to establish longitudinal care relationships with patients, and other specialists are more likely to have longitudinal care

relationships than surgical specialties but less likely than primary care specialists. We also revised our estimates by excluding (1) claims from practitioners participating in CMS capitated models, and (2) claims for established patient visits performed by certain specialties that are unlikely to have a longitudinal care relationship with a beneficiary. We also accounted for the proportion of visits billed that were furnished as consults or for the purpose of obtaining a second clinical opinion and excluded these types of visits from our estimates. We estimate that when fully adopted, HCPCS code G2211 will be billed with 54 percent of all O/O E/M visits. This fully adopted estimate is informed by considering uptake of new codes after several years. We seek comment on these utilization assumptions and the application of this proposed policy for CY 2024.

c. Request for Comment About Evaluating E/M Services More Regularly and Comprehensively

Over the last several years, we have received suggestions/recommendations outside of the rulemaking process that CMS consider using a different approach for valuing services that relies on research and data other than the AMA RUC's specialty-specific valuation recommendations. These commenters have highlighted that the evolving practice of medicine looks significantly different than it did when the resource-based relative value scale (RBRVS) was established three decades ago. Disease prevention and health promotion have grown in practice and patient expectations are higher for the management of hypertension, diabetes, and hypercholesterolemia. Additionally, more pharmaceuticals and new biologics have expanded therapeutic options for non-procedural care. Commenters have suggested convening expert panels that might review pertinent research and recommend resource recalibrations for purposes of updating relative values under the PFS. The commenters suggested that such independent assessments could support CMS and the broader health delivery and health finance community in addressing growing distortions in resource allocations under the PFS for certain types of services, including evaluation and management visits and other non-procedural/non-surgical services.

For many years, CMS has worked to address coding and payment deficiencies, explicitly focusing on instances where resources are not well accounted for in the inputs for certain services, including where significant differences in relative resources involved in furnishing care are not reflected in the coding distinctions, or where too-specific coding makes valuation at appropriate intervals impractical. As we continue ongoing work to establish resource-based relative units for PFS services, we also seek public comment about the potential range of approaches CMS could take to improve the accuracy of valuing services. We are especially interested in how we might improve the accuracy of valuation for services, and we are seeking information about how we might evaluate E/M services with greater specificity, more regularly and comprehensively.

As we consider how CMS can potentially move forward with reforms to the way we establish values for E/M and other services, we are particularly interested in receiving comments from the public on the following questions:

a. Do the existing E/M HCPCS codes accurately define the full range of E/M services with appropriate gradations for intensity of services?

b. Are the methods used by the RUC and CMS appropriate to accurately value E/M and other HCPCS codes?

c. Are the current Non-E/M HCPCS codes accurately defined?

d. Are the methods used by the RUC and CMS appropriate to accurately value the non-E/M codes?

e. What are the consequences if services described by HCPCS codes are not accurately defined?

f. What are the consequences if services described by HCPCS codes are not accurately valued?

g. Should CMS consider valuation changes to other codes similar to the approach in section II.J.5. of this rule?

We are particularly interested in ways that CMS could potentially improve processes and methodologies, and we request that commenters provide specific recommendations on ways that we can improve data collection and to make better evidence-based and more accurate payments for E/M and other services. We are particularly interested in recommendations on ways that we can make more timely improvements to our methodologies to reflect changes in the Medicare population, treatment guidelines and new technologies that represent standards of care. We are also interested in recommendations that would ensure that data collection from, and documentation requirements for, physician practices are as least burdensome as possible while also maintaining strong program integrity requirements. Finally, we are also interested in whether commenters believe that the current AMA RUC is the entity that is best positioned to provide recommendations to CMS on resource inputs for work and PE valuations, as well as how to establish values for E/M and other physicians' services; or if another independent entity would better serve CMS and interested parties in providing these recommendations.

3. Split (or Shared) Visits

The split (or shared) ''substantive portion'' policy for services furnished in facility settings was reflected in subregulatory guidance until it was withdrawn in May 2021, in response to a petition under the, since rescinded, Good Guidance regulation (see 87 FR 44002 (February 25, 2022). In the CY 2022 PFS final rule (86 FR 65150 through 65159), we finalized a policy for evaluation and management (E/M) visits furnished in a facility setting, to allow payment to a physician for a split (or shared) visit (including prolonged visits), where a physician and non-physician practitioner (NPP) provide the service together (not necessarily concurrently) and the billing physician personally performs a substantive portion of the visit. Commenters were generally supportive of our CY 2022 proposals; however, there were divided comments with regard to our proposed definition of ''substantive portion.'' Some commenters preferred the use of medical decision making (MDM) or one of the three key visit components as opposed to time for purposes of defining the ''substantive portion'' of the service.

a. Background

A split (or shared) visit refers to an E/M visit performed by both a physician and an NPP in the same group practice. In the non-facility (for example, office) setting, the rules for ''incident to'' billing apply under this circumstance. However, ''incident to'' services are not available for services furnished in a facility setting. Longstanding CMS policy has been that, for split (or shared) visits in the facility (for example, hospital) setting, the physician can bill for the services if they perform a substantive portion of the encounter. Otherwise, the NPP would bill for the service. Section 1833(a)(1)(N) of the Act specifies that payment is made for services furnished and billed by a physician at 100 percent of the PFS rate, while under section 1833(a)(1)(O)(i) of the Act, certain NPPs are paid for the services they furnish and bill for at a reduced PFS rate (85 percent of the PFS).

For CY 2023, after considering the public comments we received, we finalized that we would delay implementation of our definition of the

substantive portion as more than half of the total practitioner time until January 1, 2024. We defined ''substantive portion'' in the CY 2022 PFS final rule (86 FR 65152 through 65156) and provided for billing of split (or shared) visits in certain settings (86 FR 65156 through 65157) and for certain patient types (new and established) (86 FR 65156). After consideration of the public comments on the CY 2022 PFS proposed rule, we finalized a phased-in approach to this policy (86 FR 65153). For CY 2022, we finalized the definition of ''substantive portion'' as one of the following: either one of the three key E/M elements (that is, history, exam, or MDM) or more than half of total time. We also stated that we would delay the full implementation of the definition of ''substantive portion'' as more than half of total time until CY 2023 (86 FR 65152 and 65153).

Additionally, in the CY 2022 PFS final rule (86 FR 65158 through 65159), we finalized our proposal to create a payment modifier (modifier FS), to describe split (or shared) visits (see 86 FR 65158 through 65159 for this discussion). Over time, implementing and using this modifier will better enable us to quantify split (or shared) visits and better understand the billing patterns of practitioners that typically furnish them. Such information is helpful to CMS for program integrity purposes and may also inform us on whether we need to clarify or further revise the policy for these services in future rulemaking. To date, we have roughly one year's worth of claims data from the time the modifier was instituted as part of our ongoing engagement with interested parties. We have continued to hear concerns about our intent to implement our policy to use more than half of the total time to define the ''substantive portion'' of a split or shared visit, and have received requests to continue to recognize MDM as the ''substantive portion.'' Many of these concerns specifically reference disruptions to current team-based practice patterns, and the potential for significant adjustments to the practice's internal processes or information systems to allow for tracking visits based on time, rather than MDM. With these concerns in mind, in the CY 2023 PFS final rule (87 FR 69614 through 69616), we finalized a policy to delay implementation of our definition of substantive portion as more than half of the total practitioner time until January 1, 2024.

After much consideration, we are proposing to delay the implementation of our definition of the ''substantive portion'' as more than half of the total time through at least December 31, 2024 for the same reasons outlined in the CY 2023 PFS final rule (87 FR 69614 through 69616). We are proposing to maintain the current definition of substantive portion for CY 2024 that allows for use of either one of the three key components (history, exam, or MDM) or more than half of the total time spent to determine who bills the visit. This proposed additional delay allows interested parties to have another opportunity to comment on this policy, and gives CMS time to consider more recent feedback and evaluate whether there is a need for additional rulemaking on this aspect of our policy. We are interested in how facilities are currently implementing our split (or shared) services policy in their workflows and how facilities are currently accounting for services of billing practitioners that are performed split (or shared). We are also interested in how to better account for the services of the billing practitioner in team-based care clinical scenarios. We understand that the AMA CPT Editorial Panel is considering revisions to aspects of split or shared visits that may impact our policies, but those changes may not be finalized before this proposed rule is published. We will review the AMA CPT Editorial Panel's changes to split or shared visits when and if available before the final rule and in the context of our policy proposal. We will consider any changes that are made and their relationship to our previously finalized policies, and whether a further implementation delay beyond CY 2024 or revision of the definition of substantive portion is warranted. We would address any changes through future rulemaking.

We are proposing to amend 42 CFR 415.140 to revise the definition of ''substantive portion'' in the interim while we continue to analyze and collect information from interested parties and commenters as to whether we should permanently modify our current definition. We note the current definition of ''substantive portion'' applies for visits other than critical care visits furnished in CY 2022 through CY 2024. We are amending § 415.140 by removing ''the year 2022 and 2023'' and adding in its place ''years 2022 through 2024'' after the phrase ''For visits other than critical care visits furnished in calendar.'' Therefore, the proposed paragraph would specify, for visits other than critical care visits furnished in calendar years 2022 through 2024, *substantive portion* means either one of the three key components (history, exam, or MDM) or more than half of the total time spent by the physician and NPP performing the split (or shared) visit.

G. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires CMS to develop separate Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, practice expense (PE), and malpractice (MP)). Section 1848(e)(1)(E) of the Act provides for a 1.0 floor for the work GPCIs for the purposes of payment for services furnished on or after January 1, 2004, and before January 1, 2024. Congress recently extended the 1.0 work GPCI floor only through December 31, 2023, in division CC, section 101 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260, enacted December 27, 2020). Therefore, the CY 2024 work GPCIs and summarized GAFs do not reflect the 1.0 work floor. See Addenda D and E to this proposed rule for the CY 2024 GPCIs and summarized GAFs. These Addenda are available on the CMS website under the supporting documents section of the CY 2024 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

2. Review of the California Fee Schedule Areas Used for Payment for CY 2024

Section 220(h) of the Protecting Access to Medicare Act (PAMA) (Pub. L. 113–93, April 1, 2014) added a new section 1848(e)(6) to the Act that modified the fee schedule areas used for payment purposes in California beginning in CY 2017. Prior to CY 2017, the fee schedule areas used for payment in California were based on the revised locality structure that was implemented in 1997 as previously discussed. Beginning in CY 2017, section 1848(e)(6)(A)(i) of the Act required that the fee schedule areas used for payment in California must be Metropolitan Statistical Areas (MSAs) as defined by the Office of Management and Budget (OMB) as of December 31 of the previous year; and section 1848(e)(6)(A)(ii) of the Act required that all areas not located in an MSA must be treated as a single rest-of-State fee schedule area. The resulting modifications to California's locality structure increased its number of fee schedule areas from 9 under the previous locality structure to 27 under the MSA-based locality structure;

although for the purposes of payment, the actual number of fee schedule areas under the MSA-based locality structure is 32. We refer readers to the CY 2017 PFS final rule (81 FR 80267) for a detailed discussion of this operational decision.

Section 1848(e)(6)(D) of the Act defined transition areas as the counties in fee schedule areas for 2013 that were in the rest-of-State locality, and locality 3, which was comprised of Marin, Napa, and Solano counties. Section 1848(e)(6)(B) of the Act specified that the GPCI values used for payment in a transition area are to be phased in over 6 years, from 2017 through 2022, using a weighted sum of the GPCIs calculated under the new MSA-based locality structure and the GPCIs calculated under the PFS locality structure that was in place prior to CY 2017. That is, the GPCI values applicable for these areas during this transition period were a blend of what the GPCI values would have been for California under the locality structure that was in place prior to CY 2017, and what the GPCI values would be for California under the MSA-based locality structure. For example, in CY 2020, which represented the fourth year of the transition period, the applicable GPCI values for counties that were previously in the rest-of-State locality or locality 3 and are now in MSAs were a blend of ⅔ of the GPCI value calculated for the year under the MSA-based locality structure, and ⅓ of the GPCI value calculated for the year under the locality structure that was in place prior to CY 2017. The proportions continued to shift by ⅙ in each subsequent year so that, by CY 2021, the applicable GPCI values for counties within transition areas were a blend of ⅚ of the GPCI value for the year under the MSA-based locality structure, and ⅙ of the GPCI value for the year under the locality structure that was in place prior to CY 2017. Beginning in CY 2022, the applicable GPCI values for counties in transition areas were the values calculated solely under the new MSA-based locality structure; therefore, the phase-in for transition areas is complete. Additionally, section 1848(e)(6)(C) of the Act establishes a hold harmless requirement for transition areas beginning with CY 2017; whereby, the applicable GPCI values for a year under the new MSA-based locality structure may not be less than what they would have been for the year under the locality structure that was in place prior to CY 2017. There are 58 counties in California, 50 of which were in transition areas as defined in section 1848(e)(6)(D) of the Act. The eight counties that were not within transition areas are: Orange; Los Angeles; Alameda; Contra Costa; San Francisco; San Mateo; Santa Clara; and Ventura counties. We note that while the phase-in for transition areas is no longer applicable, the hold harmless requirement is not time-limited, and therefore, is still in effect.

For the purposes of calculating budget neutrality and consistent with the PFS budget neutrality requirements as specified under section 1848(c)(2)(B)(ii)(II) of the Act, in the CY 2017 PFS final rule (81 FR 80266), we finalized the policy to start by calculating the national GPCIs as if the fee schedule areas that were in place prior to CY 2017 are still applicable nationwide; then, for the purposes of payment in California, we override the GPCI values with the values that are applicable for California consistent with the requirements of section 1848(e)(6) of the Act. This approach to applying the hold harmless requirement is consistent with the implementation of the GPCI floor provisions that have previously been implemented—that is, as an after-the-fact adjustment that is made for purposes of payment after both the GPCIs and PFS budget neutrality have already been calculated.

Additionally, section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made. For a comprehensive discussion of this provision, transition areas, and operational considerations, we refer readers to the CY 2017 PFS final rule (81 FR 80265 through 80268).

a. Refinement to Number of Unique Fee Schedule Areas in California for CY 2024

In the CY 2020 final rule (84 FR 62622), a commenter indicated that some of the distinct fee schedule areas that were used during the period between CY 2017 and CY 2018 are no longer necessary. Specifically, with regard to the Los Angeles-Long Beach-Anaheim MSA, which contains 2 counties (across two unique locality numbers, 18 and 26) that are not transition areas, we acknowledge that we only needed more than one unique locality number for that MSA for payment purposes in CY 2017, which was the first year of the implementation of the MSA-based payment locality structure. Neither of the counties in the Los Angeles-Long Beach-Anaheim MSA (Orange County and Los Angeles County) are transition areas under section 1848(e)(6)(D) of the Act. Therefore, the counties were not subject to the aforementioned GPCI value incremental phase-in (which is no longer applicable) or the hold-harmless provision at section 1848(e)(6)(C) of the Act. Similarly, the San Francisco-Oakland-Berkeley MSA contains four counties—San Francisco, San Mateo, Alameda, and Contra Costa counties—across three unique locality numbers, 05, 06, and 07. These counties are not transition areas and will receive the same GPCI values, for payment purposes, going forward. In response to the comment, we acknowledged that we did not propose any changes to the number of fee schedule areas in California, but would consider the feasibility of a technical refinement to consolidate into fewer unique locality numbers; and if we determined that consolidation was operationally feasible, we would propose the technical refinement in future rulemaking. This refinement would ultimately change the number of distinct fee schedule areas for payment purposes in California from 32 to 29. In the CY 2023 PFS proposed rule (87 FR 46008), we proposed to identify the Los Angeles-Long Beach-Anaheim MSA, containing Orange County and Los Angeles County, by one unique locality number, 18, as opposed to two, thus retiring locality number 26, as it is no longer needed. Similarly, we proposed to identify the San Francisco-Oakland-Berkeley MSA containing San Francisco, San Mateo, Alameda, and Contra Costa counties by one unique locality number, 05, as opposed to three, thus retiring locality numbers 06 and 07, as they are no longer needed. Additionally, we noted that we would modify the MSA names as follows: the San Francisco-Oakland-Berkeley (San Francisco Cnty) locality (locality 05) would become San Francisco-Oakland-Berkeley (San Francisco/San Mateo/Alameda/Contra Costa Cnty), and Los Angeles-Long Beach-Anaheim (Los Angeles Cnty) locality (locality 18) would become Los Angeles-Long Beach-Anaheim (Los Angeles/Orange Cnty). We noted that because Marin County is in a transition area and subject to the hold harmless provision at section 1848(e)(6)(C) of the Act, we needed to retain a unique locality number for San Francisco-Oakland-Berkeley (Marin Cnty), locality 52. Based on support from commenters in the CY 2023 PFS final rule (87 FR 69621), we finalized to identify the Los Angeles-Long Beach-Anaheim MSA, containing Orange County and Los Angeles County, by one unique locality number, 18, and the San

Francisco-Oakland-Berkeley MSA containing San Francisco, San Mateo, Alameda, and Contra Costa counties by one unique locality number, 05, as proposed. We noted that, while we believed these changes were appropriate to consolidate fee schedules areas that are no longer operationally necessary, we were unable to operationalize these changes for CY 2023 due to timing constraints relating to the actions and coordination with the various systems maintainers required to effectuate changes to claims processing (87 FR 69621). Therefore, for CY 2023, there were no changes to the existing locality numbers 05, 06, 08, 18, or 26. We noted in the CY 2023 PFS final rule that we would operationalize these finalized changes for CY 2024. We reiterate here that we are operationalizing these locality number changes for CY 2024 via instruction to the MACs, and therefore, locality numbers 06, 07, and 26 will no longer be used for the PFS starting January 1, 2024. We note that these changes, when operationalized, do not have any payment implications under the PFS because these counties are not transition areas and will receive the same GPCI values, for PFS payment purposes, going forward.

H. Payment for Skin Substitutes

1. Background

In the CY 2023 PFS proposed rule, CMS outlined several objectives related to refining skin substitute policies under Medicare, including: (1) ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department setting; (2) ensuring that appropriate HCPCS codes describe skin substitute products; (3) using a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of human or animal-based material, to incorporate more consistent payment methodologies; and (4) maintaining clarity for interested parties on CMS skin substitutes policies and procedures. When considering potential changes to policies involving skin substitutes, we noted that we believe it would be appropriate to take a phased approach over multiple rulemaking cycles to examine how we could appropriately incorporate skin substitutes as supplies under the PFS ratesetting methodology. 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. 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).

Similar to how we assess costs for other incident to supplies, our approach to identifying appropriate PE direct costs for skin substitute products may include: reviewing various sources for price information, including performing market research, reviewing invoices submitted by interested parties, or reviewing cost information on Medicare claims. Further, we would assess how the incident to supplies are billed or represented while also considering the service with which it is typically furnished. For example, if the supply is billed separately, with the base service, or usually bundled and incident to the base service. Also, we would consider whether there are different supply costs or other meaningful stratifications (for example, a unit of measure or product type) that should be accounted for as we develop direct PE costs, considering how the base service is furnished.

We are soliciting comments on how best to use these approaches under our PFS ratesetting methodology as potential methods to establish appropriate payment for skin substitute products under the PFS.

2. Sources of Price Information

We have refined specific PE data inputs in recent years, using market research and publicly available data (for example, market research on medical supply and equipment items and BLS data to update clinical labor wages) to update the direct PE data inputs used in the PFS ratesetting process. Historically, under the PFS, various sources of information have helped inform payment for specific services used to establish direct PE inputs. Direct PE inputs may derive from assessing the current value of products on the market, which may be achieved by utilizing Average Sales Price (ASP) data or Wholesale Acquisition Cost data (WAC). Since some manufacturers self-report ASP/WAC data at the end of every quarter, this may help to inform CMS of the current market value of these products.

We also review submitted invoices, which reflect the specific cost of products that practitioners are paying manufacturers for these products. We note in the CY 2011 PFS final rule (75 FR 73205) we update supply and equipment prices through an invoice submission process. In this process, we consider the invoice information and incorporate it into our direct costs database if the submitted pricing data indicates the typical market price of the supply or equipment item.

While performing market research and the invoice submission process are different methods to derive pricing for specific products, reviewing cost information on Medicare claims may also help us identify the variability in product costs. For example, assessing detailed cost information on claims with skin substitute products could inform how these products are priced and allow us to consider how the skin substitutes are typically furnished and where these services are performed. This information would enable us to refine our payment policies for these products across different care settings.

We seek comment on the various cost-gathering approaches discussed above that could inform how we establish direct PE inputs for skin substitute products and appropriately develop payment rates for physician services that involve furnishing skin substitute products.

3. Approaches to Billing

We acknowledge that there are various approaches that we could use to identify and establish direct cost inputs for the skin substitute products. We are also considering how to account for these products' variability and resource costs, especially as new products increasingly become available.

Similar to how different sources of information can influence cost information for supplies, specifically considering variables such as different units of measurement, product type, product composition, or in what clinical circumstances the product is used, for example, would help us appropriately reflect costs in payment for the services that include the specific supply. We believe this to be pertinent to how we propose to pay for skin substitute products. For instance, grouping the direct costs for particular skin substitute products based on the typically associated application procedure could help us systematically incorporate the resource costs involved for different product billing scenarios. This approach can be seen in the Outpatient Prospective Payment System (OPPS), where a high-cost/low-cost system is used for skin substitute products billed with a specific procedure code based on their cost grouping.

Alternatively, when services and products are not performed frequently enough to be grouped, retaining separate procedure coding can help inform specificity and granularity for coding

and payment of these services. Specifically, we could create separate procedure coding for specific product types, which could be billed with the appropriate skin substitute application services. We would account for cost variability for the different products (that is, establishing individual or group direct cost profiles and allocating direct costs inputs based on these groupings) under any combination of approaches discussed above. We could also review the unit of measurement for billed products, as available in our internal data or received in submissions, and create direct cost groupings for the products based on the reviewed/billed units of measurement. We could also establish direct cost inputs by employing our standard 'crosswalk' method using information from interested parties. Specifically, we would derive PE inputs by reviewing similarly resourced services to establish RVUs for a service that includes the cost of the skin substitute products and other information to account for the physician's work in furnishing the skin substitute product. We would employ this method to establish payment for individual services that include specific skin substitute products or services that describe cost groupings of similarly priced skin substitute products. As we have discussed in prior rulemaking, we believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. There is a long history of using crosswalk codes for this kind of valuation under the PFS, which is generally established through notice and comment rulemaking.

We seek comment on how these methods discussed above may help reflect the resource costs involved with skin substitute products as furnished with different skin application procedures.

I. Supervision of Outpatient Therapy Services, KX Modifier Thresholds, Diabetes Self-Management Training (DSMT) Services by Registered Dietitians and Nutrition Professionals, and DSMT Telehealth Services

1. Supervision of Outpatient Therapy Services in Private Practices

(a) Remote therapeutic monitoring for physical therapists and occupational therapists in private practice.

In the CY 2023 PFS final rule, we finalized new policies that would allow Medicare payment for remote therapeutic monitoring (RTM) services, including allowing any RTM service to be furnished under our general supervision requirements (87 FR 69649). RTM refers to the use of devices to monitor a patient's health or response to treatment using non-physiological data (please see more detailed list of RTM services at section II.D. of this proposed rule). The current regulations, however, at §§ 410.59(a)(3)(ii) and 410.60(a)(3)(ii) specify that all occupational and physical therapy services are performed by, or under the direct supervision of, the occupational or physical therapist, respectively, in private practice. These regulations make it difficult for physical therapists in private practice (PTPPs) and occupational therapists in private practice (OTPPs) to bill for the RTM services performed by the physical therapist assistants (PTAs) and occupational therapy assistants (OTAs) they are supervising, since the PTPP or OTPP must remain immediately available when providing direct supervision of PTAs and OTAs (even though we noted in the CY 2022 PFS final rule that PTPPs and OTPPs were intended to be among the primary billers of RTM services (86 FR 65116)). We designated the RTM codes as ''sometimes therapy'' codes (originally in the CY 2022 PFS final rule (86 FR 65116)), meaning that these services may be furnished outside a therapy plan of care when they are performed by physicians and certain NPPs where their State practice includes the provision of physical therapy, occupational therapy, and/or speech-language pathology services. Because we did not propose revisions to §§ 410.59 and 410.60 last year for OTPPs and PTPPs, we are proposing to establish an RTM-specific general supervision policy at §§ 410.59(a)(3)(ii) and (c)(2) and 410.60(a)(3)(ii) and (c)(2) to allow OTPPs and PTPPs to provide general supervision only for RTM services furnished by their OTAs and PTAs, respectively.

We also note that Medicare requires each therapist in private practice to meet the requirements specified in our current regulations at §§ 410.59(c) and 410.60(c) to qualify under Medicare as a supplier of outpatient occupational therapy or physical therapy services. Given that occupational therapists (OTs) and physical therapists (PTs) who are not enrolled and working as employees of OTPPs or PTPPs do not meet these requirements, we believe they should continue to function under direct supervision of the OTPP or PTPP. This is consistent with the Medicare Benefit Policy Manual, Pub. 100–02, Chapter 15, section 230.4.B which states that in a private practice, OTPPs and PTPPs must provide direct supervision of all services, including those furnished by OTs and PTs who are not yet enrolled in Medicare (even if they meet the other requirements for occupational therapists and physical therapists at 42 CFR part 484). As such, we are proposing to retain the OTPP and PTPP direct supervision requirement for unenrolled PTs or OTs by clarifying that the proposed RTM general supervision regulation at §§ 410.59(c)(2) and 410.60(c)(2) applies only to the OTA and PTA and does not include the unenrolled OT or PT. We are seeking comment on this specific proposal as we want to know more about how this policy is now functioning with OTs and PTs who are not enrolled and our proposal to maintain this longstanding policy for direct supervision.

We believe this proposal will increase access to these remotely provided services performed by PTAs and OTAs under the general supervision furnished by PTPPs and OTPPs. This aligns the regulatory text at §§ 410.59 and 410.60 with the RTM general supervision policy that we finalized in our CY 2023 rulemaking.

(b) General Supervision for PTs and OTs in Private Practice Comment Solicitation: Sections 1861(p) and 1861(g) (by cross-reference to section 1861(p)) of the Act describe outpatient physical therapy and occupational therapy services furnished to individuals by physical and occupational therapists meeting licensing and other standards prescribed by the Secretary, including conditions relating to the health and safety of individuals who are furnished services on an outpatient basis. The second sentence of section 1861(p) of the Act describes outpatient therapy services that are provided to an individual by a physical therapist or occupational therapist (in their office or in such individual's home) who meets licensing and other standards prescribed by the Secretary in regulations, and differentiates the therapists that furnish these outpatient therapy services from those working for an institutional provider of therapy services. In regulations, we have specifically addressed these therapists, previously referred to as PTPPs and OTPPs, since 1999 (63 FR 58868 through 58870). Because we wanted to create consistent requirements for therapists and therapy assistants, we clarified in the CY 2005 PFS final rule with comment period (69 FR 66345) that the personnel qualifications applicable to home health agencies (HHAs) in 42 CFR part 484 are applicable to all outpatient physical therapy, occupational therapy, and speech-language pathology services. Also, in the CY 2005 PFS final rule, we

cross-referenced the qualifications for OTs and their OTAs and PTs and their PTAs for all occupational therapy and physical therapy services, respectively, including those who work in private practices, to 42 CFR part 484 by adding a basic rule at §§ 410.59(a) and 410.60(a), respectively. Under Medicare Part B, outpatient therapy services are generally covered when reasonable and necessary and when provided by PTs and OTs meeting the qualifications set forth at 42 CFR part 484. Services provided by qualified therapy assistants, including PTAs and OTAs, may also be covered by Medicare when furnished under the specified level of therapist supervision that is required for the setting in which the services are provided (institutions, and private practice therapist offices and patient homes).

In accordance with various regulations, the minimum level of supervision for services performed by PTAs and OTAs by PTs and OTs working in institutional settings is a general level of supervision (see Table A in the Report to Congress titled Standards for Supervision of PTAs and the Effects of Eliminating the Personal PTA Supervision Requirement on the Financial Caps for Medicare Therapy Services found at *https://www.cms.gov/Medicare/Billing/TherapyServices/Downloads/61004ptartc.pdf*). For example, 42 CFR 485.713 specifies that when an OTA or PTA provides services at a location that is off the premises of a clinic, rehabilitation agency, or public health agency, those services are supervised by a qualified occupational or physical therapist who makes an onsite supervisory visit at least once every 30 days. We note that the Medicare Benefit Policy Manual, Pub. 100–02, chapter 8, section 30.2.1 defines skilled nursing and/or skilled rehabilitation services as those services, furnished pursuant to physician orders, that, among other requirements, ''must be provided directly by or under the general supervision of these skilled nursing or skilled rehabilitation personnel to assure the safety of the patient and to achieve the medically desired result.'' The same manual provision notes that in the SNF setting, skilled nursing or skilled rehabilitation personnel include PTs, OTs, and SLPs. However, since 2005 in the private practice setting, we have required direct supervision for physical and occupational therapy services furnished by PTAs and OTAs, requiring an OTPP or PTPP to be immediately available to furnish assistance and direction throughout the performance of the procedure(s). We finalized this direct supervision policy in the CY 2005 PFS final rule (69 FR 66354 through 66356)—changing it from personal supervision, which required the OTPP or PTPP to be in the same room as the therapy assistant when they were providing the therapy services. Under the current regulations §§ 410.59(c)(2) and 410.60(c)(2), all services not performed personally by the OTPP or PTPP, respectively, must be performed under the direct supervision of the therapist by employees of the practice. Subsequently, in the CY 2008 PFS final rule (72 FR 66328 through 66332), we updated the qualification standards at 42 CFR part 484 for OTs, OTAs, PTs, PTAs, along with those for speech-language pathologists (SLPs).

Over the last several years, interested parties have requested that we revise our direct supervision policy for PTPPs and OTPPs to align with the general supervision policy for physical and occupational therapists working in Medicare institutional providers that provide therapy services (for example, outpatient hospitals, rehabilitation agencies, SNFs and CORFs), to allow for the general supervision of their therapy assistants. Additionally, the interested parties have informed us that all-but-one State allows for general supervision of OTAs and at least 44 States allow for the general supervision of PTAs, via their respective State laws and policies.

We are considering whether to revise the current direct supervision policy for PTPPs and OTPPs of their PTAs and OTAs, to general supervision for all physical therapy and occupational therapy services furnished in these private practices at this time, and are soliciting comments from the public that we may consider for possible future rulemaking. We are particularly interested in receiving comments regarding the possibility of changing the PTA and OTA supervision policy from direct supervision to general supervision in the private practice setting, and whether a general supervision policy could have implications for situations or conditions raised below:

- Because we want to ensure quality of care for therapy patients, could the general supervision policy raise safety concerns for therapy patients if the PT or OT is not immediately available to assist if needed? Do State laws and policies allow a PTA or OTA to practice without a therapist in a therapy office or in a patient's home?
- Could any safety concerns be addressed by limiting the types of services permitted under a general supervision policy?
- Would a general supervision policy be enhanced with a periodic visit by the PT or OT to provide services to the patient? If so, what number of visits or time period should we consider?
- Would a general supervision policy potentially cause a change in utilization? Would such a change in the supervision policy cause a difference in hiring actions by the PT or OT with respect to therapy assistants?

Interested parties have been requesting that CMS reconsider its supervision policies with respect to occupational therapy or physical therapy services, and in light of experiences during the PHE for COVID–19, we may consider proposing a general supervision policy for all services furnished by OTAs and PTAs employed by a PTPP or OTPP in the future after reviewing the comments and supporting data in response to this comment solicitation. We are, therefore, soliciting public comment, along with supporting data, about the questions and concerns we highlighted above, for our consideration for possible future rulemaking. We are further interested in public comment regarding changing §§ 410.59(a)(3)(ii), 410.59(c)(2), 410.60(a)(3)(ii), and 410.60(c)(2) to allow for general supervision of OTAs and PTAs by the OTPP and PTPP, respectively, when furnishing therapy services. Additionally, we are seeking public comment for our consideration for possible future rulemaking regarding any appropriate exceptions to allowing general supervision in the furnishing of therapy services.

2. KX Modifier Thresholds

Formerly referred to as the therapy cap amounts, the KX modifier thresholds were established through section 50202 of the Bipartisan Budget Act (BBA) of 2018 (Pub. L. 115–123, February 9, 2018). These per-beneficiary amounts under section 1833(g) of the Act (as amended by section 4541 of the Balanced Budget Act of 1997) (Pub. L. 105–33, August 5, 1997) are updated each year based on the percentage increase in the Medicare Economic Index (MEI). In the CY 2023 PFS final rule (87 FR 69688 through 69710), we rebased and revised the MEI to a 2017 base year. Specifically, these amounts are calculated by updating the previous year's amount by the percentage increase in the MEI for the upcoming calendar year and rounding to the nearest $10.00. Thus, for CY 2024, we propose to increase the CY 2023 KX modifier threshold amount by the most recent forecast of the 2017-based MEI. For CY 2024, the proposed growth rate of the 2017-based MEI is estimated to be

4.5 percent, based on the IHS Global, Inc. (IGI) first quarter 2023 forecast with historical data through the fourth quarter of 2022.[31] Multiplying the CY 2023 KX modifier threshold amount of $2,230 by the proposed CY 2024 percentage increase in the MEI of 4.5 percent ($2,230 × 1.045), and rounding to the nearest $10.00, results in a proposed CY 2024 KX modifier threshold amount of $2,330 for physical therapy and speech-language pathology services combined and $2,330 for occupational therapy services. We are also proposing that if more recent data are subsequently available (for example, a more recent estimate of the CY 2024 2017-based MEI percentage increase) later this year, we would use such data, if appropriate, to determine the CY 2024 MEI percentage increase and would apply that new estimate to formulate our values in the CY 2024 PFS final rule.

Section 1833(g)(7)(B) of the Act describes the targeted medical review (MR) process for services of physical therapy, speech-language pathology, and occupational therapy services. The threshold for targeted MR is $3,000 until CY 2028, when it will be updated by the percentage increase in the MEI. Consequently, for CY 2024, the MR threshold is $3,000 for physical therapy and speech-language pathology services combined and $3,000 for occupational therapy services. Section 1833(g)(5)(E) of the Act states that CMS shall identify and conduct targeted medical review using factors that may include the following:

(1) The therapy provider has had a high claims denial percentage for therapy services under this part or is less compliant with applicable requirements under this title.

(2) The therapy provider has a pattern of billing for therapy services under this part that is aberrant compared to peers or otherwise has questionable billing practices for such services, such as billing medically unlikely units of services in a day.

(3) The therapy provider is newly enrolled under this title or has not previously furnished therapy services under this part.

(4) The services are furnished to treat a type of medical condition.

(5) The therapy provider is part of a group that includes another therapy provider identified using the factors described previously in this section.

We track each beneficiary's incurred expenses for therapy services annually and count them towards the KX modifier and MR thresholds by applying the PFS rate for each service less any applicable MPPR amount for services of CMS-designated ''always therapy'' services (see the CY 2011 PFS final rule at 75 FR 73236). We also track therapy services furnished by critical access hospitals (CAHs), applying the same PFS-rate accrual process, even though they are not paid for their therapy services under the PFS and may be paid on a cost basis (effective January 1, 2014) (see the CY 2014 PFS final rule at 78 FR 74406 through 74410).

When the beneficiary's incurred expenses for the year for outpatient therapy services exceeds one or both of the KX modifier thresholds, therapy suppliers and providers use the KX modifier on claims for subsequent medically necessary services. Through the use of the KX modifier, the therapist and therapy provider attest that the services above the KX modifier thresholds are reasonable and necessary and that documentation of the medical necessity for the services is in the beneficiary's medical record. Claims for outpatient therapy services exceeding the KX modifier thresholds without the KX modifier included are denied. (See the CY 2023 PFS final rule at 87 FR 69650 through 69651.)

3. Diabetes Self-Management Training (DSMT) Services Furnished by Registered Dietitians (RDs) and Nutrition Professionals

During the CY 2022 PFS rulemaking, we adopted a regulation at § 410.72(d) that requires the services that RDs and nutrition professionals furnish to beneficiaries to be directly performed by them. This is based on the MNT regulations at subpart G, §§ 410.130–410.134. When developing this policy, we were only referring to MNT services. These MNT services are distinct from the DSMT services that RDs or nutrition professionals may furnish when they are or represent an accredited DSMT entity.

We note that the RD or nutrition professional, when named in or a sponsor of an accredited DSMT entity, may act as the DSMT certified provider, which is defined at section 1861(qq) of the Act as a physician, or other individual or entity to which Medicare makes payment for other services. RDs and nutrition professionals may qualify as DSMT certified providers within the meaning of the statute since they provide and bill for MNT services. This is reinforced in our sub-regulatory manual provisions (Pub. 100–02, Chapter 15, section 300.2), which specifies that DSMT certified providers may bill and be paid for the entire DSMT program and further clarifies that the RD or nutrition professional is eligible to bill on behalf of an entire DSMT program (or entity) on or after January 1, 2002, after obtaining a Medicare provider number. In addition, section 1861(qq) of the Act requires that DSMT certified providers meet quality standards established by the Secretary, except that the physician or other individual or entity shall be deemed to have met such standards if the physician or other individual or entity meets applicable standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who participated in the establishment of standards by such Board. DSMT entities are required to meet the National Standards for Diabetes Self-management Education Programs (NSDSMEP) set of quality standards at § 410.144(b). DSMT entities are also required to be recognized or accredited by CMS Accreditation Organizations (AOs). There are currently two national DSMT AOs—the American Diabetes Association (ADA) or the Association of Diabetes Care & Education Specialists (ADCES) (Medicare Program Integrity Manual, Pub. 100–08, chapter 10, section 10.2.4.B). The ADA and ADCES also review and approve the credentials of DSMT program instructors.

Interested parties have alerted us that the wording of § 410.72(d) has caused confusion for DSMT entities/suppliers and Part B Medicare Administrative Contractors (MACs) about whether RD or nutrition professionals must personally provide DSMT services. To alleviate any confusion, we believe a clarification is needed to distinguish between when a RD or nutritional professional is personally providing MNT services, in accordance with the MNT regulations, and when they are acting as or on behalf of an accredited DSMT entity and billing for DSMT services that may be provided by a group of other professionals working under an accredited DSMT entity, for example registered nurses (RNs), pharmacists, or RDs other than the sponsoring RD. Under the NSDSMEP quality standards, the RD, RN, or pharmacist is permitted to provide the educational DSMT services on a solo basis, that is without a multi-disciplinary team; however, only the RD or nutrition professional, when enrolled as a Medicare supplier, in these accredited DSMT entities is authorized by statute at section 1861(qq)(2)(A) to bill Medicare on behalf of the entire DSMT entity as the DSMT certified provider.

[31] IGI is a nationally recognized economic and financial forecasting firm with which we contract to forecast the components of the MEI and other CMS market baskets.

Consequently, we propose to amend the regulation at § 410.72(d) to clarify that a RD or nutrition professional must personally perform MNT services. Additionally, we propose to clarify that a RD or nutrition professional may bill for, or on behalf of, the entire DSMT entity as the DSMT certified provider regardless of which professional furnishes the actual education services. We propose to clarify § 410.72(d) to provide that, except for DSMT services furnished as, or on behalf of, an accredited DSMT entity, registered dietitians and nutrition professionals can be paid for their professional MNT services only when the services have been directly performed by them.

4. DSMT Telehealth Issues

(a) Distant Site Practitioners

Since 2006, RDs and nutrition professionals have been recognized as distant site practitioners for purposes of Medicare telehealth services under section 1834(m)(4)(E) of the Act. Section 1834(m)(4)(E) of the Act specifies that the practitioners listed at section 1842(b)(18)(C) of the Act, which include RDs and nutrition professionals as of 2006, can serve as distant site practitioners for Medicare telehealth services. Our regulations and sub-regulatory policies for Medicare telehealth services do not address scenarios involving the furnishing of DSMT services via telehealth when the actual services are personally furnished by individuals who provide them, for example, RNs, pharmacists, or other multidisciplinary team members, who are not recognized as telehealth distant site practitioners under the statutory definition. In keeping with the NSDSMEP quality standards, an RD is often part of a DSMT entity, and when they are, they can be considered a ''certified provider'' when they are enrolled in Medicare and intend to bill for the DSMT services, in accordance with the statutory provision at section 1861(qq)(2)(A) of the Act, which defines certified providers as physicians, or other individuals or entities designated by the Secretary, that, in addition to providing DSMT services, provides other items or services for which Medicare payment may be made. As we noted previously in this section of the proposed rule, there may be other RDs among the group or team of professionals, along with RNs and/or pharmacists, that are performing DSMT services in addition to the sponsoring or billing RD or nutrition professional functioning as the certified provider. Additionally, our Medicare Benefit Policy Manual, Pub. 100–02, Chapter 15, section 300.2 clarifies that these certified providers, including RDs or nutrition professionals, may bill for services of the DSMT entity. Since we allow RDs and other DSMT certified providers to bill on behalf of the DSMT entity when other professionals personally furnish the service in face-to-face encounters, we believe that this should also be our policy when DSMT is furnished as a Medicare telehealth service. To increase access to DSMT telehealth services, we are proposing to codify billing rules for DSMT services furnished as Medicare telehealth services at § 410.78(b)(2)(x) to allow distant site practitioners who can appropriately report DSMT services furnished in person by the DSMT entity, such as RDs and nutrition professionals, physicians, nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs), to also report DSMT services furnished via telehealth by the DSMT entity, including when the services are performed by others as part of the DSMT entity. This proposed revision to our regulation will preserve access to DSMT services via telehealth for Medicare beneficiaries in cases where the DSMT service is provided in accordance with the NSDSMEP quality standards. We note that DSMT services are on the Medicare Telehealth Services List, and are subject to the requirements and conditions of payment under section 1834(m) of the Act and § 410.78 of our regulations, including originating site and geographic location requirements, when they are in effect. See section II.D. for a discussion of Medicare telehealth policies.

(b) Telehealth Injection Training for Insulin-Dependent Beneficiaries

Currently, our manual instruction for Payment for Diabetes Self-Management Training (DSMT) in the Medicare Claims Processing Manual, Pub. 100–04, chapter 12, section 190.3.6, requires 1 hour of the 10-hour DSMT benefit's initial training and 1 hour of the 2-hour follow-up annual training to be furnished in-person to allow for effective injection training when injection training is applicable for insulin-dependent beneficiaries. This policy was clarified for 2019 to specify that in-person training only applies to a beneficiary for whom the injection training was applicable via CMS Transmittal 4173, available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4173CP.pdf*.

We believe that, with the expansion of the use of telehealth during the PHE for COVID–19, there have been significant changes in clinical standards, guidelines, and best practices regarding services furnished using interactive telecommunications technology, including for injection training for insulin-dependent patients. We do not want our policies to prevent injection training via telehealth when clinically appropriate. Consequently, we are proposing to revise our policy at 410.78(e) to allow the 1 hour of in-person training (for initial and/or follow-up training), when required for insulin-dependent beneficiaries, to be provided via telehealth. If finalized, we anticipate revising the Medicare Claims Processing Manual, Pub. 100–04, chapter 12, section 190.3.6 to reflect that flexibility.

J. Advancing Access to Behavioral Health Services

1. Implementation of Section 4121(a) of the Consolidated Appropriations Act, 2023

a. Statutory Amendments

Section 4121(a) of Division FF, Title IV, Subtitle C of the Consolidated Appropriations Act of 2023 (CAA, 2023) (Pub. L. 117–328, December 29, 2022), Coverage of Marriage and Family Therapist Services and Mental Health Counselor Services under Part B of the Medicare Program, provides for Medicare coverage of and payment for the services of health care professionals who meet the qualifications for marriage and family therapists (MFTs) and mental health counselors (MHCs) when billed by these professionals.

Specifically, section 4121(a)(1) of the CAA, 2023 amended section 1861(s)(2) of the Act by adding a new benefit category under Medicare Part B in new subparagraph (II) to include marriage and family therapist services (as defined in an added section 1861(lll)(1) of the Act) and mental health counselor services (as defined in an added section 1861(lll)(3) of the Act).

Section 4121(a)(2) of the CAA, 2023 added a new subsection (lll) to section 1861 of the Act, which defines marriage and family therapist services, marriage and family therapist (MFT), mental health counselor services, and mental health counselor (MHC). Section 1861(lll)(1) of the Act defines ''marriage and family therapist services'' as services furnished by an MFT for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the MFT is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished, as would otherwise be covered if furnished by a physician or

as an incident to a physician's professional service. Section 1861(lll)(2) of the Act defines the term MFT to mean an individual who:

- Possesses a master's or doctor's degree which qualifies for licensure or certification as a MFT pursuant to State law of the State in which such individual furnishes marriage and family therapist services;
- Is licensed or certified as a MFT by the State in which such individual furnishes such services;
- After obtaining such degree has performed at least 2 years of clinical supervised experience in marriage and family therapy; and
- Meets such other requirements as specified by the Secretary.

Section 1861(lll)(3) of the Act defines ''mental health counselor services'' as services furnished by a mental health counselor (MHC) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the MHC is legally authorized to perform under State law (or the State regulatory mechanism provided by the State law) of the State in which such services are furnished, as would otherwise be covered if furnished by a physician or as incident to a physician's professional service. Section 1861(lll)(4) of the Act defining MHC as an individual who:

- Possesses a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor, clinical professional counselor, or professional counselor under State law of the State in which such individual furnishes MHC services;
- Is licensed or certified as a mental health counselor, clinical professional counselor, or professional counselor by the State in which the services are furnished;
- After obtaining such degree has performed at least 2 years of clinical supervised experience in mental health counseling; and
- Meets such other requirements as specified by the Secretary.

Section 4121(a)(3) of the CAA, 2023 amended section 1833(a)(1) of the Act to add a new subparagraph (FF), which provides that, with respect to MFT services and MHC services under section 1861(s)(2)(II) of the Act, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for payment of a psychologist under subparagraph (L).

Section 1888(e)(2)(A)(ii) of the Act, as amended by section 4121(a)(4) of the CAA, 2023, excludes MFT and MHC services from consolidated billing requirements under the skilled nursing facility (SNF) prospective payment system. For further discussion about this exclusion of MFT and MHC services from SNF consolidated billing, see discussion in the FY 2024 SNF Prospective Payment System (PPS) proposed rule (88 FR 21316).[32] Section 4121(a)(5) of the CAA, 2023 amended section 1842(b)(18)(C) of the Act to add MFTs and MHCs to the list of practitioners whose services can only be paid by Medicare on an assignment-related basis. MFTs, MHCs, and other practitioners described in section 1842(b)(18)(C) of the Act may not bill (or collect any amount from) the beneficiary or another person for any services for which Medicare makes payment, except for deductible and coinsurance amounts applicable under Part B. More information on assignment of claims can be found at in the Medicare Claims Processing Manual, Pub. 100–04, Chapter 1, Section 30.3.1.

We also note that section 1861(aa)(1)(B) of the Act was amended by section 4121(b)(1) of the CAA, 2023 to add services furnished by MFTs and MHCs to the definition of rural health clinic services. See section III.B of this proposed rule for discussion related to MFT and MHC services furnished in RHCs and FQHCs.

Additionally, section 1861(dd)(2)(B)(i)(III) of the Act was amended by 4121(b)(2) of the CAA, 2023 to require a hospice program to have an interdisciplinary team that includes at least one social worker, MFT or MHC. For further discussion about this amended requirement for hospice program interdisciplinary teams, see section III.O of this proposed rule.

b. Proposed Changes to Regulations

Consistent with the changes to the statute described above, we are proposing to create two new regulation sections at § 410.53 and § 410.54 to codify the coverage provisions for MFTs and MHCs, respectively.

Specifically, we are proposing to define a marriage and family therapist at § 410.53 as an individual who:

- Possesses a master's or doctor's degree which qualifies for licensure or certification as a marriage and family therapist pursuant to State law of the State in which such individual furnishes the services defined as marriage and family therapist services;
- After obtaining such degree, has performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience in marriage and family therapy in an appropriate setting such as a hospital, SNF, private practice, or clinic; and
- Is licensed or certified as a marriage and family therapist by the State in which the services are performed.

We note that we are aware that there may be some States that require a number of hours of clinical supervised experience for MFT licensure that may be inconsistent with the statutory requirement in section 1861(s)(2) of the Act that requires at least 2 years of clinical supervised experience. We believe it could be possible for an MFT to have completed the required number of clinical supervised hours required for licensure in their State, but to have accomplished this in less than two years. Therefore, we are proposing a requirement for MFTs to have performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience, if consistent with State licensure requirements. We believe that 3,000 hours is roughly equivalent to the statutory requirement to have performed 2 years of clinical supervised experience and note that the regulatory requirements for clinical social workers (CSWs) at § 410.73(a)(3)(ii) allow 2 years or 3,000 hours of supervised experience. Additionally, the statutory benefit category for both MFTs and CSWs is defined as services for the diagnosis and treatment of mental illnesses. As such, we believe it would be appropriate to provide similar flexibility in the required amount of clinical supervised experience for MFTs and CSWs. We are also interested in public comments regarding States that have a supervised clinical hour requirement for MFT licensure that is less than 2 years.

We are proposing to define ''Marriage and family therapist services'' at § 410.53(b)(1) as services furnished by a marriage and family therapist for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the marriage and family therapist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished. We are also proposing at § 410.53(b)(1) that the services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service and must meet the requirements of this section.

Lastly, we are proposing at § 410.53(b)(2) that the following services do not fall under the Medicare Part B benefit category for MFT services:

[32] *https://www.govinfo.gov/content/pkg/FR-2023-04-10/pdf/2023-07137.pdf.*

• Services furnished by a marriage and family therapist to an inpatient of a Medicare-participating hospital.

Similarly, we are proposing to define a mental health counselor at § 410.54 as an individual who:

• Possesses a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor, clinical professional counselor, or professional counselor under the State law of the State in which such individual furnishes the services defined as mental health counselor services;

• After obtaining such a degree, has performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic; and

• Is licensed or certified as a mental health counselor, clinical professional counselor, or professional counselor by the State in which the services are performed. As previously explained for MFTs, and for the same reasons, we are proposing a requirement for MHCs to have performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience, if consistent with State licensure requirements. We believe that 3,000 hours is roughly equivalent to the statutory requirement to have performed 2 years of clinical supervised experience and note that the regulatory requirements for clinical social workers at § 410.73(a)(3)(ii) allows 2 years or 3,000 hours. The MHC statutory benefit category authorizes MHCs to furnish services for the diagnosis and treatment of mental illnesses as it does for CSWs. We are also interested in public comments regarding States that have a supervised clinical hour requirement for MHC licensure that is less than 2 years.

We are proposing to define ''mental health counselor services'' at § 410.54(b)(1) as services furnished by a mental health counselor (as defined in paragraph (a) of this section) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the mental health counselor is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished. We are also proposing at § 410.54(b)(1) that the services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service.

We are proposing at § 410.54(b)(2) that the following services do not fall under the Medicare Part B benefit category for MHC services:

• Services furnished by a mental health counselor to an inpatient of a Medicare-participating hospital.

We are proposing to amend § 410.10 to add marriage and family therapist services and mental health counselor services to the list of included medical and other health services. We are also proposing to amend § 410.150 to add marriage and family therapists and mental health counselors, to the list of individuals or entities to whom payment is made.

Currently, § 410.32(a)(2) lists the health care practitioners that may order diagnostic tests. Since this list currently includes CSWs and clinical psychologists (CPs), who are also authorized by statute to furnish services for the diagnosis and treatment of mental illnesses, we are proposing to amend § 410.32(a)(2) to add MFTs and MHCs to the list of practitioners who may order diagnostic tests, as for the other non-physician practitioners, to the extent that the MFT or MHC is legally authorized to perform the service under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished.

We are also proposing to codify in a new § 414.53 the payment amounts authorized under section 1833(a)(1)(FF) for MFT and MHC services. Additionally, we are proposing to codify at § 414.53 the payment amount for clinical social worker (CSW) services as authorized under section 1833(a)(1)(F) of the Act. As we reviewed our regulations to implement section 4121 of the CAA, 2023, we found that the payment amounts for CSWs are not yet codified under regulations. Specifically, we are proposing to add that the payment amount for CSW, MFT, and MHC services is 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for clinical psychologist services under the PFS.

We are also proposing to add MFTs and MHCs to the list of practitioners who are eligible to furnish Medicare telehealth services at the distant site. See section II.D. of this proposed rule for a discussion of this proposal.

Additionally, we are proposing to allow Addiction Counselors who meet all of the applicable requirements (possess a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor; after obtaining such degree have performed at least 2 years (or, as proposed, 3,000 hours) of clinical supervised experience in mental health counseling; and licensed or certified as a MHC, clinical professional counselor, or professional counselor by the State in which the services are furnished) to enroll in Medicare as MHCs. That is, under this proposal, Addiction Counselors would be considered Mental Health Counselors and would be eligible to enroll and bill Medicare for MHC services if they meet these requirements. We understand there is variation in the terminology used for licensure across States for MHCs and MFTs and are seeking information pertaining to other types of professionals who may meet the applicable requirements for enrollment as mental health counselors. We note that in past rulemaking, we have discussed the term 'mental health' to be inclusive of diagnosis and treatment of substance use disorders. For example, in the CY 2022 PFS final rule (86 FR 65061), we stated that SUD services are considered mental health services for the purposes of the expanded definition of ''interactive telecommunications system.'' We propose to apply that same interpretation for purposes of the mental health services included in the definition of MFT, MHC, and to clarify that the same interpretation applies for CSW, and CP services.

c. Coding Updates To Allow MFT and MHC Billing

In light of the new statutory benefits for MFTs and MHCs authorized by section 4121(a) of the CAA, 2023, we have considered whether updates to certain HCPCS codes are required in order to allow MFTs and MHCs to bill for the services described by those HCPCS codes. In the CY 2023 PFS final rule, we finalized new coding and payment for General Behavioral Health Integration services performed by CPs or CSWs to account for monthly care integration where the mental health services furnished by a CP or CSW serve as the focal point of care integration. In light of the new coverage under Medicare for MFT and MHC services for the diagnosis and treatment of mental illness, we are proposing to revise the code descriptor for HCPCS code G0323 in order to allow MFTs and MHCs, as well as CPs and CSWs, to be able to bill for this monthly care integration service. We note that MFTs and MHCs, like CSWs, are authorized by statute for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the MFT or MHC is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished, as would otherwise be covered if furnished by a physician or

as an incident to a physician's professional service. The proposed code descriptor for HCPCS code G0323 is: *Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist, clinical social worker, mental health counselor, or marriage and family therapist time, per calendar month. (These services include the following required elements: Initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, coordination with and/or referral to physicians and practitioners who are authorized by Medicare to prescribe medications and furnish E/M services, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.)*

Lastly, we note that consistent with the proposed changes to valuation of CPT code 99484 in the Valuation of Specific Codes section (section II.E. of this proposed rule), which describes General BHI and is the crosswalk code used for valuation of HCPCS code G0323, we are also proposing conforming updates to the valuation for work and PE inputs for HCPCS code G0323. See section II.E. of this proposed rule for further discussion of changes to the valuation for HCPCS code G0323.

We welcome comments regarding any other HCPCS codes that may require updating to allow MFTs and MHCs to bill for the services described in the HCPCS code descriptor.

d. Medicare Enrollment of MFTs and MHCs

MFTs and MHCs who meet the applicable requirements (possess a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor; after obtaining such degree have performed at least 2 years (or, as proposed, 3,000 hours) of clinical supervised experience in mental health counseling; and is licensed or certified as a MHC, clinical professional counselor, or professional counselor by the State in which the services are furnished) described in detail above in this section, as finalized, will need to enroll in Medicare as MFTs and MHCs in order to submit claims for marriage and family therapist services and mental health counselor services, respectively, furnished to Medicare beneficiaries. Under § 424.510, a provider or supplier must complete, sign, and submit to its assigned MAC the appropriate Form CMS–855 (OMB Control No. 0938–0685) application in order 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; 104 Provider Enrollment, Chain, and Ownership System), captures information about the provider or supplier that is needed for CMS or its MACs to determine whether the provider or supplier meets all Medicare requirements. We propose that the MFT and MHC supplier types, like most non-physician practitioner types, be subject to limited-risk screening under § 424.518, for we have no basis on which to assign these suppliers as a class to a higher screening category.

MFTs and MHCs that meet the proposed requirements in §§ 410.53 and 410.54 as finalized, would enroll in Medicare via the Form CMS–855I application (Medicare Enrollment Application—Physicians and Non-Physician Practitioners; OMB No. 0938–1355) and could begin submitting their enrollment applications after the publication of the CY 2024 PFS final rule. However, as the new benefit categories authorized by section 4121(a) of the CAA, 2023, do not take effect until January 1, 2024, MFT or MHC claims for MFT or MHC services furnished to Medicare beneficiaries with dates of service prior to January 1, 2024 will not be payable under Medicare Part B. MFTs and MHCs can visit *https://www.cms.gov/medicare/provider-enrollment-and-certification* for basic information on the provider enrollment process.

2. Implementation of Section 4123 of the CAA, 2023

Section 4123(a)(1) of the CAA, 2023, Improving Mobile Crisis Care in Medicare, amended section 1848 of the Act by adding a new paragraph (b)(12) regarding payment for psychotherapy for crisis services furnished in an applicable site of service. New subparagraph (A) of section 1848(b)(12) of the Act requires the Secretary to establish new HCPCS codes under the PFS for services described in subparagraph (B) that are furnished on or after January 1, 2024. Subparagraph (B) of section 1848(b)(12) of the Act describes these services as psychotherapy for crisis services that are furnished in an applicable site of service. Section 1848(b)(12)(C) of the Act specifies that the payment amount for these psychotherapy for crisis services shall be equal to 150 percent of the fee schedule amount for non-facility sites of service for each year for the services identified (as of January 1, 2022) by HCPCS codes 90839 (*Psychotherapy for crisis; first 60 minutes*) and 90840 (*Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary service)*), and any succeeding codes.

For purposes of this provision, subparagraph (D)(i) of new section 1848(b)(12) of the Act defines an applicable site of service as a site of service other than a site where the facility rate under the PFS applies and other than an office setting, while subparagraph (D)(ii) requires that the code descriptors for these new psychotherapy for crisis services be the same as the services identified (as of January 1, 2022) by HCPCS codes 90838 and 90840, and any succeeding codes, except that the new codes shall be limited to services furnished in an applicable site of service.

Therefore, consistent with the requirements described in new paragraph (12) of section 1848(b) of the Act, we are proposing to create two new G-codes describing psychotherapy for crisis services furnished in any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting: HCPCS codes GPFC1 and GPFC2.

To identify the places of service that are assigned the non-facility rate, § 414.22(b)(5)(i) states that there are usually two levels of PE RVUs that correspond to each code paid under the PFS: facility PE RVUs and non-facility PE RVUs. Under § 414.22(b)(5)(i)(A), the facility PE RVUs apply to services furnished in a hospital, skilled nursing facility, community mental health center, hospice, ambulatory surgical center, or wholly owned or wholly operated entity providing preadmission services under § 412.2(c)(5), or for services furnished via telehealth under § 410.78 (though we note that special rules relating to the PHE for COVID–19 currently apply, and we include proposals regarding the place of service for telehealth services in section II.D). Under § 414.22(b)(5)(i)(B), the non-facility rate is paid in all other settings, including a physician's office, the patient's home, a nursing facility, or a comprehensive outpatient rehabilitation facility. We provide the full list of places of service that are assigned a non-facility rate on the CMS website at *https://www.cms.gov/Medicare/Coding/place-of-service-codes.* We propose that the two new G-codes describing psychotherapy for crisis services can be

billed when the services are furnished in any non-facility place of service other than the physician's office setting. We also note that in the CY 2022 PFS final rule (86 FR 65059), in our discussion of Medicare telehealth services where the patient's home is a permissible originating site for services furnished for diagnosis, evaluation, or treatment of a mental health disorder, we indicated that we define the term ''home'' broadly to include temporary lodging, such as hotels and homeless shelters (86 FR 65059). We clarified that, for circumstances where the patient, for privacy or other personal reasons, chooses to travel a short distance from the exact home location during a telehealth service, that would qualify as the patient's home. For purposes of implementing section 1848(b)(12) of the Act, we are proposing to use the same broad definition of the patient's home for purposes of these proposed G-codes describing psychotherapy for crisis services.

The proposed new G-codes and their descriptors are:

- GPFC1 (*Psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting); first 60 minutes*); and
- GPFC2 (*Psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting); each additional 30 minutes (List separately in addition to code for primary service)*).

As required by section 1848(b)(12)(C) of the Act, we are proposing to establish a fee schedule amount for these two new G-codes that is 150 percent of the current PFS non-facility RVUs for CPT codes 90839 (*Psychotherapy for crisis; first 60 minutes*) and 90840 (*Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary service)*), respectively. Specifically, we are proposing to calculate the work, PE, and MP RVUs for HCPCS codes GPFC1 and GPFC2 by multiplying the work, PE, and MP RVUs for CPT codes 90839 and 90840, respectively, by 1.5.

We note that section 4123(a)(2) of the CAA, 2023 amends section 1848(c)(2)(B)(iv) of the Act to include a waiver of budget neutrality providing that subsection (b)(12) shall not be taken into account in applying PFS budget neutrality requirements under section 1848(c)(2)(B)(ii)(II) of the Act for 2024. Accordingly, we are proposing to exclude expected expenditures for HCPCS codes GPFC1 and GPFC2 from the budget neutrality calculation for CY 2024 PFS ratesetting.

Additionally, section 4123(d) of the CAA, 2023 requires that the Secretary use existing communication mechanisms to provide education and outreach to providers of services, physicians, and practitioners with respect to the ability of auxiliary personnel, including peer support specialists, to participate, consistent with applicable requirements for auxiliary personnel, in the furnishing of psychotherapy for crisis services billed under the PFS under section 1848 of the Act, behavioral health integration services, as well as other services that can be furnished to a Medicare beneficiary experiencing a mental or behavioral crisis. We understand that there are varying definitions of the term ''peer support specialist.'' The Substance Abuse and Mental Health Services Administration (SAMHSA) defines a ''peer support specialist'' as a person who uses their lived experience of recovery from mental illness and/or addiction, plus skills learned in formal training, to deliver services to promote recovery and resiliency. The essential principles of peer support include shared personal experience and empathy, a focus on individual strengths, and supporting individuals as they work toward recovery pursuant to a person-centered plan of care. However, for Medicare payment purposes, we note that the term auxiliary personnel is defined at § 410.26(a)(1) 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), has not been excluded from the Medicare, Medicaid, and all other Federally funded health care programs by the Office of Inspector General or had his or her Medicare enrollment revoked, and meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished. We do not include definitions of any specific types of personnel who could be included under the definition of auxiliary personnel in our regulations and are not proposing to do so through this rule. CMS anticipates conducting this outreach and education through existing communications mechanisms as required by the CAA, 2023.

3. Implementation of Section 4124 of the Consolidated Appropriations Act, 2023 (CAA, 2023)

Section 4124 of the CAA, 2023, Ensuring Adequate Coverage of Outpatient Mental Health Services under the Medicare Program, establishes Medicare coverage and payment for intensive outpatient services for individuals with mental health needs when furnished by hospital outpatient departments, community mental health centers, RHCs, and FQHCs, effective January 1, 2024. Please see the discussion of our proposed implementation of section 4124 in the CY 2024 Outpatient Prospective Payment System (OPPS) proposed rule, section VIII. Payment for Partial Hospitalization and Intensive Outpatient Services.

4. Health Behavior Assessment and Intervention (HBAI) Services

The current Health and Behavior Assessment and Intervention codes (CPT codes 96156, 96158, 96159, 96164, 96165, 96167, 96168, 96170, and 96171) were created by the CPT Editorial Panel during its September 2018 meeting. The CPT Editorial Panel deleted the six previous HBAI CPT codes and replaced them with nine new CPT codes. As discussed in the CY 2023 PFS final rule (87 FR 69541), the HBAI range of CPT codes are intended to be used for psychological assessment and treatment, when the primary diagnosis is a medical condition. A health behavior assessment under these HBAI services is conducted through health-focused clinical interviews, behavioral observation and clinical decision-making and includes evaluation of the person's responses to disease, illness or injury, outlook, coping strategies, motivation, and adherence to medical treatment. HBAI services are provided individually, to a group (two or more patients), and/or to the family, with or without the patient present, and include promotion of functional improvement, minimization of psychological and/or psychosocial barriers to recovery, and management of and improved coping with medical conditions. The HBAI codes apply to services that address psychological, behavioral, emotional, cognitive, and interpersonal factors in the treatment/management of people diagnosed with physical health issues. According to the CPT prefatory language in the CPT 2023 Professional Edition, the patient's primary diagnosis is physical in nature and the focus of the assessment and intervention is on factors complicating medical conditions and treatments. The HBAI codes capture services related to

physical health, such as adherence to medical treatment, symptom management, health-promoting behaviors, health related risky behaviors, and adjustment to physical illness.

In light of the new benefit categories authorized by section 4121(a)(2) of the CAA, 2023, which authorize MFTs and MHCs to furnish services for the diagnosis and treatment of mental illness, this prompted us to consider whether MFTs and MHCs could furnish and bill for HBAI services. Additionally, we re-examined whether CSWs could furnish and bill these HBAI codes given that their statutory benefit category also authorizes them to furnish services for the diagnosis and treatment of mental illnesses. We note that prior to the passage of the CAA, 2023, which authorized benefit categories for MFTs and MHCs, there was previously a National Coverage Determination (NCD) that stated, the CPT codes 96156, 96158, 96159, 96164, 96165, 96167 and 96168 may be used only by a Clinical Psychologist (CP), (Specialty Code 68). However, we note that this NCD was retired on December 8, 2022.[33]

Like CPs, who can currently bill Medicare for HBAI services, CSWs, MFTs, and MHCs have the education and training to address psychosocial barriers to meet the needs of patients with physical health conditions. In accordance with State law and scope of practice, CSWs, MFTs, and MHCs can assess, diagnose, and treat psychological and/or psychosocial behaviors associated with physical health conditions. Interested parties have informed us that like CSWs, MHCs and MFTs can play a key role in a multidisciplinary team approach that leads to successful outcomes in patient care, including offering integrated care within hospitals and medical practices where patients are diagnosed with physical health conditions. For example, mental health professionals such as MHCs and MFTs facilitate ''behavioral management and reinforcement, guided problem-solving, supporting patients in setting realistic and attainable goals, and teaching relaxation strategies for managing diabetes-related stressors.'' [34] In this role, mental health professionals such as CSWS, MHCs, and MFTs help patients manage mental health symptoms associated with a physical health condition. Moreover, according to the National Cancer Institute at the National Institutes of Health, mental health professionals can also provide emotional and social support to assist cancer patients in reducing ''levels of depression, anxiety, and disease and treatment-related symptoms among patients.'' [35] Therefore, we are proposing to allow the HBAI services described by CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168, and any successor codes, to be billed by CSWs, MFTs, and MHCs, in addition to CPs. We note that in order for payment to be made under Medicare for HBAI services furnished to a beneficiary, the HBAI services must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, in accordance with section 1862(a)(1)(A) of the Act.

5. Adjustments to Payment for Timed Behavioral Health Services

There is an ongoing behavioral health crisis in the United States, which has been exacerbated by the COVID–19 pandemic, the overdose crisis,[36] and worsening behavioral healthcare workforce shortages.[37] Public comments received in response to the CY 2023 PFS proposed rule described practices that furnish treatment for behavioral health conditions experiencing difficulty recruiting and retaining behavioral health clinicians and expressed concern that people are experiencing unprecedented delays in receiving medically necessary services across care settings. Commenters described workforce shortages nationwide that, combined with increasing demand for behavioral health care services, have limited Medicare beneficiary access to these vital services. Prior to the pandemic, the Health Resources and Services Administration (HRSA) projected shortages of seven selected types of behavioral health providers by 2025.[38] As of March 31, 2023, HRSA designated more than 6,635 health professional shortage areas for mental health, with more than one-third of Americans living in these shortage designations.[39] Additionally, according to SAMHSA's guide on *Addressing Burnout in the Behavioral Health Workforce Through Organizational Strategies,* staffing shortages, and high turnover rates place enormous demands on the workforce, jeopardizing the provision of care, especially to underserved individuals.[40] The behavioral health workforce experiences high levels of work-related stress, relatively low salaries, and full caseloads; these combined factors place individuals working in the behavioral health field at high risk for experiencing burnout.[41] Over 50 percent of behavioral health providers report experiencing burnout symptoms. The rate of burnout will likely increase, given the continued growth in the number of people seeking behavioral health care, behavioral health staffing, and retention challenges.[42]

In CY 2023 PFS rulemaking, we sought comment on how we can best help ensure beneficiary access to behavioral health services, including any potential adjustments to the PFS ratesetting methodology, for example, any adjustments to systematically address the impact on behavioral health services paid under the PFS. We described that as part of our review of our payment policies and systems, we understand that the PFS ratesetting methodology and application of budget neutrality may impact certain services more significantly than others based on factors such as how frequently codes are revalued and the ratio of physician work to PE. In the CY 2018 PFS final rule (82 FR 52999), we discussed feedback we received from some interested parties suggesting that, for codes with very low direct PE inputs, our methodology for allocating indirect PE does not produce a differential between facility and nonfacility PE RVUs that accurately reflects the relative indirect costs involved in furnishing services in non-facility settings. We stated that primary therapy and counseling services available to Medicare beneficiaries for the treatment of behavioral health conditions, including substance use disorders, are among the services most

[33] *https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=57754&ver=12&=.*

[34] Powell PW, Hilliard ME, Anderson BJ (2014). Motivational interviewing to promote adherence behaviors in pediatric type 1 diabetes. *Curr Diab Rep.* 2014;14(10):531. 10.1007/sll892–014–0531–z.

[35] National Cancer Institute at the National Institutes of Health, (nd). ''Stress and Cancer'' *https://www.cancer.gov/about-cancer/coping/feelings/stress-fact-sheet.*

[36] *https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/.*

[37] *https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/behavioral-health-2013-2025.pdf.*

[38] *https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/behavioral-health-2013-2025.pdf.*

[39] Health Resources and Services Administration, Health Workforce Shortage Areas, *https://data.hrsa.gov/topics/health-workforce/shortage-areas.*

[40] *https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/bh-workforce-projections-fact-sheet.pdf.*

[41] Kelly, R.J., Hearld, L.R. Burnout and Leadership Style in Behavioral Health Care: a Literature Review. *J Behav Health Serv Res* 47, 581–600 (2020). *https://doi.org/10.1007/s11414-019-09679-z.*

[42] *https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/pep22-06-02-005.pdf.*

affected by our methodology. For example, we stated at the time that, for the most commonly reported psychotherapy service (CPT code 90834), the difference between the nonfacility and facility PE RVUs was only 0.02 RVUs, which seemed unlikely to represent the difference in relative PE resource costs in terms of administrative labor, office expense, and all other expenses incurred by the billing practitioner for 45 minutes of psychotherapy services when furnished in the office setting versus the facility setting. We agreed with these interested parties that the site of service differential for these services produced by our PE methodology seems unlikely to reflect the relative resource costs for the practitioners furnishing these services in nonfacility settings. For example, we believe the 0.02 RVUs, which translated at the time to approximately $0.72, was unlikely to reflect the relative administrative labor, office rent, and other overhead involved in furnishing the 45-minute psychotherapy service in a nonfacility setting. Consequently, we modified our PE methodology to establish a minimum nonfacility PE RVU for certain outlier codes with very low direct PE inputs as compared to work RVUs, most of which are primarily furnished by behavioral health professionals. We finalized a policy to implement only one quarter of the minimum value for nonfacility indirect PE for the identified outlier codes over a 4-year transition period, beginning with CY 2018. We stated that we recognized that this change in the PE methodology could significantly impact the allocation of indirect PE RVUs across all PFS services (82 FR 53000).

In light of increasing patient needs for behavioral health services and continued workforce shortages, we have been examining a number of dynamics in our processes for developing values for behavioral health services under the PFS. We continue to consider approaches to ensuring that the relative values we establish for these services accurately reflect the resources involved in furnishing them, especially since any potential systemic undervaluation could serve as an economic deterrent to furnishing these kinds of services and be a contributing factor to the workforce shortage.

Interested parties have long raised concerns regarding the valuation of services that primarily involve person-to-person interactions with beneficiaries, particularly those services that are comprised of conversational interactions rather than physical interactions, because these services require minimal equipment and supplies compared to other services, and therefore, valuation is based almost entirely on the practitioner's work. Because the physician/practitioner work RVU is developed based on the time and intensity of the service, the issues regarding the valuation of these types of services are particularly pronounced for services that are billed in time units (like psychotherapy codes) that directly reflect the practitioner time inputs used in developing work RVUs, compared to other services that are not billed in time units in which work RVUs are based on estimates of typical time, usually based on survey data. For example, a 2016 report by the Urban Institute entitled *Collecting Empirical Physician Time Data*[43] (the Urban Institute report) reviewed empirical time estimates for 60 services paid under the PFS with relative values developed based on time estimates derived from survey data (as opposed to actual reported time). The Urban Institute report suggested that there may be systemic overestimations of times for these services within the PFS, which would lead to overvaluation of these services and, by implication, undervaluation of other services.

The dynamic described by the Urban Institute report can lead to systemic undervaluation for some kinds of time-based codes for several, interrelated reasons. First, overestimates of time for some kinds of codes compared to other kinds of codes results in ''implied intensity'' (that is the ratio of work RVU/per minute, sometimes referred to by the AMA RUC as intra-service work per unit of time, or IWPUT) that is artificially low. This is important since we understand that the implied intensity is used as part of the AMA RUC review of survey data to contextualize the credibility of data and the resulting recommended work RVUs compared to codes with similar times. CMS' review of the RUC recommendations similarly utilizes implied intensity as important contextual information in order to assess the relative values assigned to particular services.

The second reason this dynamic could result in potential undervaluation of certain services is that time-based codes that describe one-on-one time with the patient are highly unlikely to become more efficient over multiple years. In contrast, surgical procedures tend to become more efficient over the years as they become more common, professionals gain more experience with them, improved technology is deployed, and other general operational improvements are implemented. Meanwhile, 45 minutes of psychotherapy remains static in terms of efficiency since, by definition, it requires 45 minutes of time, personally spent by the billing professional, one-on-one with the patient. Moreover, even if there were efficiencies that reduced the time required to furnish therapy services, the services would then be reported with time-based codes with lower total values. Additionally, in contrast to services such as procedures that utilize clinical staff, no part of the one-on-one therapy service can be performed by clinical staff working with the billing professional. This means that any overestimations in the initial estimates of time used to established work times and values, as discussed above, are likely compounded over time as there are gains in efficiencies for some services in terms of time, clinical staff delegation, and improved technology, but no such gains for other services.

For many professionals who provide a heterogenous range of services paid under the PFS, this phenomenon may not have a significant overall impact on their Medicare PFS payments. However, this phenomenon would have an outsized impact on Medicare PFS payments for professionals who predominantly furnish services involving person-to-person interactions with patients that are reported and valued in time-based units. It would not be logical to assume that the marketplace ignores this dynamic, since the opportunity for increased revenue generation through efficiency for timed, one-on-one services is limited as compared to services for which there are multiple avenues to gain efficiencies.

We also recognize that, while this underlying valuation dynamic may create distortion of increasing magnitude over time, the quickly changing needs of Medicare beneficiaries relative to behavioral health also likely contribute to systemic distortion. This is especially the case as beneficiaries rely on behavioral health professionals for ongoing care of chronic and acute mental health needs. In other words, at the same time that the intensity of the work involved in furnishing services to Medicare beneficiaries increases, the work RVUs assigned to these services may be initially undervalued relative to other services that are valued based on potentially inflated time data, and therefore, may not accurately reflect the current relative resource costs associated with these services.

[43] *https://www.urban.org/sites/default/files/publication/87771/2001123-collecting-empirical-physician-time-data-piloting-approach-for-validating-work-relative-value-units_0.pdf.*

One approach to curb the impact of this dynamic would be to conduct more frequent revaluations of these kinds of services, including timed psychotherapy services. However, our current valuation process relies primarily, as noted, on times reported through survey data of professionals who furnish these services and assessment by the RUC of those survey data. We believe that survey results from the professionals that currently provide behavioral health services, including physicians, psychologists, and social workers could reflect the increased intensity of the work due to changes in the complexity of care for beneficiaries, but would be unlikely to address any relative undervaluation of work estimates. We are interested in working with the broader community, including the AMA RUC, to address these specific concerns over the long term.

However, given the emerging need for access to behavioral health care and the continuing difficulties in behavioral health workforce capacity, we believe it would be appropriate to take immediate steps to improve the accuracy of the valuation of these services until we can develop systemic solutions to longstanding process limitations. Consequently, we propose to address the immediate need for improvement in valuation for timed psychotherapy services in such a way that considers the policy we initially finalized in the CY 2020 PFS final rule (84 FR 62856) to address valuation distortions for primary and longitudinal care through implementation of an add-on code for office/outpatient E/M services that involve inherent complexity, and are proposing to reestablish in this rule. Our proposed implementation of that policy is discussed in section II.F. of this proposed rule. Like E/M visits that are furnished for primary and longitudinal care, we believe that the psychotherapy codes similarly describe treatment that is ongoing or longitudinal, and therefore, we believe it is appropriate to propose to address the need for improvement in valuation for timed psychotherapy services based on the proposed valuation for the inherent complexity add-on code for office/outpatient E/M services.

Under this proposal, we would apply an adjustment to the work RVUs *for* the psychotherapy codes payable under the PFS. We propose to base this adjustment on the difference in total work RVUs for office/outpatient E/M visit codes (CPT codes 99202–99205 and 99211–99215) billed with the proposed inherent complexity add-on code (HCPCS code G2211) compared to the total work RVUs for visits that are not billed with the inherent complexity add-on code. This would result in an approximate upward adjustment of 19.1 percent for work RVUs for these services, comparable to the relative difference in office/outpatient visits that are also systemically undervalued absent such an adjustment, which we are proposing to implement over a 4-year transition. In making significant adjustments to RVUs in past rulemaking, we have implemented such changes using a 4-year transition, noting that a transition period allows for a more gradual adjustment for affected practitioners. We are proposing to apply this adjustment to the following time-based psychotherapy codes that describe one-on-one time with the patient that are significantly unlikely to become more efficient over multiple years: CPT code 90832 (*Psychotherapy, 30 minutes with patient*); CPT code 90834 (*Psychotherapy, 45 minutes with patient*); CPT code 90837 (*Psychotherapy, 60 minutes with patient*); 90839 (*Psychotherapy for crisis; first 60 minutes*); CPT code 90840 (*Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary service*); CPT code 90845 (*Psychoanalysis*); 90846 (*Family psychotherapy (without the patient present), 50 minutes*); CPT code 90847 (*Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes*); CPT code 90849 (*Multiple-family group psychotherapy*); CPT code 90853 (*Group psychotherapy (other than of a multiple-family group*) and newly proposed HCPCS codes GPFC1 and GPFC2 ((*Psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting*). We are not proposing to include CPT codes 90833, 90836, and 90838 in this list of codes for which we would make the adjustment because these are add-on codes for psychotherapy that is performed with an E/M visit and under our proposal described at section II.E of this proposed rule, E/M codes will be eligible to be billed with HCPCS code G2211, therefore, the psychotherapy codes that are performed with an E/M visit will already be eligible for an adjustment to account for the resources costs involved in furnishing longitudinal care. We believe that implementing an adjustment to the work RVUs for psychotherapy services concurrent with implementation of HCPCS code G2211 will help address distortions that may occur within our valuation process that may otherwise result in understated estimates of the relative resources involved in furnishing psychotherapy services. We recognize that many other services share some similarities with these psychotherapy services. For example, there are other services that are reported in time units. Likewise, there are other codes that primarily describe conversational interactions between medical professionals and beneficiaries. However, we believe that these services are unique because neither technology nor clinical staff can be utilized to increase efficiency, and because these services represent the significant majority of services furnished by certain types of professionals. If finalized, the implementation of this proposal for CY 2024, concurrent with the proposal to implement the inherent complexity add-on code, if finalized, will also mitigate any negative impact in valuation for psychotherapy services based on redistributive impacts if we were to finalize only the inherent complexity add-on code for E/M visits without proposing and finalizing any adjustments for psychotherapy. We welcome comments on this proposal, including and especially how the PFS valuation processes for these services and other services with similar characteristics can be improved in the future in order to mitigate the kinds of distortions described above.

Additionally, as noted above in this section, in the CY 2018 PFS final rule (82 FR 52999), we identified a set of outlier codes for which we believed it would be appropriate to establish a minimum nonfacility indirect PE RVU that would be a better reflection of the resources involved in furnishing these services. For each of the outlier codes, we compared the ratio between indirect PE RVUs and work RVUs that result from the application of the standard methodology to the ratio for a marker code, which was CPT code 99213. The finalized change in the methodology then increased the allocation of indirect PE RVUs to the outlier codes to at least one quarter of the difference between the two ratios. We stated we believed this approach reflected a reasonable minimum allocation of indirect PE RVUs, but that we did not have empirical data that would be useful in establishing a more precise number. We finalized implementation of one quarter of the minimum value for nonfacility indirect PE for the identified outlier codes. We stated that we recognized that this change in the PE methodology could have a significant impact on the allocation of indirect PE RVUs across all PFS services and finalized that we

would implement this change over a 4-year transition, beginning in CY 2018 and ending in CY 2021. We welcome comments on whether we should consider further adjustments to the nonfacility indirect PE for the identified outlier codes. Specifically, we request comment on whether this minimum value adjustment to the indirect PE for certain services sufficiently accounted for the resources involved in furnishing these services, or whether we should consider further adjustments, such as applying 50 percent of the calculated minimum value for nonfacility indirect PE values for these services, and whether we should consider implementing further changes using a similar 4-year transition.

6. Updates to the Payment Rate for the PFS Substance Use Disorder (SUD) Bundle (HCPCS Codes G2086–G2088)

In the CY 2023 PFS final rule (87 FR 69772 through 69774), we finalized a modification to the payment rate for the non-drug component of the bundled payment for episodes of care under the Opioid Treatment Program (OTP) benefit to base the rate for individual therapy on a crosswalk to CPT code 90834 (*Psychotherapy, 45 minutes with patient*), which reflects a 45-minute psychotherapy session, instead of a crosswalk to CPT code 90832 (*Psychotherapy, 30 minutes with patient*), as was our current policy at the time. We received public comments urging us to consider adopting this modification for other bundled payments for SUD under the PFS, such as the bundled rate for office-based SUD treatment, to reflect the complexity of treating these patients and ensure that there is consistent and sufficient access to counseling for SUD across settings of treatment. The commenters noted that some patients who are prescribed buprenorphine in non-OTP settings will have similarly complex care needs requiring more intensive therapeutic care, and that by recognizing the appropriate complexity and intensity of the services in setting the rates, CMS can incentivize more office-based practices to offer these services and build out the treatment teams that deliver this care.

In the CY 2020 PFS final rule (84 FR 62673 through 62677), we finalized the establishment of bundled payments for the overall treatment of OUD, including management, care coordination, psychotherapy, and counseling activities. We stated that for the purposes of valuation of HCPCS codes 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*) and 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*), we assumed two individual psychotherapy sessions per month and four group psychotherapy sessions per month, and noted that we understand that the number of therapy and counseling sessions furnished per month will vary among patients and also fluctuate over time based on the individual patient's needs. We are persuaded by the public comments received in response to the CY 2023 PFS proposed rule requesting that these codes be priced consistent with the crosswalk codes used to value the bundled payments made for OUD treatment services furnished at OTPs, as beneficiaries receiving buprenorphine in settings outside of OTPs may have similarly complex care needs as compared to beneficiaries receiving OUD treatment services at OTPs. In order to update the valuation for HCPCS codes G2086 and G2087, we are proposing to increase the current payment rate to reflect two individual psychotherapy sessions per month, based on a crosswalk to the work RVUs assigned to CPT code 90834 (*Psychotherapy, 45 minutes with patient*), rather than CPT code 90832 (*Psychotherapy, 30 minutes with patient*). The current work RVU assigned to CPT code 90834 is 2.24, compared to the work RVU assigned to CPT code 90832, which is 1.70, which results in a difference of 0.54 work RVUs. Because the bundled payments described by HCPCS codes G2086 and G2087 include two individual psychotherapy sessions per month, we are proposing to add 1.08 RVUs to the work value assigned to HCPCS codes G2086 and G2087, which results in a new work RVU of 8.14 for HCPCS code G2086 and 7.97 for HCPCS code G2087. We note that as described above, we are also proposing to update the work RVUs assigned to CPT code 90834 in this proposed rule. If our proposal to update the work RVUs for the standalone psychotherapy codes is finalized, CPT code 90834 would be assigned a work RVU of 2.35. In that case, our proposed update to HCPCS codes G2086 and G2087 would also reflect the updated work RVUs for 90834, and would result in a work RVU of 8.36 for HCPCS code G2086 and a work RVU of 8.19 for HCPCS code G2087.

7. Comment Solicitation on Expanding Access to Behavioral Health Services

In recent years, we have made efforts to undertake rulemaking and establish policies to expand access to behavioral health services, consistent with the CMS Behavioral Health Strategy, which aims to strengthen quality and equity in behavioral health care; improve access to substance use disorders prevention, treatment, and recovery services; ensure effective pain treatment and management; improve mental health care and services; and utilize data for effective actions and impact.[44] We continue to be interested in hearing feedback regarding ways we can continue to expand access to behavioral health services. For example, we welcome feedback regarding ways to increase access to behavioral health integration (BHI) services, including the psychiatric collaborative care model; whether we could consider new coding to allow interprofessional consultation to be billed by practitioners who are authorized by statute for the diagnosis and treatment of mental illness; intensive outpatient (IOP) services furnished in settings other than those addressed in the CY 2024 OPPS proposed rule; and how to increase psychiatrist participation in Medicare given their low rate of participation relative to other physician specialties. Additionally, we are seeking comment on whether there is a need for potential separate coding and payment for interventions initiated or furnished in the emergency department or other crisis setting for patients with suicidality or at risk of suicide, such as safety planning interventions and/or telephonic post-discharge follow-up contacts after an emergency department visit or crisis encounter, or whether existing payment mechanisms are sufficient to support furnishing such interventions when indicated.

We welcome comments from the public on these topics as well as any other ways we might consider expanding access to behavioral health services for Medicare beneficiaries.

8. Request for Information on Digital Therapies, Such as, But Not Limited to, Digital Cognitive Behavioral Therapy

The widespread adoption and use of software technologies, including, but not limited to digital therapeutics, is creating new ways to treat patients. In recent years, the Food and Drug Administration (FDA) has reviewed and cleared several mobile medical applications (''apps'') that have been

[44] *https://www.cms.gov/cms-behavioral-health-strategy.*

shown to demonstrate a reasonable assurance of safety and effectiveness for addressing a variety of health conditions including sleep disorders disturbances and substance use disorders. These breakthrough devices include apps for depression and anxiety. Our understanding is that these mobile medical apps generally require a prescription or referral from a clinician and are used for specific medical purposes rather than general wellness and education.

As technologies have evolved, we have sought public comment and expanded Medicare payment under Part B for use of technologies in remote monitoring of treatment and physical health. Beginning in 2018, CMS began making separate payment for the services described by CPT code 99091, which paid for collection and interpretation of physiologic data digitally stored and/or transmitted to the practitioner. Beginning in 2019, we began paying for additional new remote physiologic monitoring (RPM) codes.

We have continued to improve and expand payment for remote treatment and monitoring in subsequent years. In 2022, we began paying for a new class of CPT codes (98975, 98980, and 98981) for Remote Therapeutic Monitoring (RTM) in addition to RPM, which enabled reimbursement of monitoring of non-physiologic data, to help ensure Medicare beneficiaries have access to these services. RTM is currently limited to monitoring respiratory system status, musculoskeletal status, and therapy adherence, or therapy response (87 FR 69647). However, we continue to add, clarify, and refine payment for RTM codes.

In the CY 2023 PFS final rule (87 FR 69645), we finalized a new RTM code for supply of a device for cognitive behavioral therapy monitoring (CPT Code 989X6 *Remote therapeutic monitoring (e.g., therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily)*) *recording(s) and/or programmed alert(s) transmission to monitor cognitive behavior therapy, each 30 days).* In that rule, we noted specialty societies indicated the technologies for this service are still evolving, and as a result, there were no invoices for devices specific to the cognitive behavioral therapy monitoring services described by the code that could be shared. We accepted the RUC recommendation to contractor price CPT code 989X6, a PE-only device code. We stated we would work with Medicare Administrative Contractors (MACs) to better understand the devices and device costs they encounter as they review claims for payment for the new cognitive behavioral monitoring code.

For both RPM and RTM codes, the device used must meet the FDA definition of a device as described in section 201(h) of the Federal Food, Drug and Cosmetic Act (FFDCA). As we continue to gather information on how remote monitoring services are used in clinical practice and experience with coding and payment policies for these codes, we request information on the following areas to improve our understanding of the opportunities and challenges related to our coverage and payment policies, as well as claims processing, as we consider the need for further practitioner education, program instructions, and guidance, or potential future rulemaking regarding these services.

- How do practitioners determine which patients might be best served by digital therapeutics? How do practitioners monitor the effectiveness of prescribed interventions, such as, but not limited to, for their patients on an ongoing basis once the intervention has begun?
- We seek comment and real-life examples where digital cognitive behavioral therapy or other digital enabled therapy services are used by clinicians, and how the technology is imbedded in various practice models. For example, how is the patient evaluated and/or how is the treating clinician involved in the services received when the patient participates in digital cognitive behavioral therapy?
- What standards have interested parties developed or consulted to ensure the physical safety and privacy of beneficiaries utilizing digital cognitive behavioral therapy (CBT) and/or other digital therapeutics for behavioral health?
- What are effective models for distribution/delivery of digital therapeutics, such as prescription digital mental health therapy products to patients? What best practices exist to ensure that patients have the necessary support and training to use applications effectively?
- What practitioners and auxiliary staff are involved in furnishing RPM and RTM services, including training patients on its use, and to what extent is additional training or supervision of auxiliary staff necessary to provide an appropriate for and/or recommended standard of care in the delivery of these services?
- How are data that are collected by the technology maintained for recordkeeping and care coordination?
- What information exists about how an episode of care should be defined, particularly in circumstances when a patient may receive concurrent RTM or digital CBT services from two different clinicians engaged in separate episodes of care?
- We noted in previous rulemaking that even when multiple medical devices are provided to a patient, the services associated with all the medical devices 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. We seek information on the type and frequency of circumstances that involve multiple medical devices and multiple clinicians. How might allowing multiple, concurrent RTM services for an individual beneficiary affect access to health care, patient out-of-pocket costs, the quality of care, health equity, and program integrity?
- Do interested parties believe digital CBT could be billed using the existing remote therapeutic monitoring codes described by CPT codes 98975, 98980, and 98981? What impediments may exist to using these codes for digital CBT?
- In the past, commenters generally supported the concept of a generic RTM device code, and offered a wide variety of possible use cases, including where FDA approved devices and devices that have gone through other premarket pathways exist for the purpose of monitoring various conditions that do not meet the current scope of the existing RTM codes.

++ What are the advantages and disadvantages of a generic RTM device code, versus specific RTM codes?

++ Would generic device codes undermine or stall progress toward a wider set of specific codes that would provide less ambiguity on reimbursement?

++ How might generic RTM codes for supply of a device be valued given the broad array of pricing models?

- What scientific and clinical evidence of effectiveness should CMS consider when determining whether digital therapeutics for behavioral health are reasonable and necessary?
- What aspects of digital therapeutics for behavioral health should CMS consider when determining whether it fits into a Medicare benefit category, and which category should be used?
- If CMS determines the services fit within an existing Medicare benefit category or if other coverage requirements are met, what aspects of delivering digital cognitive based therapy services should be considered when determining potential Medicare payment? Under current practice models, are these products used as

incident-to supplies or are they used independent of a patient visit with a practitioner? If used independently of a clinic visit, does a practitioner issue an order for the services?

- Are there barriers to digital CBT reaching underserved populations, and would a supervision requirement impact access to digital CBT for underserved populations?
- What strategies, if any, within the digital therapeutics for behavioral health support disadvantaged/hard to reach populations in advancing equity in health care services?
- What are some potential considerations for protecting the privacy and confidentiality of the patient population in digital therapeutics, including compliance with State behavioral health privacy requirements?

K. Proposals on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services

1. Medicare Payment for Dental Services

a. Overview

Section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. (Collectively here, we will refer to ''the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth'' as ''dental services.'') In the CY 2023 PFS final rule (87 FR 69663 through 69688), we identified certain clinical scenarios where payment is permitted under both Medicare Parts A and B for certain dental services in circumstances where the services are not considered to be in connection with dental services within the meaning of section 1862(a)(12) of the Act.

The regulation at § 411.15(i)(3)(i) includes examples of services for which payment can be made under Medicare Parts A and B for dental services, furnished in an inpatient or outpatient setting, that are inextricably linked to, and substantially related to the clinical success of, certain other covered services (hereafter in this section, ''inextricably linked to other covered services'').

Recognizing that there may be other instances where covered services necessary to diagnose and treat the individual's underlying medical condition and clinical status may require the performance of certain dental services, we are proposing to expressly identify other instances where dental services are inextricably linked to other covered services such that they are not in connection with dental services within the meaning of section 1862(a)(12) of the Act. At the same time, we recognize that there are dental services that are not inextricably linked to other covered services. In these instances, we continue to believe that Medicare payment is precluded by section 1862(a)(12) of the Act, except when, due to the patient's underlying medical condition and clinical status or the severity of the dental procedure, hospitalization is required; and that in those instances, the Medicare Part A exception provided under section 1862(a)(12) of the Act would apply.

In the CY 2023 PFS final rule (87 FR 69682, 69685, 69687), we also established a process for the public to submit additional dental services that may be inextricably linked to other covered services for our consideration and review, and finalized a policy to permit payment for certain dental services, such as dental examinations and necessary treatment, prior to or contemporaneously with the treatment of head and neck cancers, beginning in CY 2024.

We are proposing to codify in section § 411.15(i)(3)(i)(A) additional policies to permit payment for certain dental services that are inextricably linked to, and substantially related and integral to, the clinical success of, other covered services. We are also proposing to make non-substantive technical changes to improve clarity of the regulation text.

b. Other Medical Services for Which Dental Services May Be Inextricably Linked

In the CY 2023 PFS final rule, we discussed whether we should specify that payment can be made under Medicare Parts A and B for certain dental services prior to the initiation of immunosuppressant therapy, joint replacement procedures, or other surgical procedures. We stated that we remain committed to exploring the inextricable link between dental and covered services associated with immunosuppressant therapy, joint replacement surgeries, and other surgical procedures, and that we welcomed continued engagement with the public to review the clinical evidence to determine whether certain dental services were inextricably linked to covered services (87 FR 69668 and 69680 through 69686).

We partnered with researchers at the Agency for Healthcare Research and Quality (AHRQ) to consider the relationship between dental services and specific covered services, and review available clinical evidence regarding the relationship between dental services and medical services in the treatment of cancer using chemotherapeutic agents, which may lead to more clinically severe infections and often involve immunosuppression in patients. [45] [46] The AHRQ report[47] regarding dental services and the link between medical services is available at *https://effectivehealthcare.ahrq.gov/products/receiving-chemotherapy-cancer/rapid-review.* For example, it is generally understood that many chemotherapeutic agents used in the treatment of cancer target rapidly proliferating cells (which include those cells found in healthy tissue, like the oral mucosa). This targeting of rapidly reproducing cells in the oral mucosa can lead to the development of oral mucositis, which can negatively affect individuals with periodontitis and other dental conditions more severely, especially when they are exposed to higher doses/duration of chemotherapy.[48] Another example of a dental-related issue resulting from covered services that are immunosuppressive in nature is medication-related osteonecrosis of the jaw (MRONJ). MRONJ may occur as an adverse effect when patients with cancer receive specific covered services, such as high-dose antiresorptive and/or antiangiogenic drug therapy (for example, high doses of bisphosphonates or drugs like denosumab used to treat osteoporosis) or bone-modifying therapy in conjunction with their chemotherapy regimen. Patients with existing dental disease are most at risk for developing MRONJ secondary to bone-modifying therapy. MRONJ complicates the cancer treatment and can lead to reduced survival rates up to 3 years post-

[45] Immunosuppression describes an impairment of the cells of a patient's immune system and a reduction in their ability to fight infections and other diseases.

[46] National Cancer Institute. NCI Dictionary of Cancer Terms. 2019. Available at *https://www.cancer.gov/publications/dictionaries/cancer-terms.*

[47] Hickam DH, Gordon CJ, Armstrong CE, Coen MJ, Paynter R, Helfand M. The Efficacy of Dental Services for Reducing Adverse Events in Those Receiving Chemotherapy for Cancer. Rapid Response. (Prepared by the Scientific Resource Center under Contract No. 75Q80122C00002.) AHRQ Publication No. 23–EHC021. Rockville, MD: Agency for Healthcare Research and Quality; June 2023. DOI: *https://doi.org/AHRQEPCRAPIDDENTALCANCER.*

[48] Poulopoulos A, Papadopoulos P, Andreadis D. Chemotherapy: oral side effects and dental interventions -a review of the literature. Stomatological Disease and Science. 2017; 1:35–49. *http://dx.doi.org/10.20517/2573–0002.2017.03.*

treatment.[49] Dental services to identify and treat oral complications/comorbidities prior to and, sometimes, throughout chemotherapy treatment have been associated with improved outcomes for the patient receiving medical services in the treatment of cancer.[50] Further, AHRQ noted that there is abundant worldwide experience and related standards of care in the management of patients whose medical conditions require chemotherapy regimens that induce immunosuppression, and that this experience has led to an understanding of how improved dental care potentially can reduce the incidence of serious infections and improve overall patient outcomes.

The AHRQ examined the effects of dental care prior to treatment on the success of medical services for patients receiving chemotherapy regimens (primary medical service) in the treatment of cancer (primary medical illness). As part of this analysis, AHRQ identified 26 primary research studies, 7 systematic reviews, and 5 practice guidelines that outline benefits and harms of pre-treatment dental services and their effects on cancer chemotherapy regimens. The studies were selected using specific inclusion criteria: a sample of patients beginning cancer treatment within two months; targeted dental services occurring prior to cancer treatment; outcomes data, such as rates of serious adverse events, quality of life, cancer relapse rates, mortality, or adherence to cancer treatment; and a minimum sample size of 10 patients.

The 26 primary research studies identified by AHRQ included prospective cohort studies, retrospective cohort studies, randomized controlled trials, and registry-based studies. From this group of studies, AHRQ found evidence to support that dental evaluation/treatment prior to cancer treatment led to decreased incidence and/or less severity of serious oral infections and complications (such as, oral mucositis and osteonecrosis) with the covered services, as well as requiring fewer emergency treatments.[51] [52] There was further evidence found in systematic reviews that showed a possible increased incidence of oral mucositis when dental treatment is not administered at least 2–3 weeks prior to initiation of cancer treatment, further complicating the totality of services a patient received to treat their cancer.[53] They note that treatment of a broad range of malignancies often requires the use of chemotherapeutic agents that suppress the body's production of white blood cells, thereby impairing the body's ability to resist serious (often life-threatening) bacterial and fungal infections, and that the route of entry of these offending bacteria can be the mouth. AHRQ also analyzed several clinical practice guidelines that supported a dental evaluation/treatment before initiating chemotherapy so that any oral complications could be mitigated prior to initiating care to treat the cancer. [54] [55] [56]

c. Submissions Received Through Public Submission Process

In the CY 2023 PFS final rule, we stated that we believed there may be additional clinical scenarios we have not yet identified under which Medicare payment could be made for certain dental services on the basis that dental services are inextricably linked to other covered services (87 FR 69686). In order to ensure we are appropriately considering other potential clinical scenarios that may involve such dental services, we finalized an annual public process, including notice and comment rulemaking, whereby interested parties can submit recommendations for other clinical scenarios for potential inclusion on the list of dental services for which payment can be made under § 411.15(i)(3)(i).

Through this process, we stated that we would review clinical evidence to assess whether there is an inextricable link between certain dental and covered services because the standard of care for that medical service is such that one would not proceed with the medical procedure or service without performing the dental service(s) because the covered services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services, or where dental services are a clinical prerequisite to proceeding with the primary medical procedure and/or treatment (87 FR 69685). We also stated that, section 1862(a)(12) of the Act does not apply only when dental services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered services, such that the standard of care for that medical service would be compromised or require the dental services to be performed in conjunction with the covered services. (87 FR 69666) As such, we requested that documentation accompanying recommendations should include medical evidence to support that certain dental services are inextricably linked to certain other covered services. Specifically, we requested that the medical evidence should:

(1) Provide support that the provision of certain dental services leads to improved healing, improved quality of surgery, and the reduced likelihood of readmission and/or surgical revisions, because an infection has interfered with the integration of the medical implant and/or interfered with the medical implant to the skeletal structure;

(2) Be clinically meaningful and demonstrate that the dental services result in a material difference in terms of the clinical outcomes and success of the procedure such that the dental services are inextricably linked to, and substantially related and integral to the clinical success of, the covered services; and

(3) Be compelling to support that certain dental services would result in clinically significant improvements in quality and safety outcomes (for example, fewer revisions, fewer readmissions, more rapid healing, quicker discharge, and quicker rehabilitation for the patient). (87 FR 69686)

[49] Corraini, P., Heide-Jørgensen, U., Schiødt, M., Nørholt, S. E., Acquavella, J., Sørensen, H. T., & Ehrenstein, V. (2017). Osteonecrosis of the jaw and survival of patients with cancer: a nationwide cohort study in Denmark. Cancer medicine, 6(10), 2271–2277. *https://doi.org/10.1002/cam4.1173.*

[50] Poulopoulos A, Papadopoulos P, Andreadis D. Chemotherapy: oral side effects and dental interventions -a review of the literature. Stomatological Disease and Science. 2017; 1:35–49. *http://dx.doi.org/10.20517/2573–0002.2017.03.*

[51] Watson EE, Metcalfe JE, Kreher MR, et al. Screening for Dental Infections Achieves 6-Fold Reduction in Dental Emergencies During Induction Chemotherapy for Acute Myeloid Leukemia. JCO Oncol Pract. 2020 11;16(11):e1397-e405. doi: *https://dx.doi.org/10.1200/OP.20.00107. PMID: 32609586.*

[52] Owosho AA, Liang STY, Sax AZ, et al. Medication-related osteonecrosis of the jaw: An update on the memorial sloan kettering cancer center experience and the role of premedication dental evaluation in prevention. Oral Surg Oral Med Oral Pathol Oral Radiol. 2018 May;125(5):440–5. doi: *https://dx.doi.org/10.1016/j.oooo.2018.02.003. PMID: 29580668.*

[53] Mazzetti T, Sergio da Silva Santos P, Spindola Antunes H, et al. Required time for pre-oncological dental management—A rapid review of the literature. Oral Oncol. 2022 11;134:106116. doi: *https://dx.doi.org/10.1016/j.oraloncology.2022.106116. PMID: 36115328.*

[54] Elad S, Cheng KKF, Lalla RV, et al. MASCC/ISOO clinical practice guidelines for the management of mucositis secondary to cancer therapy. Cancer. 2020 Oct 1;126(19):4423–31. doi: *https://dx.doi.org/10.1002/cncr.33100. PMID: 32786044.*

[55] Yarom N, Shapiro CL, Peterson DE, et al. Medication-Related Osteonecrosis of the Jaw: MASCC/ISOO/ASCO Clinical Practice Guideline. J Clin Oncol. 2019 Sep 1;37(25):2270–90. doi: *https://dx.doi.org/10.1200/JCO.19.01186. PMID: 31329513.*

[56] Butterworth C, McCaul L, Barclay C. Restorative dentistry and oral rehabilitation: United Kingdom National Multidisciplinary Guidelines. J Laryngol Otol. 2016 May;130(S2):S41–S4. PMID: 27841112.

We stated that interested parties should submit medical evidence to support, for the recommended clinical scenario, the inextricable link between certain dental services and other covered services by providing any of the following:

(1) Relevant peer-reviewed medical literature and research/studies regarding the medical scenarios requiring medically necessary dental care;

(2) Evidence of clinical guidelines or generally accepted standards of care for the suggested clinical scenario;

(3) Other ancillary services that may be integral to the covered services; and/or

(4) Other supporting documentation to justify the inclusion of the proposed medical clinical scenario requiring dental services (87 FR 69686, 69687).

We stated that we intended to use the PFS annual rulemaking process to discuss public submissions when considering whether the recommended dental services associated with certain clinical scenarios should be considered outside the scope of the general preclusion on payment for dental services under section 1862(a)(12) of the Act because they are inextricably linked to other covered services. We continue to believe that public feedback is important, especially when considering Medicare payment for dental services that may benefit the clinical outcomes for certain covered services. We believe that using our annual notice and comment rulemaking process to discuss submitted recommendations will allow the public to comment and submit further medical evidence to assist us in evaluating whether certain dental services furnished in certain clinical scenarios would meet the standard to permit Medicare payment for the dental services. Under the public process established in the CY 2023 PFS final rule, recommendations received by February 10th of a calendar year would be reviewed for consideration and potential inclusion within the PFS proposed rule for the subsequent calendar year. The deadline for submissions for potential consideration for CY 2024 rulemaking was February 10, 2023. We received eight submissions from various organizations on or before February 10, 2023. We received one submission after the deadline that presented nominations for covered services that have already been addressed by this payment policy.

Submissions included recommendations for payment under Medicare Parts A and B of dental services prior to covered services associated with the treatment of cancer (chemotherapy, chimeric antigen receptor (CAR) T-cell therapy, bone-modifying agents or antiresorptive therapy), total joint arthroplasty, all cardiovascular procedures, diabetes treatment, treatment for sickle-cell anemia and hemophilia, and systemic autoimmune diseases. Additionally, many submissions recommended that CMS refine certain terminology surrounding previously finalized policies, specifically around whether payment can be made for dental services furnished during and after the performance of certain covered services.

Several submissions recommended that Medicare make payment under Parts A and B for dental services prior to covered services associated with the treatment of patients with leukemia and lymphoma, as well as other cancers. Most submitting organizations stated that, by examining and addressing the oral health of the patient prior to the initiation of chemotherapy in the treatment of cancer, with or without radiation, oral complications could be appropriately addressed or prevented that would improve the clinical success of the overall cancer treatment. Submissions also recommended Medicare payment under Parts A and B for dental services before, during, and after CAR T-cell therapy and other lymphodepleting covered services (lymphodepleting therapy involves a short course of chemotherapy that targets T-cells, preconditioning the body prior to enhance treatments like CAR T-cell therapy). These submissions stressed the need to detect early and monitor dental issues and to avoid the increased risk of related infections and complications.

Most submissions stated that medication-related osteonecrosis of the jaw (MRONJ) is a serious complication of antiresorptive and/or antiangiogenic drug therapy used to help manage the treatment of cancer. Several recommended that Medicare make payment under Parts A and B for dental services for patients where high-dose bisphosphonate therapy for cancers is indicated, such as blood and solid tumor cancers and metastatic cancers associated with risk of osteonecrosis of the jaw. These submissions recommended payment of dental services prior to and during antiresorptive therapy or prior to, during, and after the use of bone-modifying drugs. One provided references that support the provision of dental services to prevent, or as part of treatment for MRONJ. Another submission stated that the risk of MRONJ is significantly greater in patients receiving antiresorptive therapy in connection with cancer treatment compared to patients receiving antiresorptive therapy for osteoporosis. However, the submitter stated that the combination of poly-pharmaceutical management of cancer patients and related immunosuppression are risk factors for MRONJ without exposure to antiresorptive agents, and that it would be difficult to identify a single medication as the etiologic agent for MRONJ in case reports or mini-case series. The submitter stated that prevention of MRONJ would be the clinical gold standard.

One submission also recommend that Medicare make payment under Parts A and B for dental services prior to all cardiovascular procedures. In their view, the provision of dental services to reduce risk of perioperative and postoperative infection and complications is critical to ensure optimal surgical outcomes for all patients requiring invasive and/or interventional cardiac procedures. They cited a literature review in support of the need for screening and treatment for oral/dental infections prior to cardiac surgery. This submission did not recommend dental services prior to a specific cardiovascular procedure; rather, it recommended dental services prior to all cardiovascular procedures. The literature review they cited, (which we discuss below at section II.K.3. of this proposed rule) noted that there was a mixture of medical literature to support the performance of dental services prior to all cardiac procedures in part because such cardiovascular procedures are more urgent or emergent than elective.

One submission recommended that Medicare make payment under Medicare Parts A and B for dental services prior to joint replacement surgeries, specifically total knee and hip arthroplasty. The submitting organization stated that the provision of dental services prior to or contemporaneously with joint replacement surgeries may result in more rapid healing and quicker rehabilitation, especially if a known dental infection could be addressed and potentially prevent surgical and rehabilitation complications for the patient. However, the submission acknowledged that there is no consensus on whether performing dental services prior to joint replacement surgeries improves the clinical outcomes of the medical service, or whether it is typical in practice to furnish dental services before joint replacement procedures.

Other submissions recommended Medicare make payment for dental services for patients diagnosed with a

specific condition(s), such as patients with poorly controlled diabetes mellitus, or individuals living with sickle cell disease (SCD) or hemophilia.

Submissions also recommended Medicare payment for dental services for persons affected by systemic autoimmune disease. They argued that dental services are an essential component of medical treatment for these individuals who are at much higher risk of advanced dental decay, dental loss, and/or gum disease. They stated that reducing oral infection of the mucosa, teeth, and gums; oral inflammation; and tooth loss through consistent oral management reduces the systemic impact that these dental conditions have on a patient's systemic autoimmune disease. One submission stated that oral health disparities disproportionately affect members of racial or ethnic minority groups, which they offered is most pronounced in populations aged 65 and older. Another presented their proposal to bridge the gap in health equity and to improve the health outcomes for those ages 65 and older living with autoimmune diseases.

We thank all those who submitted recommendations for clinical scenarios for which they believe Medicare payment for dental services would be consistent with the policies we codified and clarified in the CY 2023 PFS final rule under which Medicare payment could be made for dental services when inextricably linked to other covered services. We continue to encourage interested parties to engage with us regularly and to submit recommendations for our consideration of additional clinical scenarios where dental services may be inextricably linked to specific covered services. As stated earlier, interested parties should provide evidence to support or refute that at least one of the three criteria listed above for submissions is met. Furthermore, submissions should focus on the inextricably linked relationship between dental and medical services, not a specific medical condition, and whether it is not clinically advisable to move forward with the medical service without having first completed the dental service(s). We remind readers that, to be considered for purposes of CY 2025 PFS rulemaking, submissions through our public process for recommendations on payment for dental services should be received by February 10, 2024, via email at *MedicarePhysicianFeeSchedule@cms.hhs.gov*. Interested parties should include the words ''dental recommendations for CY 2025 review'' in the subject line of their email submission to facilitate processing. We stress to submitters that recommendations must include at least one of the types of evidence listed earlier when submitting documentation to support the inextricable link between specified dental services and other covered services. We note that we may also consider recommendations that are submitted as public comments during the comment period following the publication of the PFS proposed rule.

2. Proposed Additions to Current Policies Permitting Payment for Dental Services Inextricably Linked to Other Covered Services

Under our current policy, we have identified several clinical scenarios where dental services are inextricably linked to a primary medical service that is covered by Medicare, such that Medicare payment for the dental services is not precluded by section 1862(a)(12) of the Act. After further review of current medical practice, and through internal and external consultations and consideration of the submissions received through the public process established in the CY 2023 PFS final rule (87 FR 69669), we believe there are additional circumstances that are clinically similar to the scenarios we codified in our regulation at § 411.15(i)(3)(i) as examples of clinical scenarios under which Medicare payment may be made for certain dental services because they are inextricably linked to other covered medical service(s).

In the case of the proposed primary, covered services, we believe that dental services are inextricably linked to, and substantially related and integral to the clinical success of, the proposed covered services because such dental services serve to mitigate the substantial risk to the success of the medical services, due to the occurrence and severity of complications caused by the primary medical services, including infection. Additionally, section 1862(a)(12) of the Act does not apply only when dental services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered services, such that the standard of care for that medical service would be compromised or require the dental services to be performed in conjunction with the covered services or if the dental services are considered to be a critical clinical precondition to proceeding with the primary medical procedure and/or treatment. As such, we believe the dental services are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to, and substantially related and integral to the clinical success of, the following medical services, and the statutory dental exclusion would not apply:

(1) Chemotherapy when used in the treatment of cancer;

(2) CAR T-Cell therapy, when used in the treatment of cancer; and

(3) Administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer.

As such, we propose to amend our regulation at § 411.15(i)(3)(i)(A) to permit payment under Medicare Parts A and Part B for:

(1) Dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered: chemotherapy when used in the treatment of cancer, chimeric antigen receptor (CAR) T-cell therapy when used in the treatment of cancer, and the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of; and

(2) Medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with: chemotherapy when used in the treatment of cancer, CAR T-cell therapy when used in the treatment of cancer, and the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer. Furthermore, we propose that payment under the applicable payment system could also be made for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and use of the operating room as currently described in our regulation at § 411.15(i)(3)(ii).

a. Dental Services Inextricably Linked to Chemotherapy Services When Used in the Treatment of Cancer

In the CY 2023 PFS final rule (87 FR 69663 through 69688), and as described in section II.K.1 of this proposed rule, we stated that we would continue to study the relationship between dental care and medical services that cause immunosuppression in patients, and the risk of dental infection and complications that arise because of the treatment-induced immunosuppression. As discussed in section II.K.1 of this proposed rule, we received submissions through the public process and comments on the CY 2023 PFS proposed rule requesting that Medicare payment should be permitted under Parts A and B for dental services when medical services that cause

immunosuppression are being provided to treat a variety of medical conditions.

Commenters asserted that immunocompromised patients are at an increased risk of serious infection that can lead to severe conditions (87 FR 69683). We stated that we agreed with commenters that individuals who are immunocompromised may be prone to serious infection, and that we would continue to consider feedback and the clinical literature provided by interested parties to determine whether there are other clinical scenarios, such as the initiation of immunosuppressive therapies, where Medicare payment should not be excluded for dental services under section 1862(a)(12) of the Act, because the services are inextricably linked to certain other covered services.

In the CY 2023 PFS final rule (87 FR 69681) and as discussed in section II.K.2 of this rule, we stated that we were finalizing a policy for CY 2024 that Medicare Parts A and B payment may be made for dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting, as well as medically necessary diagnostic and treatment services to eliminate an oral or dental infection, prior to or contemporaneously with Medicare-covered treatments for head and neck cancer. We stated that removing infections in the oral cavity is necessary to prepare patients for treatment and is inextricably linked to the clinical success of treatment for cancers of the head and neck. Additionally, as described in the comments received on the CY 2023 PFS proposed rule and summarized in the CY 2023 PFS final rule (87 FR 69683), commenters suggested that the patient population with any cancer receiving chemotherapy treatments required dental services that were linked to the clinical success of the completion of the chemotherapy treatment. They indicated that immunocompromised patients, such as individuals with blood cancers (leukemia and lymphoma) or other types of cancers, are at increased risk of serious infection that can lead to severe complications and adverse outcomes. Commenters provided information showing that chemotherapy drugs used for treatment of head and neck cancers can have many side effects, including sores and lesions in the mouth and throat tissues, difficulty swallowing, bleeding in the mouth, and tooth decay. Additionally, commenters stated that, because chemotherapy reduces the body's ability to fight opportunistic infections, patients who begin chemotherapy with untreated infections (including infections in the oral cavity) are at risk of developing a number of complications, ranging from fungal or viral infections of the mouth and throat to systemic infections or fatal sepsis. Commenters observed that complications arising from untreated infections could cause treatment interruptions which could compromise the success of the treatment and the patient's outcomes. One commenter observed that the need for removing oral infection prior to starting chemotherapy is analogous to the rationale for providing oral care prior to renal transplant, and thus (like a dental exam prior to renal transplant) should be considered substantially related and inextricably linked to the clinical success of the treatment. Commenters recommended that patients receiving chemotherapy for head or neck cancer receive a dental exam and stabilization, if applicable. Several commenters noted that providing an oral exam prior to starting chemotherapy is the standard of care in many cancer centers (87 FR 69681 through 69683).

Additionally, in the CY 2023 PFS final rule (87 FR 69682), we stated that many commenters recommended that we permit payment under Medicare Parts A and B for dental services prior to treatment for all types of cancer patients instead of just those with head and neck cancers; commenters suggested that the linkage between the medical services (chemotherapy, with or without radiation) and dental services was the same whether the medical services are used to specifically treat head and neck cancers or other cancers. Commenters stated that the increased risk of infections and sepsis among cancer patients could constitute major health setbacks that are costly to treat and can compromise the success of the cancer treatment. We reiterated that we would continue to review and evaluate information that supports the relationship between dental care and covered treatments for cancer (including treatments related to conditions not localized in the head, neck, or oral cavity), and have continued to study this issue.

We believe immunosuppression is commonly understood to be a suppression or reduction of the body's immune response, which can be caused by various factors that increase susceptibility to infections and an increased risk of developing certain types of conditions.[57] There is significant and abundant worldwide experience and research regarding the care of patients whose medical conditions require chemotherapy regimens that induce acute immunosuppression.[58] [59] The treatment of a broad range of malignancies often requires the use of chemotherapeutic agents that in turn suppress the body's production of white blood cells, thereby impairing the body's ability to resist serious (potentially life-threatening) infections. The route of entry of the offending pathogens can be the mouth.[60] [61] [62] Therefore, individuals receiving chemotherapy treatment for cancer who become immunosuppressed may be more susceptible to infection and other adverse events with serious consequences for the patient. We understand that medical services used in the treatment of cancer, such as chemotherapy, induce immunosuppression. As such, we believe that cancer patients being treated with chemotherapy represent an acutely-impacted, immunocompromised patient population due to the nature of the effects of such chemotherapy treatment. If dental or oral infections are left undetected or untreated in these patients, serious complications may occur, negatively impacting the clinical success of the medical services and outcomes for the patients. Moreover, the immunosuppression induced by the chemotherapy medical services in the treatment of cancer increases the likelihood and intensity of complications for the patient that could potentially jeopardize or impact the ability to complete the totality of the treatment across a normal course of treatment.[63] [64] If an oral or dental

[57] Abbas AK, Lichtman AH, Pillai S. Basic Immunology: Functions and Disorders of the Immune System. 5th edition. Philadelphia: Elsevier; 2016. Chapter 8, Immune Suppression.

[58] Spijkervet FKL, Schuurhuis JM, Stokman MA, et al. Should oral foci of infection be removed before the onset of radiotherapy or chemotherapy? Oral Dis. 2021 Jan;27(1):7–13. doi: *https://dx.doi.org/10.1111/odi.13329*. PMID: 32166855.

[59] Hanna N, Einhorn LH. Testicular cancer: a reflection on 50 years of discovery. J Clin Oncol. 2014 Oct 1;32(28):3085–92. doi: *https://dx.doi.org/10.1200/JCO.2014.56.0896*. PMID: 25024068.

[60] Mirowski GW, Bettencourt JD, Hood AF. Oral infections in the immunocompromised host. Semin Cutan Med Surg. 1997 Dec;16(4):249–56. doi: *https://dx.doi.org/10.1016/s1085-5629(97)80013-2*. PMID: 9421215.

[61] Greenberg MS, Cohen SG, McKitrick JC, et al. The oral flor as a source of septicemia in patients with acute leukemia. Oral Surg Oral Med Oral Pathol. 1982 Jan;53(1):32–6. PMID: 6948251.

[62] King A, Irvine S, McFadyen A, et al. Do we overtreat patients with presumed neutropenic sepsis? Postgrad Med J. 2022 Nov;98(1165):825–9. doi: *https://dx.doi.org/10.1136/postgradmedj-2021-140675*. PMID: 34611037.

[63] Spijkervet FKL, Schuurhuis JM, Stokman MA, et al. Should oral foci of infection be removed before the onset of radiotherapy or chemotherapy? Oral Dis. 2021 Jan;27(1):7–13. doi: *https://dx.doi.org/10.1111/odi.13329*. PMID: 32166855.

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infection is not properly diagnosed and treated prior to and/or during the chemotherapy in the treatment of cancer, which suppresses the immune system, there may be an increased risk for local and systemic infections from odontogenic sources; and furthermore, the successful completion of that treatment could be compromised. Additionally, if such an infection is not treated, then there is an increased likelihood of morbidity and mortality resulting from the spreading of the local infection to sepsis [65] [66]

Individuals undergoing chemotherapy services used in the treatment of cancer who become immunosuppressed by the treatment may also experience oral mucositis, which often facilitates entry of oral bacteria into the body, potentially increasing the risk of infection for the patient and compromising the chemotherapy regimen. The risk of mucositis and potential complications to the clinical success of medical services for cancer treatment is similar to the risk for patients receiving Hematopoietic Stem Cell Transplants (HSCT) and bone marrow transplants,[67] [68] for which we finalized payment for certain dental services prior to these medical services (87 FR 69677). These potential complications, resulting from the combined immunosuppression and mucositis caused by the chemotherapy services, present a risk to the patient and the success of the medical chemotherapy regimen, unless mitigated by the provision of dental services. Additionally, as described above, evidence found in systematic reviews showed a possible increased incidence of oral mucositis when dental treatment is not administered at least 2–3 weeks prior to initiation of cancer treatment, further complicating the totality of services a patient received to treat their cancer.[69]

Moreover, as described above in section II.K.1. of this proposed rule, dental services to identify and treat oral complications/comorbidities prior to and, sometimes, throughout chemotherapy treatment have been associated with improved outcomes for the patient receiving medical services in the treatment of cancer.[70] Additionally, as discussed in section II.K.1. of this proposed rule, research studies support that dental evaluation/treatment prior to cancer treatment led to decreased incidence and/or less severity of serious oral infections and complications (such as, oral mucositis and osteonecrosis) with the medical services, as well as requiring fewer emergency treatments.[71] [72]

Consequently, we believe that the evidence supports that the standard of care is such that one would not proceed with the chemotherapy when used in the treatment of cancer without performing the dental services, because the covered services would or could be significantly and materially compromised, such that clinical outcomes of the chemotherapy treatment could be compromised absent the provision of the inextricably-linked dental services.

As described in the CY 2023 PFS final rule (87 FR 69685), we noted that evidence to support the linkage between the dental and covered services could include information demonstrating that the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to clear the patient of an oral or dental infection; or, in instances where a known oral or dental infection is present, the standard is such that the medical professional would not proceed with the medical service until the patient received the necessary treatment to eradicate the infection. Our review of relevant clinical practice guidelines demonstrated that multiple professional societies recommend the performance of dental services prior to the initiation of or during chemotherapy.[73] [74] For instance, the United Kingdom published a guideline for dental evaluation and treatment before and after treatments for head and neck cancer (5th edition of the UK Multi-Disciplinary Guidelines for Head and Neck Cancer), based on guidance from the National Institute for Health and Care Excellence (NICE) and expert recommendations: ''Preventive oral care must be delivered to patients whose cancer treatment will affect the oral cavity, jaws, salivary glands and oral accessibility.'' [75] Additionally, as described in the CY 2023 PFS final rule (87 FR 69680), several commenters provided data regarding the treatment of head and neck cancer that illustrated that conditions such as oral mucositis or osteonecrosis of the jaw that occur during the treatment may compromise the clinical success of the primary medical service (chemotherapy for the treatment of head and neck cancer), potentially leading to multiple hospitalizations, including systemic infections or fatal sepsis, if dental infections remained untreated.

We believe chemotherapy used in the treatment of cancer causes acute immunosuppression, causing significant oral complications and adverse events, including the possibility of an oral or dental infection, which in turn may lead to serious and imminent risks to the success of the primary medical procedures and treatments. These treatment-induced complications, including possible infection, prevent the ability to proceed with the primary, covered medical service (that is, lead to delays in treatment and/or cause inability of the patient to complete the course of treatment, thereby potentially reducing effectiveness of the therapy)

[64] Hanna N, Einhorn LH. Testicular cancer: a reflection on 50 years of discovery. J Clin Oncol. 2014 Oct 1;32(28):3085–92. doi: *https://dx.doi.org/10.1200/JCO.2014.56.0896*. PMID: 25024068.

[65] Ruescher TJ, Sodeifi A, Scrivani SJ, Kaban LB, Sonis ST. The impact of mucositis on alpha-hemolytic streptococcal infection in patients undergoing autologous bone marrow transplantation for hematologic malignancies. Cancer 1998;82(11):2275–2281. [PubMed: 9610710].

[66] Vera-Llonch M, Oster G, Ford CM, Lu J, Sonis S. Oral mucositis and outcomes of allogeneic hematopoietic stem-cell transplantation in patients with hematologic malignancies. Support Care Cancer May;2007 15(5):491–496. [PubMed: 17139495].

[67] Vera-Llonch M, Oster G, Ford CM, Lu J, Sonis S. Oral mucositis and outcomes of allogeneic hematopoietic stem-cell transplantation in patients with hematologic malignancies. Support Care Cancer May,2007 15(5):491–496. [PubMed: 17139495].

[68] Ruescher TJ, Sodeifi A, Scrivani SJ, Kaban LB, Sonis ST. The impact of mucositis on alpha-hemolytic streptococcal infection in patients undergoing autologous bone marrow transplantation for hematologic malignancies. Cancer 1998;82(11):2275–2281. [PubMed: 9610710].

[69] Mazzetti T, Sergio da Silva Santos P, Spindola Antunes H, et al. Required time for pre-oncological dental management—A rapid review of the literature. Oral Oncol. 2022 11;134:106116. doi: *https://dx.doi.org/10.1016/j.oraloncology.2022.106116. PMID: 36115328.*

[70] Poulopoulos A, Papadopoulos P, Andreadis D. Chemotherapy: oral side effects and dental interventions-a review of the literature. Stomatological Disease and Science. 2017; 1:35–49. *http://dx.doi.org/10.20517/2573-0002.2017.03.*

[71] Watson EE, Metcalfe JE, Kreher MR, et al. Screening for Dental Infections Achieves 6-Fold Reduction in Dental Emergencies During Induction Chemotherapy for Acute Myeloid Leukemia. JCO Oncol Pract. 2020 11;16(11):e1397–e405. doi: *https://dx.doi.org/10.1200/OP.20.00107. PMID: 32609586.*

[72] Owosho AA, Liang STY, Sax AZ, et al. Medication-related osteonecrosis of the jaw: An update on the memorial sloan kettering cancer center experience and the role of premedication dental evaluation in prevention. Oral Surg Oral Med Oral Pathol Oral Radiol. 2018 May;125(5):440–5. doi: *https://dx.doi.org/10.1016/j.oooo.2018.02.003. PMID: 29580668.*

[73] Butterworth C, McCaul L, Barclay C. Restorative dentistry and oral rehabilitation: United Kingdom National Multidisciplinary Guidelines. J Laryngol Otol. 2016 May;130(S2):S41–S4. PMID: 27841112.

[74] American Academy of Pediatric Dentistry. Dental management of pediatric patients receiving immunosuppressive therapy and/or head and neck radiation. The Reference Manual of Pediatric Dentistry. Chicago, Ill.; 2022:507–16.

[75] Butterworth C, McCaul L, Barclay C. Restorative dentistry and oral rehabilitation: United Kingdom National Multidisciplinary Guidelines. J Laryngol Otol. 2016 May;130(S2):S41–S4. PMID: 27841112.

and the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection. In the case of the Medicare covered chemotherapy when used in the treatment of cancer, dental services serve to mitigate the likelihood of occurrence and severity of complications caused by the primary medical services, including infection, and consequently the dental services facilitate the successful completion of the prescribed course of treatment and therefore the dental services are integral and inextricably linked to these medical services, and the statutory dental exclusion would not apply.

We believe that proceeding without a dental or oral exam and necessary diagnosis and treatment of any presenting infection of the mouth prior to chemotherapy when used in the treatment of cancer could lead to systemic infection or sepsis, as well as other complications for the patient. We also believe that an oral or dental infection could present substantial risk to the success of chemotherapy when used in the treatment of cancer, such that the standard of care would be to not proceed with the procedure when there is a known oral or dental infection present. We believe dental services furnished to identify, diagnose, and treat oral or dental infections prior to and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with chemotherapy when used in the treatment of cancer are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to these other covered services.

We also seek comment on whether we should consider radiation therapy in the treatment of cancer more broadly (not in conjunction with chemotherapy, and not in relation to head and neck cancer treatment) as medical services that may be inextricably linked to dental services. We do not believe that radiation therapy alone necessarily leads to the same level of treatment-induced immunosuppression as for cancer patients receiving chemotherapy since radiation specifically targets malignant cells and has more targeted and localized effects on the body as compared to system-wide immunosuppression effects of chemotherapy for cancer treatment. However, we seek comment on whether dental services prior to radiation therapy in the treatment of cancer, when furnished without chemotherapy, such as second line therapy for metastasized cancer in the head and neck, would be inextricably linked to the radiation therapy services, and therefore payable under Medicare Parts A and B.

In summary, after consideration of clinical practice guidelines, recommendations provided by the public, and our analyses of the studies and research available regarding the connection between dental services and the clinical success of chemotherapy services, we believe that there is an inextricable link between certain dental and chemotherapy services when used in the treatment of cancer because the standard of care is such that one would not proceed with the medical procedure or service without performing the dental service(s) because the covered medical services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services and that dental services are a clinical prerequisite to proceeding with the chemotherapy services when used in the treatment of cancer. Chemotherapy services when used in the treatment of cancer cause immunosuppression which may lead to significant oral complications and adverse events, including the possibility of an oral or dental infection, which in turn lead to serious and imminent risks to the success of the primary medical procedures and treatments. The complications, including possible infection, may prevent the ability to both initiate and proceed with the primary, covered medical service (that is, lead to delays in treatment and/or cause inability of the patient to complete the course of treatment, thereby potentially reducing effectiveness of the therapy) such that the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection. In the case of chemotherapy services when used in the treatment of cancer, dental services serve to mitigate the likelihood of occurrence and severity of complications caused by the primary medical services, including infection, and consequently the dental services facilitate the successful completion of the prescribed course of treatment. Therefore, we believe the dental services are integral and inextricably linked to the chemotherapy when used in the treatment of cancer, and the statutory dental exclusion under section 1862(a)(12) of the Act would not apply.

We are proposing to add this clinical scenario to the examples of clinical scenarios under which payment can be made for certain dental services in our regulation at § 411.15(i)(3)(i)(A). Specifically, we propose to amend the regulation to include dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered chemotherapy when used in the treatment of cancer; and, medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with chemotherapy when used in the treatment of cancer. We seek comments on all aspects of this proposal. Additionally, we note that we are proposing to make payment for dental services that are inextricably linked to chemotherapy used in the treatment of cancer with or without the use of other therapy types, including radiation therapy in the treatment of cancer. That is, this proposal is not meant to be limited to cases where chemotherapy in the treatment of cancer is provided without the use of other therapies. We seek comment on this aspect of the proposal.

b. Dental Services Inextricably Linked to CAR T-Cell Therapy, When Used in the Treatment of Cancer

In the CY 2023 PFS final rule (87 FR 69677), commenters stated that individuals receiving CAR T-cell treatment for cancer may also require dental services, suggesting that these dental services are inextricably linked to covered CAR T-cell medical services, asserting that dental and oral services improve clinical outcomes for these types of medical services. We also received submissions through the public process providing evidence to show that dental services are inextricably linked to the clinical success of CAR T-cell medical services and other lymphodepleting therapy when used in the treatment of cancer. The submissions stated that, because CAR T-cell medical services cause a patient to be immunosuppressed, an untreated oral or dental infection could complicate or compromise the clinical outcome of the CAR T-cell medical service. Two submissions cited research indicating that patients undergoing CAR T-cell therapy and other lymphodepleting therapy, which is a short course of chemotherapy for the purpose of killing off a portion (or all) of the patient's own lymphocytes and/or other white blood cells prior to an immunotherapy or a bone marrow transplant, experience a higher infection risk in the first 100 days post-

treatment.[76] Submitters also stressed the need to detect early and monitor for dental issues during CAR T-cell therapy in order to avoid the increased risk of related infections and complications. These submissions also highlighted that clinical practice guidelines recommend dental services prior to initiating the CAR T-cell therapy and other lymphodepleting therapy in order to eliminate any sources of infection before and during treatment.[77] [78] [79] [80] [81]

After consideration of clinical practice guidelines, recommendations provided by the public, and our analyses of the studies and research available regarding the connection between dental services and the clinical success of CAR T-cell therapy, we are persuaded that dental services to diagnose and treat infection prior to CAR T-cell therapy are inextricably linked to the clinical success of CAR T-cell therapy, and that these services also represent a clinically analogous scenario to dental services for which Medicare payment under Parts A and B is currently permitted when furnished in the inpatient or outpatient setting, such as prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures. We believe there is an inextricable link between dental and CAR T-cell therapy when used in the treatment of cancer because the standard of care is such that one would not proceed with the medical procedure or service without performing the dental service because the covered medical services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services and that dental services are a clinical prerequisite to proceeding with the CAR T-cell therapy when used in the treatment of cancer.

We believe that proceeding without a dental or oral exam and necessary diagnosis and treatment of any presenting infection of the mouth prior to (CAR) T-cell therapy when used in the treatment of cancer could lead to systemic infection or sepsis, as well as other complications for the patient. We also believe that an oral or dental infection could present substantial risk to the success of the (CAR) T-cell therapy when used in the treatment of cancer, such that the standard of care would be to not proceed with the procedure when there is a known oral or dental infection present. We believe dental services furnished to identify, diagnose, and treat oral or dental infections prior to and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with (CAR) T-cell therapy when used in the treatment of cancer are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to these other covered medical services. As such, we are proposing to add this clinical scenario to the examples of clinical scenarios under which payment can be made for certain dental services in our regulation at § 411.15(i)(3)(i)(A). Specifically, we propose to amend the regulation to include a dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered CAR T-cell therapy when used in the treatment of cancer; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, CAR T-cell therapy when used in the treatment of. We seek comments on all aspects of this proposal.

We also seek comment on whether we should add as an example of dental services for which payment may be made under Medicare Parts A and B other types of lymphodepleting medical services used for cancer treatment, in addition to those used in conjunction with CAR T-cell therapy for cancer treatment. Commenters specifically stated that CAR T-Cell therapies constituted lymphodepleting therapies, and we believe there may be other immunotherapies that may have a similar lymphodepletion component, but we received no specific information regarding such therapies. Evidence submitted by the public through the finalized public submission process indicates that treatment-induced immunosuppression may also occur with lymphodepleting medical services, and that complications caused by the treatment-induced immunosuppression, including possible infection, may prevent the ability to proceed with the primary, covered medical service (that is, lead to delays in treatment and/or cause inability of the patient to complete the course of treatment, thereby potentially reducing the effectiveness of the therapy) and the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection. However, we request comment on what specific medical services also involve lymphodepletion and should therefore be considered in addition to CAR T-cell therapy. We also request additional information regarding how those specific services might be impacted by dental infections/conditions. We note that if we receive compelling clinical evidence, we may finalize in the CY 2024 PFS final rule additional clinical scenarios, such as dental services prior to other types of specific lymphodepleting medical services where the treatment may induce immunosuppression for patients with cancer and the standard of care would be to not proceed with the medical services without having first complete the dental services, where payment could be made under Medicare Part A or Part B. We are seeking comment on whether there is a significant quality of care detriment if certain dental services are not provided prior to these other types of lymphodepleting medical services, and if so, we request a description of that systematic evidence. Specifically, similar to the evidence we requested in the CY 2023 PFS proposed rule, we are looking for medical evidence that the provision of certain dental services leads to improved healing, improved quality of surgery, and the reduced likelihood of readmission and/or surgical revisions, because an infection has interfered with the integration of the implant and interfered with the implant to the

[76] Wudhikarn K, Palomba ML, Pennisi M, Garcia-Recio M, Flynn JR, Devlin SM, Afuye A, Silverberg ML, Maloy MA, Shah GL, Scordo M, Dahi PB, Sauter CS, Batlevi CL, Santomasso BD, Mead E, Seo SK, Perales MA. Infection during the first year in patients treated with CD19 CAR T cells for diffuse large B cell lymphoma. Blood Cancer J. 2020 Aug 5;10(8):79. *doi: 10.1038/s41408–020–00346–7.* PMID: 32759935; PMCID: PMC7405315.

[77] Elad S, Raber-Durlacher JE, Brennan MT, Saunders DP, Mank AP, Zadik Y, Quinn B, Epstein JB, Blijlevens NM, Waltimo T, Passweg JR, Correa ME, Dahllöf G, Garming-Legert KU, Logan RM, Potting CM, Shapira MY, Soga Y, Stringer J, Stokman MA, Vokurka S, Wallhult E, Yarom N, Jensen SB. Basic oral care for hematology-oncology patients and hematopoietic stem cell transplantation recipients: a position paper from the joint task force of the Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology (MASCC/ISOO) and the European Society for Blood and Marrow Transplantation (EBMT). Support Care Cancer. 2015 Jan;23(1):223–36. Epub 2014 Sep 5. PMID: 25189149; PMCID: PMC4328129. *doi: 10.1007/s00520–014–2378–x.*

[78] University of Michigan, CAR–T Cell Patient Dental Clearance Instructions, no date. CellularTherapyDentalForm.pdf (*umich.edu*).

[79] Guideline on dental management of pediatric patients receiving chemotherapy, hematopoietic cell transplantation, and/or radiation. Pediatr Dent, 2008; 30(7 Suppl):219–225.

[80] McGuire DB, Correa ME, Johnson J, Wienandts P. The role of basic oral care and good clinical practice principles in the management of oral mucositis. Support Care Cancer, 2006; 14(6):541–547. *doi:10.1007/s00520–006–0051–8 8.*

[81] Vendrell Rankin K, Jones DL, Redding SW (Eds.), Oral Health in Cancer Therapy: A Guide for Health Care Professionals [3rd edition], Baylor Oral Health Foundation and the Cancer Prevention and Research Institute of Texas, 2008. *https://doi.org/10.1002/9781118416426.ch101.*

skeletal structure. If commenters are able to provide us with compelling evidence to support that a dental exam and necessary treatment prior to specific other lymphodepleting medical services where the treatment may induce immunosuppression for patients with cancer, would result in clinically significant improvements in quality and safety outcomes, for example, fewer revisions, fewer readmissions, more rapid healing, quicker discharge, quicker rehabilitation for the patient, then we would consider whether such dental services may be inextricably linked to, and substantially related and integral to the clinical success of, the specific lymphodepleting medical services for patients with cancer.

c. Dental Services Inextricably Linked To Administration of High-Dose Bone-Modifying Agents (Antiresorptive Therapy) When Used in the Treatment of Cancer

As discussed above, submissions received through the public process we established in the CY 2023 PFS final rule stated that medication-related osteonecrosis of the jaw (MRONJ) is a serious complication of the administration of bone-modifying agents (such as bisphosphonates and denosumab, and other biosimilar agents) used when managing certain cancers.[82] MRONJ is a rare occurrence, multifactorial in nature, and can have the same clinical presentation in patients who have not been exposed to an antiresorptive medication.[83] that Medicare make payment under Parts A and B for dental services for patients where high-dose bisphosphonate therapy for cancers is indicated and recommended payment for dental services prior to and during antiresorptive therapy or prior to, during, and after the use of bone-modifying drugs. Additionally, in our internal review of clinical practice guidelines, we noted that one professional society provided recommendations regarding dental services prior to the initiation of, or during, the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer. Specifically, the Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology (MASCC/ISOO) and American Society of Clinical Oncology (ASCO) Clinical Practice Guideline[84] states that cancer patients should receive an oral care assessment (including a comprehensive dental, periodontal, and oral radiographic exam, when feasible) prior to initiating the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer in order to reduce complications and manage modifiable risk factors. We believe that this practice guideline demonstrate that the standard of care would be to address dental infections prior to proceeding with the covered medical procedure, including oral care assessments and the completion of medically necessary dental procedures prior to the start of the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer, especially as these dental concerns and/or procedures may relate to the cancer treatment and avoidance of MRONJ.

In summary, after consideration of clinical practice guidelines, recommendations provided by the public, and our analyses of the studies and research available regarding the connection between dental services and the clinical success of the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer, we are proposing to add this clinical scenario to the examples of clinical scenarios under which payment can be made for certain dental services in our regulation at § 411.15(i)(3)(i)(A). We believe that there is an inextricable link between dental and administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer because the standard of care is such that one would not proceed with the medical procedure or service without performing the dental service because the covered medical services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services and that dental services are a clinical prerequisite to proceeding with the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer. Specifically, we propose to amend the regulation to include dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered the administration of Medicare-covered high-dose bone-modifying agents (antiresorptive therapy), when used in the treatment of cancer; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, administration of high-dose bone-modifying agents (antiresorptive therapy), when used in the treatment of cancer. We seek comments on all aspects of this proposal.

We note that in the CY 2023 PFS final rule (87 FR 70225) and now codified in our regulation at § 411.15(i)(3)(i), we finalized that for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service, payment may be made under Medicare Parts A and B for services when furnished in either the inpatient or outpatient setting; therefore, we proposed that these provisions would apply to the proposed amendments to regulation at § 411.15(i)(3)(i) to allow for payment under Medicare Parts A and Part B in either the inpatient or outpatient setting. We further propose that payment under the applicable payment system could also be made for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and use of the operating room as described in our regulation at § 411.15(i)(3)(ii).

If the proposed policies are finalized, we anticipate making conforming changes to the Medicare Benefit Policy Manual (IOM Pub. 100–02) to reflect the final changes or clarifications. Additionally, if finalized, we intend to issue educational and outreach materials to inform billing and payment for any policies finalized in the final rule We seek comments on these proposals.

d. Proposed Amendments to Regulations Regarding Dental Services Inextricably Linked to Treatment for Head and Neck Cancer

In the CY 2023 PFS final rule, we finalized for CY 2024 that payment under Medicare Parts A and B can be made for an oral or dental examination as part of a comprehensive workup in either the inpatient or outpatient setting, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection, prior to and contemporaneously with treatments (radiation, chemotherapy, and surgery) for head and neck cancer (87 FR 69671, 69677, and 69681–69682). We note that we stated the policy in some instances

[82] American Association of Oral and Maxillofacial Surgeons. (2022). Medication-related osteonecrosis of the Jawn-2022 update (position paper). Available at: *https://www.aaoms.org/docs/govt_affairs/advocacy_white_papers/mronj_position_paper.pdf.*

[83] American Association of Oral and Maxillofacial Surgeons. (2022). Medication-related osteonecrosis of the Jawn-2022 update (position paper). Available at: *https://www.aaoms.org/docs/govt_affairs/advocacy_white_papers/mronj_position_paper.pdf.*

[84] Yarom N, Shapiro CL, Peterson DE, et al. Medication-Related Osteonecrosis of the Jaw: MASCC/ISOO/ASCO Clinical Practice Guideline. J Clin Oncol. 2019 Sep 1;37(25):2270–90. doi: *https://dx.doi.org/10.1200/JCO.19.01186.* PMID: 31329513.

without explicitly including both ''prior to'' and ''contemporaneously with.'' (87 FR 69669, 69681, 69682, and 69687.)

We also indicated that we wanted to continue to consider various aspects of our finalized policy and that we anticipated additional clarifying rulemaking on this final policy for CY 2024. In the CY 2023 PFS final rule we stated that we wanted to examine the clinical data and consider whether greater specificity may be needed to describe the medical services involved in this type of treatment. We stated that we were cognizant of concerns that, absent clear guidelines and definitions, beneficiaries, practitioners, and MACs may need additional information prior to providing payment under Medicare Parts A and B, and without it could lead to inconsistent application of the policy. In particular, we stated that it is important to determine whether any additional guidance is necessary to identify conditions considered ''head and neck cancer'' and qualifying covered medical services considered within the treatments for these cancers beyond just radiation (with or without chemotherapy).

Upon further study, as pointed out by one submitter, we understand that the term ''head and neck cancer'' encompasses a multitude of pathologies that often require multi-modality therapies including radiation, chemotherapy and surgery. This submitter noted that approximately 80 percent of head and neck cancer patients will receive radiation therapy at least once during the course of their disease. While the majority of head and neck cancers are squamous cell carcinomas that originate from the mucosa of the oral cavity, pharynx or larynx, they may also arise from the salivary glands, the nasal cavities and the paranasal sinuses. They can be locally advanced, regionally metastatic to the cervical nodes and can spread to distant sites such as the lungs and liver. According to the submitter, regardless of origin, the clinical diagnostic and therapeutic approaches for head and neck cancers are fundamentally similar, and treatment modalities often result in both acute and chronic oral toxicities.

If unaddressed, existing oral or dental infection may compromise the delivery of the appropriate modalities of care (radiation, chemotherapy, surgery). The standard of care is to address and eliminate oral and dental infections prior to the treatment of some (or many) head and neck cancers. Additionally, as discussed in section II.K.2.a of this proposed rule, the complications caused by treatment-induced vulnerabilities, which may include infection and osteoradionecrosis, can prevent the ability to proceed with the primary, covered medical service (that is, can lead to delays in treatment and/or cause inability of the patient to complete the course of treatment, thereby potentially reducing effectiveness of the therapy); and the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection.

As discussed in the CY 2023 final rule, we believe that addressing any oral or dental infection prior to the initiation of treatment serves to minimize the potential development of the treatment-induced complications. Moreover, we believe that these treatment-induced complications can occur as a result of and during multiple rounds of treatment.

Therefore, we are proposing to clarify that Medicare Parts A and B payment may be made for dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting, as well as for the medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to the initiation of, or during, treatments for head and neck cancer, whether primary or metastatic, regardless of site of origin, and regardless of initial modality of treatment.

In summary, we are proposing to amend our regulation at § 411.15(i)(3)(i)(A) to allow for payment under Medicare Parts A and Part B for:

(1) Dental or oral examination in either the inpatient or outpatient setting prior to the initiation of, or during, Medicare-covered treatments for head and neck cancer; and

(2) Medically necessary diagnostic and treatment services to eliminate an oral or dental infection in either the inpatient or outpatient setting prior to the initiation of, or during, Medicare-covered treatments for head and neck cancer.

We note that in the CY 2023 PFS final rule (87 FR 70225) and now codified in our regulation at § 411.15(i)(3)(i), we finalized that for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service, payment may be made under Medicare Parts A and B for services when furnished in either the inpatient or outpatient setting; therefore, we proposed that these provisions would apply to the proposed amendments to regulation at § 411.15(i)(3)(i) to allow for payment under Medicare Parts A and Part B in either the inpatient or outpatient setting. We further propose that payment under the applicable payment system could also be made for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and use of the operating room as described in our regulation at § 411.15(i)(3)(ii). If finalized, we anticipate making conforming changes to the Medicare Benefit Policy Manual (IOM Pub. 100–02) to reflect the final changes or clarifications. We seek comments on all aspects of these proposals.

3. Request for Information on Dental Services Integral to Covered Cardiac Interventions

In the CY 2023 PFS final rule, we finalized a policy to permit payment for dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered cardiac valve replacement or valvuloplasty procedures; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the cardiac valve replacement or valvuloplasty procedure (87 FR 69675).

We recognized that, without a dental or oral exam and necessary diagnosis and treatment of any presenting infection of the mouth prior to a cardiac valve replacement or valvuloplasty procedure, an undetected, non-eradicated oral or dental infection could lead to bacteria seeding the valves and the surrounding cardiac muscle tissues involved with the surgical site and conceivably leading to systemic infection or sepsis, all of which increase the likelihood of unnecessary and preventable acute and chronic complications for the patient (87 FR 69667).[85] Specifically, we noted that the replaced valve is also at risk of being a seeding source for future endocarditis. Endocarditis can carry a high risk of mortality for these patients, and eliminating an infection prior to or contemporaneously with the procedure would be important for preventing future endocarditis related to the new valve (87 FR 69678).

We also concluded that an oral or dental infection could present a substantial risk to the success of organ transplants, such that the standard of care would be to not proceed with the procedure when there is a known oral or dental infection present. We stated

[85] Knox, K.W., & Hunter, N. (1991). The role of oral bacteria in the pathogenesis of infective endocarditis. Australian dental journal, 36(4), 286–292. *https://doi.org/10.1111/j.1834–7819.1991.tb00724.x.*

that we believe dental services furnished to identify, diagnose, and treat oral or dental infections prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to these other covered medical services (89 FR 69667).

We encouraged the public to use the public submission process finalized in the CY 2023 PFS final rule to identify additional clinical scenarios and related medical evidence to support an inextricable link between specified dental services and other covered medical services.

Through the submission process, an interested party has encouraged CMS to consider extending Medicare payment to include dental services to eliminate infection prior to all cardiovascular procedures, as the mitigation of risks of perioperative and postoperative infection and complications is critical to ensure optimal surgical outcomes for all patients requiring invasive and/or interventional cardiac procedures. This submission noted that the current standard of care does not conclusively require dental evaluation, diagnosis, or treatment services prior to certain cardiac procedures, perhaps in part because such cardiac procedures are often performed on a more urgent or emergent basis where there is not an opportunity to consider the possible presence of dental infection. Moreover, the submission noted that much of the scientific literature is inconclusive as to whether pre-operative dental treatments impact postoperative surgical outcomes in cardiovascular surgery, including cardiac valve procedures.[86] A systematic literature review by Cotti *et al.* found that, based upon expert opinion, there is general agreement on the need for screening and treatment of oral/dental infections in patients who are to undergo cardiac surgery (although no standardized clinical guidelines or protocols exist to outline the screening process, in terms of either dental treatment options and/or timing of such procedures in relation to the planned cardiac intervention).[87] The authors convened an expert panel from six Italian scientific societies (including cardiologists, cardiac surgeons, and dental specialists) to establish a consensus on early screening and resolution of dental or periodontal infections prior to cardiac surgery, that they intended would result in a standardized protocol for evaluating oral infections and dental treatments for cardiac patients to be used in the interventional preparation phase by both dental and cardiac teams.[88] The authors noted, however, the lack of scientific evidence on the risk-to-benefit ratio for perioperative dental treatment in patients undergoing cardiovascular surgery.

We believe, after further review of current medical practice, through consultations with interested parties (including commenters on last year's final rule and those commenting on current topics) and our medical officers, and through evidence submitted through the public submission process we established in the CY 2023 PFS final rule, that there may be additional circumstances that are clinically similar to examples we codified in our regulation at § 411.15(i)(3)(i) where Medicare payment for dental services could be made under other clinical circumstances where the dental services are inextricably linked to a covered cardiac medical service(s).

To gain further understanding of any potential relationship between dental services and specific covered cardiac medical services, we again partnered with researchers at the AHRQ to review available clinical evidence regarding the relationship between dental services and covered cardiac medical services, including implantation of ventricular assist devices, artificial pacemakers, implantable defibrillators, synthetic vascular grafts and patches, and coronary and vascular stents. This AHRQ report[89] is available at *https://effectivehealthcare.ahrq.gov/products/implantable-cardiovascular-devices/rapid-review.*

As stated in their report, the available evidence does not permit conclusions regarding the effect of pre-treatment dental care for preventing downstream infections related to any of these devices. They noted that professional society guidelines endorse the provision of patient education on routine oral hygiene practices but have not recommended other pre-treatment dental care prior to insertion of these devices. They also noted that professional society guidelines recommend ongoing routine dental examinations for some patients treated with cardiovascular devices.

Nonetheless we seek comment to identify additional cardiac interventions (that is, specific medical services) where the risk of infection posed to beneficiaries is similar to that associated with cardiac valve replacement or valvuloplasty. We note that, in order to consider whether certain dental services are inextricably linked to the clinical success of other covered medical services, we need to identify specific medical services for which there is clinical evidence that certain dental services are so integral to the clinical success that they are inextricably linked to other covered service(s). We encourage interested parties to use the public submission process to submit recommendations and relevant clinical evidence for establishing this connection. Above, in section II.K.1.c. of this proposed rule, we have described the various types of documentation to support recommendations through this process. We are considering, and seek comment on, whether the following cardiac interventions are examples of specific medical services for which dental services are inextricably linked to clinical success: implantation of electronic devices in the heart, such as pacemakers, cardioverter defibrillators, and monitors. We are also considering, and seek comment on, whether the following procedures would be considered examples of specific medical services for which dental services are inextricably linked to their clinical success: the placement of intracardiac or intravascular foreign material, such as a stent or for hemodialysis, or for a vascular access graft, whereas you would not proceed with the medical service without having first completed a dental evaluation and/or treatment as determined necessary. We seek comment on whether preoperative and perioperative dental services are inextricably linked to any other covered cardiac interventions as supported by clinical evidence.

[86] Lockhart, P.B., DeLong, H.R., Lipman, R.D., Estrich, C.G., Araujo, M.W.B. and Carrasco-Labra, A. (2019). Effect of dental treatment before cardiac valve surgery: Systematic review and meta-analysis. Journal of the American Dental Association,150(9). 739–747. *https://doi.org/10.1016/j.adaj.2019.04.024.*

[87] Cotti, E., Cairo, F., Bassareo, P.P., Fonzar, F., Venturi, M., Landi, L., Parolari, A., Franco, V., Fabiani, C., Barili, F., Di Lenarda, A., Gulizia, M., Borzi, M., Campus, G., Musumeci, F., and Mercuro, G. (2019). Perioperative dental screening and treatment in patients undergoing cardiothoracic surgery and interventional cardiovascular procedures. A consensus report based on RAND/UCLA methodology. International Endodontic Journal,53. 186–199. *https://doi.org/10.1111/iej.13166.*

[88] *Ibid.*

[89] Hickam DH, Gordon CJ, Armstrong CE, Paynter R. The Efficacy of Dental Services for Reducing Adverse Events in Those Undergoing Insertion of Implantable Cardiovascular Devices. Rapid Response. (Prepared by the Scientific Resource Center under Contract No. 75Q80122C00002.) AHRQ Publication No. 23–EHC020. Rockville, MD: Agency for Healthcare Research and Quality; June 2023. DOI: *https://doi.org/AHRQEPCRAPIDDENTALCARDIO.*

4. Request for Comment on Dental Services Integral to Specific Covered Services To Treat Sickle Cell Disease (SCD) and Hemophilia

Interested parties using the public submission process we finalized in the CY 2023 PFS final rule urged us to propose to provide that payment can be made for dental services for individuals living with SCD and hemophilia.

These submissions provided information and references supporting prevention of dental infection among individuals with SCD to reduce need for more extensive procedures that may result in bleeding complications and require hospitalization. They also provided information detailing increased dental caries and periodontal disease in people with SCD,[90] many of whom lose a number of teeth, which greatly limits nutrition, general well-being, and overall quality of life.

We seek comment on whether certain dental services are inextricably linked to other covered services used in the treatment of SCD, such as, but not limited to, hydroxyurea therapy. We seek comment identifying such covered services for SCD and whether an inextricable link is supported by clinical evidence as described in section II.K.1.c. of this proposed rule.

Interested parties also urged us to propose a policy to permit payment for dental services for individuals living with hemophilia. They noted that periodic dental care reduces the risks of dental complications requiring haemostatic therapy (such as tooth extractions that may require clotting factor treatment) or oral surgeries requiring clotting factor replacement therapy.[91] [92] [93]

We note that many submitters stated that good dental and oral health benefits a patient's overall health generally. Several commenters on the CY 2023 PFS proposed rule also expressed that good oral hygiene, along with routine dental services, contributes to better outcomes for patients. We recognized in the CY 2023 PFS final rule in response to those comments that there is a great deal of evidence suggesting that dental health is generally an important component of overall health; however, we are interested in comments on whether certain dental services are considered so integral to the primary covered services that the necessary dental interventions are inextricably linked to, and substantially related and integral to clinical success of, the primary covered services such that they are not subject to the statutory preclusion on Medicare payment for dental services under section 1862(a)(12) of the Act.

We seek comment on whether certain dental services are inextricably linked to certain other covered services for hemophilia, supported by clinical evidence as described in section II.K.1.c., above. We seek comment identifying such covered services for the treatment of hemophilia. We also seek comment specifically on whether dental services such as prophylaxis are a standard of care in the management of hemophilia.

5. Request for Comment Regarding Dental Services Possibly Inextricably Linked to Other Medicare-Covered Services

Commenters, submitters, and other interested parties have urged us to consider the importance of access to oral health care for people with chronic auto-immune conditions, and other chronic disease conditions, such as, but not limited to, diabetes. We understand and appreciate the interest in such requests. Because the Medicare statute generally prohibits payment for dental services payment may only be made when the dental services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered services. We urge interested parties to consider the circumstances under which dental services are inextricably linked to specific covered services (not diagnoses) used to treat patients with auto-immune conditions or other chronic conditions, supported by clinical evidence as described in section II.K.1.c. of this proposed rule.

We have encouraged interested parties who believe certain dental services are inextricably linked to certain covered services to use our public submission process to provide information on these clinical scenarios, supported by clinical evidence or other documentation, as discussed in section II.K.1.c. of this proposed rule, such as that it would be the standard of care to not proceed with the medical service without having completed the dental service. Commenters are welcome to submit additional information regarding clinical scenarios presented in the CY 2023 PFS rulemaking discussions, which we are not proposing for the CY 2024, such as dental services involved with the treatment of chronic conditions such as, but not limited to, diabetes (87 FR 69686). As summarized above in section II.K.1.c. of this proposed rule, through the public submission process we finalized in the CY 2023 PFS final rule, interested parties should submit medical evidence to support an inextricable link between certain dental services and covered services by providing any of the following:

(1) Relevant peer-reviewed medical literature and research/studies regarding the medical scenarios requiring medically necessary dental care;

(2) Evidence of clinical guidelines or generally accepted standards of care for the suggested clinical scenario;

(3) Other ancillary services that may be integral to the covered services; and/or

(4) Other supporting documentation to justify the inclusion of the proposed medical clinical scenario requiring dental services.

As discussed above in section II.K.1.c. of this proposed rule, in order to consider whether certain dental services are inextricably linked to the clinical success of other covered services, we need to identify specific medical services for which there is medical evidence that certain dental services are so integral to the clinical success that they are inextricably linked to the covered service. The medical evidence should support that in the case of surgery, the provision of certain dental services leads to improved healing, improved quality of surgery, and the reduced likelihood of readmission and/or surgical revisions, because an infection has interfered with the integration of the medical implant and/or interfered with the medical implant to the skeletal structure. Medical evidence should be clinically meaningful and demonstrate that the dental services result in a material difference in terms of the clinical outcomes and success of the primary medical procedure such that the dental services are inextricably linked to, and substantially related and integral to, the

[90] Kakkar M, Holderle K, ShethM, Arany S, Schiff L, Planerova A. Orofacial Manifestation and Dental Management of Sickle Cell Disease: A Scoping Review. Anemia. 2021 Oct 22; 2021:5556708. Doi: 10.1155/2021/5556708. PMID: 34721900; PMCID: PMC8556080.

[91] Raso S, Napolitano M, Sirocchi D, Siragusa S, Hermans C. The important impact of dental care on haemostatic treatment burden in patients with mild haemophilia. Haemophilia. 2022 Nov;28(6):996–999. doi: 10.1111/hae.14626. Epub 2022 Jul 25. PMID: 35879819.

[92] Srivastava A, Santagostino E, Dougall A, Kitchen S, Sutherland M, Pipe SW, Carcao M, Mahlangu J, Ragni MV, Windyga J, Llinás A, Goddard NJ, Mohan R, Poonnoose PM, Feldman BM, Lewis SZ, van den Berg HM, Pierce GF; WFH Guidelines for the Management of Hemophilia panelists and co-authors. WFH Guidelines for the Management of Hemophilia, 3rd edition. Haemophilia. 2020 Aug;26 Suppl 6:1–158. doi: 10.1111/hae.14046. Epub 2020 Aug 3. Erratum in: Haemophilia. 2021 Jul;27(4):699. PMID: 32744769.

[93] Peisker A, Raschke GF, Schultze-Mosgau S. Management of dental extraction in patients with Haemophilia A and B: a report of 58 extractions. Med Oral Patol Oral Cir Bucal. 2014 Jan 1;19(1):e55–60. doi: 10.4317/medoral.19191. PMID: 24121912; PMCID: PMC3909433.

clinical success of the covered services. Medical evidence should support that the dental services would result in clinically significant improvements in quality and safety outcomes (for example, fewer revisions, fewer readmissions, more rapid healing, quicker discharge, and quicker rehabilitation for the patient), or, medical evidence should demonstrate that the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection.

6. Request for Information on Implementation of Payment for Dental Services Inextricably Linked to Other Specific Covered Services

We continue to consider improvements to our payment policies for dental services as finalized in the CY 2023 PFS final rule (87 FR 69663 through 69688). As such, we are interested in receiving comments from interested parties on ways to best continue to implement these policies. Additionally, given comments and questions we have received from interested parties through rulemaking and the public submission process, we want to provide further clarity on the policies we finalized in the CY 2023 PFS final rule. Therefore, we are requesting comments on several policies related to implementation of policies for dental services for which Medicare payment can be made.

In the CY 2023 PFS final rule, we clarified and codified our policy on payment for dental services and added in § 411.15(i)(3)(i) of our regulation examples of circumstances where payment can be made for certain dental services, including a dental exam and services to diagnose and eliminate an oral or dental infection prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures (87 FR 69664 through 69667).

We provided as examples of dental services that could be furnished to eradicate infection services such as, but not limited to, diagnostic services, evaluations and exams (for example, CDT codes payable with D0120, D0140 or D0150), extractions (for example, CDT codes payable with D7140, D7210), restorations (removal of the infection from tooth/actual structure, such as filling procedures—for example, CDT codes payable with D2000–2999), periodontal therapy (removal of the infection that is surrounding the tooth, such as scaling and root planing—for example, CDT codes payable with D4000–4999, more specifically D4341, D4342, D4335 and D4910), or endodontic therapy (removal of infection from the inside of the tooth and surrounding structures, such as root canal—for example, CDT codes payable with D3000–3999). However, we continue to believe that additional dental services, such as a dental implant or crown, may not be considered immediately necessary to eliminate or eradicate the infection or its source. Therefore, we reiterate that such additional services would not be inextricably linked to the specific covered services. As such, no Medicare payment would be made for the additional services that are not immediately necessary to eliminate or eradicate the infection. We further clarify that we did not in CY 2023 nor are we proposing in CY 2024 to adjust any payment policy for services involving the preparation for, or placement of dentures, and maintain that these services are not payable under Medicare Parts A and B. We also reiterate our policy, as finalized in the CY 2023 PFS final rule, that Medicare could make payment for dental services occurring over multiple visits, as clinically appropriate. We refer readers to 87 FR 69678 for a more full description of this policy.

We continue to recognize that many Medicare beneficiaries have separate or supplemental dental coverage, such as through a Medigap plan, another private insurance plan offering commercial dental coverage, or for those individuals dually eligible for Medicare and Medicaid, through a state Medicaid program. As a result, we seek comment on the coordination of multiple dental benefits that Medicare beneficiaries may have, if and how other plans currently cover and pay for dental services, and what type of guidance CMS should provide about the dental payment policies we have established and their relationship to other separate or supplemental dental coverages. We also seek comment on approaches utilized by other plans to mitigate issues with third party payment, including when Medicare is secondary payer and when coordinating with state Medicaid programs. In addition, we note there is an informal practice where dental professionals may submit a dental claim to Medicare for the purposes of producing a denial so that Medicaid or another third-party payer can make primary payment. Given the complexity of dental professionals submitting claims for purposes of denial, we seek comment on the impact of third-party payers, including state Medicaid programs, requiring a Medicare denial for adjudication of primary payment for dental services that are not inextricably linked to another specific covered service. In these cases where the dental services are not inextricably linked to another specific covered service, dental professionals must include the appropriate HCPCS modifier on the respective dental claim form, which serves as a certification that the professionals believe that Medicare should not pay the claim. We also seek comment regarding an informal process on claims denials for the purposes of supporting payment by other payers is currently achieved in practice when using the dental claim form 837d. We note that the submission of a claim without one or more of the HCPCS modifier(s) meant to produce a denial shows belief by the enrolled billing practitioner that Medicare, not another payer, should be the primary payer in accordance with all applicable payment policies. As such, submission of a claim for dental services without such a modifier would mean that the billing practitioner believes the dental service is inextricably linked to another Medicare-covered service, or that payment for the service is otherwise permitted under our regulation at § 411.15(i). We seek comment on the practices of other payers related to submission of claims in order to generate a denial and how these practices impact claim submission and claim adjudication with third party payers, including state Medicaid programs. Additionally, we are seeking comment on types of guidance, such as best practices or criteria, that are needed for purposes of coordinating payment for dental services under the policies specified in the rule.

As described in the CY 2023 PFS final rule (87 FR 69663 through 69688), Medicare payment under Parts A and B may be made for dental services that are inextricably linked to the covered primary service. We believe the dental and covered services would most often be furnished by different professionals, and that in order for the dental services to be inextricably linked to the covered services such that Medicare payment can be made, there must be coordination between these professionals. This coordination should occur between the practitioners furnishing the dental and covered services regardless of whether both individuals are affiliated with or employed by the same entity. This coordination can occur in various forms such as, but not limited to, a referral or exchange of information between the practitioners furnishing the dental and covered services. Additionally, any

evidence of coordination between the professionals furnishing the primary medical service and dental services should be documented. If there is no evidence to support exchange of information, or integration, between the professionals furnishing the primary medical service and the dental services, then there would not be an inextricable link between the dental and other covered services within the meaning of our regulation at § 411.15(i)(3). As such, Medicare payment for the dental services would be excluded under section 1862(a)(12) of the statute (though payment for the dental services might be available through supplemental health or dental coverage). Additionally, we are seeking information regarding the potential impact of these payment policies in settings other than inpatient and outpatient facilities, such as federally qualified health centers, rural health clinics, etc. We understand that some Medicare beneficiaries may access dental services in these settings and seek to understand what, if any, impact may potentially occur within the context of this payment policy.

As stated in the CY 2023 PFS final rule, we note that, to be eligible to bill and receive direct payment for professional services under Medicare Part B, a dentist must be enrolled in Medicare and meet all other requirements for billing under the PFS. Alternatively, a dentist not enrolled in Medicare could perform services incident to the professional services of a Medicare enrolled physician or other practitioner. In that case, the services would need to meet the requirements for incident to services under § 410.26, including the appropriate level of supervision, and payment would be made to the enrolled physician or practitioner who would bill for the services (87 FR 69673). In the CY 2023 PFS final rule (87 FR 69687), we finalized that we would continue to contractor price the dental services for which payment is made under § 411.15(i)(3). We will maintain this policy and continue to contractor price the dental services for which payment is made under § 411.15(i)(3) for CY 2024. Additionally, in the CY 2023 PFS final rule, we agreed with the suggestions made by commenters that there may be publicly available data sources that could aid MACs in determining these payment rates in order to account for geographic variation. Recognizing that dental offices may range in the services that they provide, from simple office visits to complex surgical procedures, dental services will continue to be contractor priced. We are seeking comment on what specific information could help inform appropriate payment for these dental services (87 FR 69679).

In the CY 2023 PFS final rule (87 FR 69682), we stated that we would update our payment files, so that these dental services could be billed appropriately under the applicable payment system for services furnished in either the inpatient or outpatient setting. We have revised the HCPCS and PFS payment and coding files to include payment indicators for Current Dental Terminology (CDT) codes, such as bilateralism, multiple procedures, and other indicators that are included in the PFS Relative Value (RVU) files (posted at our website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-relative-value-files*) for CDT codes. We seek comment on whether payment indicators as outlined in the PFS RVU files appropriately align with existing dental billing and coding conventions, or whether edits are necessary. Medical and dental providers should bill using CDT or Current Procedure Terminology (CPT) codes where applicable, and for claims submissions during CY 2023, should submit claims using the professional or institutional claim forms, as appropriate. Although we propose to continue contractor pricing services billed using CDT codes, we are soliciting comment on whether the current payment indicators included for these CDT codes follow existing dental billing conventions, for example, for payment adjustment for multiple procedures, and whether there is a need for additional guidance regarding the submission of claims for services for which payment is permitted under the regulation at § 411.15(i)(3). In the CY 2023 PFS final rule (87 FR 69679), we acknowledged the need to address and clarify certain operational issues, and we are continuing to work to address these operational issues, including efforts to adopt the dental claim form. These efforts include continuing to work with our MACs and encouraging continued feedback from interested parties to help identify concerns or questions regarding the submission and processing of dental claims.

Finally, in order to promote the correct coding and processing of Medicare claims, dentists who practice general or specialized dentistry currently self-designate their specialty under two specialty codes, specialty 19 (oral surgery—dentists only) or specialty 85 (maxillofacial surgery). We seek comment on whether additional specialty codes should be considered for use in Medicare, and if so, what are the other specific specialties that should be included. We also seek comment on whether these specialty codes may impact the coordination of benefits with a third-party payer. Finally, we recognize that issues could occur related to coordination of benefits for dual eligible beneficiaries, for example beneficiaries with hemophilia, and we seek comment on how to best coordinate a potential payment policy in this area with respect to state Medicaid plans or private insurance. We also seek comment on other coordination of benefits issues, or implementation topics that would be helpful for CMS to address in relation to continuing to implement these PFS payment policies.

III. Other Provisions of the Proposed Rule

A. Drugs and Biological Products Paid Under Medicare Part B

1. Provisions From the Inflation Reduction Act Relating to Drugs and Biologicals Payable Under Medicare Part B (§§ 410.152, 414.902, 414.904, 489.30)

Drugs and biologicals (for the purposes of the discussion in this section III.A., ''drugs'') payable under Medicare Part B fall into three general categories: those furnished incident to a physician's service (hereinafter referred to as ''incident to'') (section 1861(s)(2) of the Act), those administered via a covered item of durable medical equipment (DME) (section 1861(n) of the Act), and others as specified by statute (for example, certain vaccines described in sections 1861(s)(10)(A) and (B) of the Act). Payment amounts for most drugs separately payable under Medicare Part B 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.

The Inflation Reduction Act (Pub. L. 117–169, August 16, 2022) (hereinafter referred to as ''IRA'') contains several provisions that affect payment limits or beneficiary out-of-pocket costs for certain drugs payable under Part B. Among those provisions, two affect payment limits for biosimilar biological products (hereinafter referred to as ''biosimilars''):

- Section 11402 of the IRA amends the payment limit for new biosimilars furnished on or after July 1, 2024 during the initial period when ASP data is not available. We are proposing to codify this provision in regulation.
- Section 11403 of the IRA makes changes to the payment limit for certain

biosimilars with an ASP that is not more than the ASP of the reference biological for a period of 5 years. We implemented section 11403 of the IRA under program instruction,[94] [95] as permitted under section 1847A(c)(5)(C) of the Act. We are now proposing conforming changes to regulatory text to reflect these provisions.

In addition, two provisions (among others in the IRA) make statutory changes that affect beneficiary out-of-pocket costs for certain drugs payable under Medicare Part B:

- Section 11101 of the IRA requires that beneficiary coinsurance for a Part B rebatable drug is to be based on the inflation-adjusted payment amount if the Medicare payment amount for a calendar quarter exceeds the inflation-adjusted payment amount, beginning on April 1, 2023. We issued initial guidance implementing this provision, as permitted under section 1847A(c)(5)(C) of the Act, on February 9, 2023.[96] We are proposing conforming changes to regulatory text.
- Section 11407 of the IRA provides that for insulin furnished through an item of DME on or after July 1, 2023, the deductible is waived and coinsurance is limited to $35 for a month's supply of insulin furnished through a covered item of DME. We have implemented this provision under program instruction for 2023, as permitted under section 11407(c) of the IRA.[97] We are now proposing to codify this provision in a manner that is consistent with the program instruction for 2023.

a. Payment for Drugs Under Medicare Part B During an Initial Period

Section 1847A of the Act provides for certain circumstances in which the payment limit of a drug is based on its wholesale acquisition cost (WAC). For a single source drug or biological (as defined in section 1847A(c)(6)(D) of the Act), the Medicare payment could have a WAC-based payment determined under the methodology specified in section 1847A(b)(4) of the Act and described at § 414.904(d)(1), which requires that payment limits for such drugs are determined using the lesser of ASP plus 6 percent or WAC plus 6 percent. Typically, the ASP-based payment limit is the lesser of the two. Under section 1847A(c) of the Act, payments for new drugs during an initial period for which ASP data is not sufficiently available are based on WAC or the Medicare Part B drug payment methodology in effect on November 1, 2003. Historically, WAC-based payment under section 1847A(c)(4) of the Act was up to 106 percent of WAC, but in the CY 2019 PFS final rule (83 FR 59661 through 59666), we adopted a policy of paying up to 103 percent of WAC in this instance. Subsequently, section 6 of the Sustaining Excellence in Medicaid Act of 2019 (Pub. L. 116–39, enacted August 6, 2019), amended section 1847A(c)(4) of the Act to specify, effective January 1, 2019, a payment limit not to exceed 103 percent of the WAC or based on the Part B drug payment methodology in effect on November 1, 2003 during an initial period when ASP data is not sufficiently available. There were no regulatory changes at that time. Therefore, we are proposing to amend § 414.904(e)(4) to reflect this statutory change.

More recently, section 11402 of the IRA amended section 1847A(c)(4) of the Act by adding subparagraph (B), which limits the payment amount for biosimilars during the initial period described in section 1847A(c)(4)(A) of the Act. The provision requires that for new biosimilars furnished on or after July 1, 2024, during the initial period when ASP data is not sufficiently available, the payment limit for the biosimilar is the lesser of (1) an amount not to exceed 103 percent of the WAC of the biosimilar or the Medicare Part B drug payment methodology in effect on November 1, 2003, or (2) 106 percent of the lesser of the WAC or ASP of the reference biological, or in the case of a selected drug during a price applicability period, 106 percent of the maximum fair price of the reference biological.

We propose to codify these changes to section 1847A(c)(4) of the Act at § 414.904. Specifically, we are proposing to revise paragraph (e)(4) at § 414.904 by adding paragraphs (e)(4)(i)(A) and (B) to conform the regulatory text for WAC-based payment limits before January 1, 2019 and for such payment limits on or after January 1, 2019 with the requirements established in section 6 of the Sustaining Excellence in Medicaid Act of 2019. We are also proposing to add paragraphs (A) and (B) to § 414.904(e)(4)(ii) to codify the payment limit for new biosimilars furnished on or after July 1, 2024 during the initial period as required by section 1847A(c)(4)(B) of the Act.

b. Temporary Increase in Medicare Part B Payment for Certain Biosimilar Biological Products

Consistent with section 1847A(b)(8) of the Act, Medicare Part B payment limit for a biosimilar is its ASP plus 6 percent of the reference biological product. In the CY 2016 PFS final rule (80 FR 71096 through 71101), we clarified that the payment limit for a biosimilar biological product is based on the ASP of all National Drug Codes (NDCs) assigned to the biosimilar biological products included within the same billing and payment code and amended § 414.904(j) to reflect this policy. In the CY 2018 PFS final rule (82 FR 53182 through 53186), we finalized a policy to separately assign individual biosimilar biological products to separate billing and payment codes and pay for biosimilar biological products accordingly. However, we did not change the regulation text at § 414.904(j) at that time.

Section 11403 of the IRA amended section 1847A(b)(8) of the Act by establishing a temporary payment limit increase for qualifying biosimilar biological products furnished during the applicable 5-year period. Section 1847A(b)(8)(B)(iii) of the Act defines ''qualifying biosimilar biological product'' (hereinafter referred to as ''qualifying biosimilars'') as a biosimilar biological product (as described in section 1847A(b)(1)(C) of the Act) with an ASP (as described in section 1847A(b)(8)(A)(i) of the Act) less than the ASP of the reference biological for a calendar quarter during the applicable 5-year period. Section 11403 of the IRA requires that a qualifying biosimilar be paid at ASP plus 8 percent of the reference biological's ASP rather than 6 percent during the applicable 5-year period. Section 1847A(b)(8)(B)(ii) of the Act defines the applicable 5-year period for a qualifying biosimilar for which payment has been made using ASP (that is, payment under section 1847A(b)(8) of the Act) as of September 30, 2022 as the 5-year period beginning on October 1, 2022. For a qualifying biosimilar for which payment is first made using ASP during the period beginning October 1, 2022 and ending December 31, 2027, the statute defines the applicable 5-year period as the 5-year period beginning on the first day of such calendar quarter of such payment.[98]

[94] *https://www.cms.gov/files/document/r11496cp.pdf.*

[95] *https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice.*

[96] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.*

[97] *https://www.congress.gov/bill/117th-congress/house-bill/5376/text.*

[98] In accordance with these provisions, the ASP Drug Pricing File reflects the temporary increased payment limit for qualifying biosimilars beginning with the October 2022 file available at *https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice.*

In this proposed rule, we propose to add definitions of ''applicable 5-year period'' and ''qualifying biosimilar biological product'' at § 414.902 to reflect the definitions in statute, and we propose to make conforming changes to regulatory text to reflect the requirements mandated under section 1847A(b)(8)(B) of the Act for the temporary payment limit increase for qualifying biosimilar biological products at § 414.904 (j) by adding paragraphs (j)(1) and (2).

c. Inflation-Adjusted Beneficiary Coinsurance and Medicare Payment for Medicare Part B Rebatable Drugs

Section 11101(a) of the IRA amended section 1847A of the Act by adding a new subsection (i), which requires the payment of rebates into the Supplementary Medical Insurance Trust Fund for Part B rebatable drugs if the payment limit amount exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. The provisions of section 11101 of the IRA are currently being implemented through program instruction, as permitted under section 1847A(c)(5)(C) of the Act. As such, we issued final guidance for the computation of inflation-adjusted beneficiary coinsurance under section 1874A(i)(5) of the Act and amounts paid under section 1833(a)(1)(EE) of the Act on February 9, 2023.[99] [100] For additional information regarding implementation of section 11101 of the IRA, please see the inflation rebates resources page at *https://www.cms.gov/inflation-reduction-act-and-medicare/inflation-rebates-medicare.*

Section 1847A(i)(5) of the Act requires that for Part B rebatable drugs, as defined in section 1847A(i)(2)(A) of the Act, furnished on or after April 1, 2023, in quarters in which the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act (or, in the case of selected drugs described under section 1192(c) of the Act, the amount specified in section 1847A(b)(1)(B) of the Act), exceeds the inflation-adjusted payment amount determined in accordance with section 1847A(i)(3)(C) of the Act, the coinsurance will be 20 percent of the inflation-adjusted payment amount for such quarter (hereafter, the inflation-adjusted coinsurance amount). This inflation-adjusted coinsurance amount is applied as a percent, as determined by the Secretary, to the payment amount that would otherwise apply for such calendar quarter in accordance with section 1847A(b)(1)(B) or (C) of the Act, as applicable, including in the case of a selected drug. In this proposed rule, we propose to codify the coinsurance amount for Part B rebatable drugs as required by section 1847A(i)(5) of the Act in § 489.30, specifically by adding a new paragraph (b)(6).

Section 11101(b) of the IRA amended section 1833(a)(1) of the Act by adding a new subparagraph (EE), which requires that if the inflation-adjusted payment amount of a Part B rebatable drug exceeds the payment amount described in section 1847A(i)(3)(A)(ii)(I) (or, in the case of a selected drug, the payment amount described in section 1847A(b)(1)(B), the Part B payment will, subject to the deductible and sequestration, equal the difference between such payment amount and the inflation-adjusted coinsurance amount. In this proposed rule, we propose to codify the Medicare payment for Part B rebatable drugs in § 410.152, specifically by adding new paragraph (m).

d. Limitations on Monthly Coinsurance and Adjustments to Supplier Payment Under Medicare Part B for Insulin Furnished Through Durable Medical Equipment

Drugs furnished through a covered item of DME are covered under Medicare Part B as provided in sections 1861(n) and (s)(6) of the Act. Insulin administered through covered DME, such as a durable insulin pump, is covered under this benefit. As required by section 1842(o)(1)(C) and (D) of the Act, effective January 1, 2017, infusion drugs furnished through DME, including insulin, are paid under section 1847A of the Act (see 82 FR 53180 through 53181), which is typically ASP plus 6 percent. Prior to July 1, 2023, beneficiaries are responsible for coinsurance of 20 percent of the payment amount of such insulin, subject to the Part B deductible.

Section 11407 of the IRA made three changes to the manner in which beneficiaries pay for insulin furnished through covered DME. First, section 11407(a) of the IRA amended section 1833(b) of the Act to waive the Part B deductible for insulin furnished through covered DME on or after July 1, 2023. Second, section 11407(b)(2) of the IRA amended section 1833(a) of the Act to establish a limit of $35 on the beneficiary coinsurance amount for a month's supply of such insulin furnished on or after July 1, 2023. This statutory change means that the beneficiary coinsurance responsibility, which is limited to $35 for a month's supply of insulin, could equal less than 20 percent if the Part B payment amount of a month's supply of insulin is greater than $175. Third, section 11407(b)(2) of the IRA also added a new sentence to section 1833(a) of the Act to require the Secretary to increase to the Medicare Part B payment to above 80 percent in the case the coinsurance amount for insulin furnished through covered DME equals less than 20 percent of the payment amount to pay for the full difference between the payment amount and coinsurance. The adjustment specified in paragraph (b)(2) ensures the supplier is not responsible for the reduction in the beneficiary coinsurance amount.

The above provisions were implemented through program instruction,[101] as required by section 11407(c) of the IRA, for CY 2023. Section 80 in Chapter 17 and section 140 in Chapter 20 of the Medicare Claims Processing Manual will be updated to reflect these changes, effective July 1, 2023. To operationalize this provision, the $35 coinsurance limit applies to the duration of the calendar month in which the date of service occurs. As stated in the section 110.5, Chapter 15 of the Medicare Benefit Policy Manual,[102] the date of service on the claim must be the date that the beneficiary or authorized representative receives the insulin or, for mail order, the date the insulin is shipped. A new $35 coinsurance limit for a month's supply applies to each calendar month. It follows that, as stated in the program instruction, when a 3-month supply (that is, the amount of such insulin that is required for treatment for up to 3 calendar months) is billed for insulin furnished through covered DME, that a coinsurance limit of $105 would apply for that 3-calendar month period ($35 coinsurance limit for each month's supply of insulin). The program instruction also states that the Medicare Administrative Contractors (MACs) will ensure that coinsurance does not exceed $35 for a 1-month supply or $105 for a 3-month supply for claims billing insulin administered through covered DME.

[99] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.*

[100] In addition, beginning with the April 2023 ASP Drug Pricing file, the file includes the coinsurance percentage for each drug and specifies ''inflation-adjusted coinsurance'' in the ''Notes'' column if the coinsurance for a drug is less than 20 percent of the Medicare Part B payment amount. Drug pricing files are available at *https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice.*

[101] *https://www.cms.gov/files/document/r11917cp.pdf.*

[102] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/bp102c15.pdf.*

Here, we propose to codify these elements (that are currently in program instruction) for CY 2024 and future years in regulation text, because section 11407(c) of the IRA states that only implementation for CY 2023 may be through program instruction or other forms of guidance. Specifically, we propose to codify the new statutory monthly coinsurance limits of $35 for a 1-month supply and $105 for a 3-month supply at § 489.30 by adding paragraph (b)(7) and the adjustment to the provider payment at § 410.152 by adding paragraph (n). In addition, we propose to codify at § 489.30 that the $35 coinsurance limit for a month's supply of insulin furnished through covered DME will apply to the duration of the calendar month in which the date of service (or services) occurs. In other words, the $35 coinsurance limit will apply for a month's supply of insulin each calendar month. Similarly, we propose to codify that the $105 coinsurance limit for 3 months' supply of insulin furnished through covered DME will apply to the duration of the calendar month in which the date of service (or services) occurs and the 2 following calendar months

2. Request for Information (RFI): Drugs and Biologicals Which Are Not Usually Self-Administered by the Patient, and Complex Drug Administration Coding

Section 1861(s)(2)(A) of the Act allows Medicare to pay for services and supplies, including drugs and biologicals (hereafter, drugs) that are not usually self-administered by the patient, which are furnished as ''incident to'' a physician's professional service. Section 112 of the Benefits, Improvements & Protection Act of 2000 (BIPA) (Pub. L. 106–554, December 21, 2000) amended the above-referenced sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Act, which formerly referred to drugs ''which cannot be self-administered,'' to read, ''which are not usually self-administered.'' Drugs that are ''usually self-administered'' are thus statutorily excluded from coverage and payment under Part B under the ''incident to'' benefit.

We have provided definitions and other guidance for MACs regarding determinations on drugs that are ''not usually self-administered by the patient'' in Chapter 15, Section 50.2 of the Medicare Benefit Policy Manual. Chapter 15 also describes the evidentiary criteria that MACs should use in determining whether a drug is usually self-administered. The guidance directs MACs to publish a description of the process they use to make that determination, and to publish a list of the drugs that are subject to the self-administered exclusion on their website. The guidance also requires that this list include the data and rationale that led to the determinations. This list is referred to as the ''self-administered drug (SAD) list,'' and each MAC maintains their own version of the list, which is applicable to that MAC's area of jurisdiction. While the lists are often similar between MACs, they are not identical. Drugs that are put on a SAD list are excluded from Part B coverage, but in those situations, they are almost always covered by Medicare Part D prescription drug coverage. For several years, interested parties have requested that we update and clarify this SAD list guidance. These parties believe that the current guidance may not adequately address circumstances posed by newly approved drugs.

In a similar vein, we have received concerns from interested parties that non-chemotherapeutic complex drug administration payment has become increasingly inadequate due to existing coding and Medicare billing guidelines that do not accurately reflect the resources used to furnish these infusion services. Interested parties have asserted that these infusion services are similar to complex and clinically intensive Chemotherapy and Other Highly Complex Biological Agent Administration (''Chemotherapy Administration'') services that are billed using CPT code series 96401–96549, as opposed to Therapeutic, Prophylactic, and Diagnostic Injections and Infusion services billed using CPT code series 96360–96379. We note that we discuss our policies for these services in Pub. 100–04 Medicare Claims Processing Manual, Chapter 12, Section 30.5D.

We are soliciting comments on the above two policy areas, since they both involve Part B drug payment policies that have been impacted by new developments in the field. In an effort to promote coding and payment consistency and patient access to infusion services, we are seeking comment and information from interested parties regarding the relevant resources involved, as well as inputs and payment guidelines and/or considerations, that could be used in determining appropriate coding and payment for complex non-chemotherapeutic drug administration. We are seeking comment on whether or not we should revise our policy guidelines as discussed to better reflect how these specific infusion services are furnished and should be billed.

We are also soliciting comments regarding our policies on the exclusion of coverage for certain drugs under Part B which are usually self-administered by the patient. Specifically, we are soliciting comments regarding our policies for the following items:

- Definitions of the following terms, as referenced in this section:
  - ++ ''Administered.''
  - ++ ''Self-Administered.''
  - ++ ''Usually.''
  - ++ ''By the patient.''
- The process for determining which drugs are classified as those ''not usually self-administered by the patient.''
- The process for issuing decisions on which drugs are classified as those ''not usually self-administered by the patient,'' and the process for issuing any changes to those classifications.
- The relevant resources involved, as well as inputs and payment guidelines and/or considerations, that could be used in determining appropriate coding and payment for complex non-chemotherapeutic drug administration.
- Whether or not CMS should revise policy guidelines to better reflect how complex non-chemotherapeutic drug administration infusion services are furnished and billed.

3. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect To Discarded Amounts (§§ 414.902 and 414.940)

a. Background

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021) (hereinafter is referred to as ''the Infrastructure Act'') amended section 1847A of the Act to redesignate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug (hereafter referred to as ''refundable drug''). The refund amount is the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges for the drug in a given calendar quarter.

In the CY 2023 PFS final rule (87 FR 69710 through 69734), we adopted many policies to implement section 90004 of the Infrastructure Act. We finalized the requirement that billing providers and suppliers report the JW modifier for all separately payable drugs with discarded drug amounts from single use vials or single use packages payable under Part B, beginning January 1, 2023. We also finalized the requirement that billing providers and suppliers report the JZ modifier for all

such drugs with no discarded amounts beginning no later than July 1, 2023, and we stated that we would begin claims edits for both the JW and JZ modifiers beginning October 1, 2023 (87 FR 69718 through 69719). Subsequent to the issuance of the CY 2023 PFS final rule, CMS published the JW Modifier and JZ Modifier Policy Frequently Asked Questions (FAQ) document [103] addressing the correct use of these modifiers. We adopted a definition of ''refundable single-dose container or single-use package drug'' at 42 CFR 414.902, which also specifies exclusions from this definition (87 FR 69724). These three exclusions are: radiopharmaceutical or imaging agents, certain drugs requiring filtration, and drugs approved by FDA on or after November 15, 2021, and for which payment has been made under Part B for fewer than 18 months. Regarding reports to manufacturers, we specified that CMS would send reports (including information described in section 1847A(h)(1) of the Act) for each calendar quarter on an annual basis to all manufacturers of refundable drugs (87 FR 69726). We finalized the manner in which the refund amount will be calculated at § 414.940 (87 FR 69731). Regarding drugs with unique circumstances for which CMS can increase the applicable percentage otherwise applicable for determining the refund, we adopted an increased applicable percentage of 35 percent for drugs reconstituted with a hydrogel and with variable dosing based on patient-specific characteristics (87 FR 69731). Lastly, we adopted a dispute resolution process through which manufacturers can challenge refund calculations, and we established enforcement provisions (including manufacturer audits, provider audits, and civil money penalties required by statute) (87 FR 69732 through 69734).

As noted in the CY 2023 PFS final rule (87 FR 69711), sections 11101 and 11102 of the Inflation Reduction Act (IRA) (Pub. L. 117–169, August 16, 2022) established new requirements under which manufacturers must pay inflation rebates if they raise their prices for certain Part B and Part D drugs faster than the rate of inflation. Drug manufacturers are required to pay rebates to Medicare if prices for certain Part B drugs increase faster than the rate of inflation for quarters beginning with the first quarter of 2023; drug manufacturers are required to pay rebates to Medicare if prices for certain Part D drugs increase faster than the rate of inflation over 12-month periods, starting with the 12-month period that began October 1, 2022.

We explained that we believe implementation of the Part B and Part D inflation rebate programs established under the IRA should be considered together with the operational implications of the discarded drug refunds, because the refunds and rebates both require CMS to accept from drug manufacturers payments that must be deposited into the Federal Supplementary Medical Insurance (SMI) Trust Fund.

Therefore, to align the operation of these programs and minimize burden, we declined to finalize some aspects of the invoicing and collection of discarded drug refunds. Specifically, we declined to finalize the timing of the initial reports and which quarters' information will be included in each report. We also declined to finalize specific dates by which manufacturer refund obligations are due and those associated with the dispute resolution process, as those are scheduled in tandem with the reporting dates. Lastly, we stated our intent to address these aspects in future rulemaking.

In this proposed rule, we propose the date of the initial report to manufacturers, the date for subsequent reports, method of calculating refunds for discarded amounts in lagged claims data, method of calculating refunds when there are multiple manufacturers for a refundable drug, increased applicable percentages for certain drugs with unique circumstances, and a future application process by which manufacturers may apply for an increased applicable percentage for a drug, which would precede proposals to increase applicable percentages in rulemaking. We also propose modification to the JW and JZ modifier policy for drugs payable under Part B from single-dose containers that are furnished by a supplier who is not administering the drug.

b. Provision of Information to Manufacturers

In the CY 2023 PFS final rule (87 FR 69724 through 69726), we discussed our proposals related to meeting the requirements under section 1847A(h)(1) of the Act related to the timing and contents of the report to manufacturers, including what types of information to include, which quarters' data we would include in the initial report, the amount of lagged claims data we would include, whether to send reports quarterly or annually, and the definition of a manufacturer. However, we explained that due to the enactment of the IRA and our efforts to align the operations of the refunds with the inflation rebate programs and minimize burden, we did not finalize certain aspects of the discarded drug refund provision. Specifically, we did not finalize the date that we would send the first report to manufacturers or which quarters' information would be included in each report.

Although we did not finalize the noted aspects related to timing, we adopted regulations at § 414.940(a)(3) providing that we will send reports to manufacturers on an annual basis and indicated in the preamble text that reports will contain discard information (described in section 1847A(h)(1)(A) of the Act) for each calendar quarter (87 FR 69724 through 69726). We also finalized that we will send reports to all manufacturers of refundable drugs. In addition, in response to commenters suggesting that we provide manufacturers an opportunity to engage with us on discard amount data in the first year of this provision's implementation, we stated that we would issue, no later than December 31, 2023, a preliminary report on estimated discarded amounts based on available claims data from the first two quarters of CY 2023.

To implement the discarded drug refund in a timely manner, we propose to issue the initial refund report to manufacturers, to include all calendar quarters for 2023, no later than December 31, 2024. (Note that this report, which we refer to as the ''initial refund report'' in this proposed rule, would be separate and distinct from the preliminary report that we intend to issue by December 31, 2023, that will include estimated discarded amounts based on available claims data for the first two quarters of CY 2023.)

With respect to subsequent annual reports, that is, reports for quarters in 2024 and thereafter, we intend to align delivery of the refund reports with the delivery of Part B and Part D inflation rebate reports to the extent practicable. As stated in the initial guidance for Part B inflation rebates,[104] inflation rebate reports will be sent on a quarterly basis, each no later than 6 months after the end of the calendar quarter as required in section 1847A(i)(1)(A) of the Act. Consistent with section 1847A(i)(1)(C) of the Act, CMS may delay reporting Part B inflation rebate information for

[103] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf.*

[104] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.*

calendar quarters in CY 2023 and CY 2024 until September 30, 2025.[105]

To align these reports, we propose that, other than for the initial refund report, we will send annual refund reports for discarded drug refunds for the 4 quarters of a calendar year at or around the time we send Part B inflation rebate report for the first quarter of the following year. Thus, for example, we would send the second refund report for the calendar quarters in 2024 when we send the inflation rebate report for Q1 2025, which is required to be sent no later than September 30, 2025.

As noted in the CY 2023 PFS final rule (87 FR 69725), because providers and suppliers have a 12-month period to submit Medicare Part B claims, including claims for drugs payable under Part B, there can be a lag between the date of service when a drug is administered and when the claim is submitted and adjudicated. Therefore, there is a lag in available JW modifier data for any given date of service quarter. An evaluation of July 2010 Medicare Part B claims in the Physician/Supplier-Carrier setting showed that 91.68, 96.84, and 98.32, and 99.13 percent of claims were final at 3, 6, 9, and 12 months, respectively, following the date of service. At 24 and 48 months after the date of service, 99.83 and 100 percent of the claims, respectively, were considered to be final. Since, based on our evaluation of the 2010 claims data, a small percentage of lagged claims data from a calendar quarter likely would not be available when the quarter is first included on a report, we propose that annual reports (subsequent to the initial report) include lagged claims data (that is, true-up information) for quarters from 2 calendar years prior. In other words, we propose that each report would include information for 8 calendar quarters: 4 from the previous calendar year (hereafter, referred to as new refund quarters) and 4 from 2 calendar years prior (hereafter, referred to as updated refund quarters). We propose all reports (except the initial refund report) would include the following information for updated refund quarters to address lagged claims data:

- The updated total number of units of the billing and payment code of such drug, if any, that were discarded during such updated refund quarter, as determined using a mechanism such as the JW modifier used as of the date of enactment of this subsection (or any such successor modifier that includes such data as determined appropriate by the Secretary).
- The updated refund amount that the manufacturer is liable for with respect to such updated quarter that was not previously accounted for in the prior year's report.

For example, as proposed above, the second annual report (sent no later than September 30, 2025) would include: (1) the total number of units of the billing and payment code of such drug, if any, that were discarded during new refund quarters (all calendar quarters in 2024), (2) the refund amount that the manufacturer is liable for pursuant to section 1847A(h)(3) of the Act for all calendar quarters in 2024, (3) the updated total number of units of the billing and payment code of such drug, if any, that were discarded during the updated refund quarters (all calendar quarters in 2023), and (4) the refund amount that the manufacturer is liable for or the amount CMS owes the manufacturer pursuant to section 1847A(h)(3) of the Act for all calendar quarters in 2023 that was not accounted for in the previous year's report.

We are proposing to define ''new refund quarter'' and ''updated refund quarter'' at § 414.902 and to revise § 414.940(a)(3) to reflect the inclusion of lagged data in reports subsequent to the initial refund report. We solicit comment on these proposals. See section III.A.3.d. of this rule for the proposed calculation of refund amounts for updated refund quarters.

c. Manufacturer Provision of Refund

In the CY 2023 PFS final rule (87 FR 69726 through 69727) we adopted § 414.940(b), which requires manufacturers to pay refunds in 12-month intervals in a form and manner specified by CMS. In the CY 2023 PFS final rule (87 FR 69727), we also discussed our proposal for the timing of both the initial report and manufacturers' corresponding refund obligations. That is, we proposed to issue reports to manufacturers by October 1 and require refund obligations to be paid by December 31, except in circumstances where a dispute is pending. Regulations at § 414.940(b)(2) specify that in the case that a disputed report results in a refund amount due, that amount must be paid no later than 30 days after resolution of the dispute.

However, we declined to finalize the deadlines by which manufacturer refund obligations are due and those associated with the dispute resolution process, as those timelines correspond with the dates of the annual refund reports and, as explained above, we declined to finalize the timeline for the report in the CY 2023 PFS final rule in order to align the operation of the discarded drug refunds with the inflation rebate programs. In the CY 2023 PFS final rule (87 FR 69727), we stated our intent to revisit the process and timeline for manufacturers' provisions of refunds in future rulemaking.

As described in section III.A.3.b. of this proposed rule, we are proposing to issue the initial refund report to manufacturers no later than December 31, 2024. Accordingly, we propose to require that the refund amounts specified in the initial refund report be paid no later than February 28, 2025, except in circumstances where a report is under dispute. We believe a payment deadline that is two calendar months after the issuance of the report provides adequate time for manufacturers to review the reports and submit a dispute if needed prior to the refund payment deadline.

As noted above, we are proposing that we will issue the second annual refund report to manufacturers no later than September 30, 2025, and once annually thereafter no later than September 30 for every year thereafter. Accordingly, we are proposing to require manufacturers to pay refunds specified in each report (beginning with the second report) no later than December 31 of the year in which the report is sent, except in circumstances where a report is under dispute. In cases in which a manufacturer disputes a report, beginning with the initial refund report, any manufacturer liability determined upon the resolution of the dispute would be due by the above stated due date or 30 days following the resolution, as described in § 414.940(b)(2), whichever is later. We propose to revise § 414.940(b)(1) to reflect these dates.

d. Refund Amount

(1) Calculation of Refund Amounts for Updated Quarters

As discussed in section III.A.3.b. of this proposed rule, we are proposing to include information for lagged claims data in all reports other than the initial report. In addition, we propose that such additional lagged JW modifier data, if any, will be used to calculate revisions to the manufacturer refund amount. Specifically, we propose to calculate the refund with updated data in the same manner as was finalized in the 2023 PFS final rule (87 FR 69727) and subtract the refund amount that already paid for such refundable drug for such quarter to determine the updated quarter refund amount. We propose that the refund amount owed

[105] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.*

by a manufacturer, with respect to a refundable drug assigned to a billing and payment code for an updated refund quarter is the amount equal to the estimated amount (if any) by which:

- The product of:

++ The total number of units of the billing and payment code for such drug that were discarded during such quarter; and

++ The amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such quarter.

- Exceeds the difference of:

++ An amount equal to the applicable percentage of the estimated total allowed charges for such a drug (less the amount paid for packaged drugs) during the quarter; and

++ The refund amount previously paid for such refundable drug for the given quarter.

We propose that if the resulting refund calculation for an updated quarter is a negative number, then it will be netted out of the any refund owed for other updated quarters or new quarters.

We propose to revise § 414.940 by adding new paragraphs (c)(2) and (3) to reflect the above proposed method of calculation of revisions to the refund amount owed for quarters in the year that is two calendar years prior.

(2) Calculation of Refund for a Drug When There Are Multiple Manufacturers

In the CY 2023 PFS final rule (87 FR 69727 through 69731), consistent with section 1847A(h)(3) of the Act, we adopted regulations at § 414.940(c) specifying the manner in which the refund amount will be calculated with respect to a refundable drug of a manufacturer assigned to a billing and payment code for a calendar quarter beginning on or after January 1, 2023. The refund for which the manufacturer is liable is the amount equal to the estimated amount (if any) by which:

- The product of:

++ The total number of units of the billing and payment code for such drug that were discarded during such quarter; and

++ The amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such quarter;

- Exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such a drug (less the amount paid for packaged drugs) during the quarter.

We stated we will estimate the total allowed charges during the quarter by multiplying the drug's payment amount for the quarter by the total number of units of the billing and payment code of such drug that were subject to JW modifier reporting including those for which the JZ modifier would be required if no units were discarded. As specified in section 1847A(h)(1)(C) of the Act, the total number of units of the billing and payment code of a refundable drug paid during a calendar quarter for purposes of subparagraph (A)(i) and the determination of the estimated total allowed charges for the drug in the quarter for purposes of paragraph (3)(A)(ii) exclude such units that are packaged into the payment amount for an item or service and are not separately payable.

Because refundable drugs are single source drugs or biologicals, they typically will have one manufacturer. However, a refundable drug could have more than one manufacturer, for example, in the circumstance where a refundable drug is produced by one manufacturer, and also by one or more manufacturer(s) that is a repackager or relabeler. Multiple manufacturers of a refundable drug could also occur in the case of one or more authorized generic products that are marketed under the same FDA-approval as the original FDA applicant. In such cases, the National Drug Codes (NDCs) for the drug typically are assigned to the same billing and payment code, and each manufacturer is responsible for reporting ASP data to CMS, which includes sales volume. In the CY 2023 PFS final rule (87 FR 69724 through 69726), we stated that we would identify the manufacturer responsible for the provision of refunds by the labeler code of the refundable drug.

Therefore, there is a need to establish a method for apportioning billing units of a refundable drug sold during a calendar quarter in situations where there are multiple manufacturers of a refundable drug. When calculating the refund amount owed by manufacturers for a refundable drug that has more than one manufacturer, we propose to identify such refundable drugs using the ASP sales data reported for the calendar quarter for which a refund amount is calculated. Furthermore, we propose to apportion financial responsibility for the refund amount among each manufacturer in the following manner: by dividing the sum of the individual manufacturer's billing units sold during the refund quarter for all the manufacturer's NDCs assigned to the billing and payment code (as reported in the ASP data submissions), by the sum of all manufacturers' billing units sold during the refund quarter for all NDCs of the refundable drug assigned to the billing and payment code (as reported in the ASP data submissions).

This calculation approach is consistent with the approach for apportioning inflation rebate obligations discussed in section 50.13 of the Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments,[106] released on February 9, 2023.

We propose to apportion the discarded drug refund when there is more than one manufacturer for a refundable drug, using the proportion of billing unit sales, expressed as a percentage, attributed to each NDC (at the NDC–11 level) assigned to the billing and payment code for such refund quarter. The number of billing unit sales for each NDC would be the reported number of NDCs sold (as submitted in the ASP report to CMS each quarter) multiplied by the billing units per package for such NDC. We propose that the refund amount attributed to such NDCs for which the manufacturer is liable would be the amount equal to the estimated amount (if any) by which:

- The product of:

++ The total number of units of the billing and payment code for such drug that were discarded during such quarter;

++ The percentage of billing unit sales of the applicable code attributed to the NDC; and

++ The amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such quarter;

- Exceeds an amount equal to the product of:

++ The applicable percentage of the estimated total allowed charges for such a drug (less the amount paid for packaged drugs) during the quarter; and

++ The percentage of billing unit sales of the applicable code attributed to the NDC.

For example, if a billing and payment code for a refundable drug includes three NDCs, each from a different manufacturer as shown below in Table 18, there were 3,000 units discarded during the refund quarter, the payment limit amount for the refundable drug was $50.00 per billing unit, the applicable percentage was 10 percent, and the estimated total allowed charges for the refundable drug during the refund quarter was $1.05 million, the proposed calculation for the refund amount owed by Manufacturer 1 would

[106] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.*

be as follows: (3,000)(23.81%)($50) − (21,000)(10%)(23.81%)($50) = refund amount of $10,714.50.

TABLE 18: Example of Proportion of Sales Calculation when there are Multiple Manufacturers for a Refundable Drug

NDC	Manufacturer	Refund Quarter Sales (billing units)	Proportion of Sales (percent)
12345-6789-01	Manufacturer 1	5,000	23.81%
23456-7890-01	Manufacturer 2	6,000	28.57%
34567-8901-01	Manufacturer 3	10,000	47.62%
	TOTAL:	21,000	100%

The report to manufacturers described in section 1847A(h)(1) of the Act and discussed in the previous section III.A.3.b. of this proposed rule, in the case that there are multiple manufacturers for a refundable drug, would include: (1) the total number units of the billing and payment code of such drug attributed to the manufacturer's NDC assigned to the billing and payment code of the refundable drug that were discarded during such quarter, if any; and (2) the refund amount that the manufacturer of that NDC is liable for pursuant to section 1847A(h)(3) of the Act. We propose that this method of calculation apply beginning with calendar quarters in CY 2023 included in the initial refund report, which we propose to be sent no later than December 31, 2024. We propose that this method of calculation would be done for new refund quarters and updated refund quarters.

We propose to revise § 414.940 by adding a new paragraph (c)(4) to reflect the above proposed method of calculation of the refund amount attributed to a NDC when there are multiple manufacturers.

(3) Increased Applicable Percentage for Drugs With Unique Circumstances

Section 1847A(h)(3)(B)(ii) of the Act provides that, in the case of a refundable drug that has unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act, the Secretary may increase the applicable percentage otherwise applicable as determined appropriate by the Secretary. In the CY 2023 PFS final rule (87 FR 69727 through 69731), we adopted an increased applicable percentage of 35 percent for drugs reconstituted with a hydrogel and with variable dosing based on patient-specific characteristics (§ 414.490(d)(1)). We have identified only one drug, Jelmyto® (mitomycin for pyelocalyceal solution), with such unique circumstances. We stated in that final rule that we recognize that there are drug products that may indeed have other unique circumstances, and that an increased applicable percentage for these products would have to be determined through future notice and comment rulemaking, as required by the statutory provision. We stated that we planned to collect additional information about drugs that may have unique circumstances along with potential increased applicable percentages that might be appropriate for such drugs, and to collect additional information about a process to identify unique circumstances based on manufacturer input. We explained that we would revisit additional increased applicable percentages for drugs that have unique circumstances, and a process to identify such circumstances, through future notice and comment rulemaking. To that end, we hosted a town hall meeting on February 1, 2023 to discuss what criteria would be appropriate to determine whether a refundable drug has unique circumstances, and whether a categorical approach (that is, unique circumstances that apply to more than one drug), drug-by-drug approach, or a hybrid of these two approaches should be used for determining drugs for which an increased applicable percentage is appropriate.

After considering input from interested parties provided at the town hall and in subsequent meetings, in this proposed rule, we are proposing a hybrid approach to determining when it is appropriate to increase the applicable percentage for a drug with unique circumstances. First, we are proposing two categorical unique circumstances along with proposed increased applicable percentages and, secondly, we are proposing an application process so manufacturers may request that CMS consider whether an increased applicable percentage would be appropriate for a particular drug in light of its unique circumstances (and if an increased applicable percentage is considered appropriate it would then be proposed in future notice-and-comment rulemaking).

As discussed in the CY 2023 PFS final rule and further discussed at the town hall, many interested parties requested CMS increase applicable percentages (defined at § 414.940(c)(3) as 10 percent, except where an increased applicable percentage is applied in paragraph (d) of that section) for drugs packaged with small vial fill amounts or low-volume products (generally, those with a fill amount less than 1 mL). These parties stated that, for certain drugs, the small volume of drug contained in the vial (as identified on the package or FDA labeling) often represents the minimum volume necessary to safely and effectively prepare and administer the prescribed dose. Certain labeled amounts that are unused and discarded include amounts remaining in the syringe hub, amounts remaining in the syringe that are not part of the prescribed dose, amounts left in the vial that cannot be removed (such as drug adhering to the side of the vial or pooling around the vial stopper), and amounts left in the vial when it contains enough drug for two administration attempts.

We agree that such drugs have unique circumstances, because certain FDA-labeled amounts on the vial or package are unused and discarded after administration of the labeled dose, and these amounts are not available to be administered. The unique circumstances described for such drugs are similar to loss of product from filtration described in section 1847A(h)(8)(B)(ii) of the Act because in both circumstances, such amounts lost are amounts that are not part of the recommended dose and are not available to be administered to the patient (one being loss due to labeled amounts remaining in the filter and the other due to labeled amounts remaining

in other areas such as the vial or syringe).

Since not all drugs with small fill volumes have certain labeled amounts that are unused and discarded, we believe more specific criteria are required to identify certain drugs with unique circumstances in this case. For example, if a drug is available as 0.8 mL in a prefilled syringe, the total volume in the presentation is small, however, the entire labeled amount in the syringe may be administered to the patient as part of a labeled dose; the unique circumstances described above only occur when the volume of the labeled dose that is withdrawn from a vial or container is very small and there is a labeled amount that is unused and discarded and not available for administration, (based on drugs currently available in the market, we have observed this to occur with doses contained within less than 0.4 mL). Therefore, we propose an increased applicable percentage for drugs with a ''low volume dose.'' We consider a low volume dose to be a dose of a drug for which the volume removed from the vial containing the labeled dose does not exceed 0.4 mL (which is about 8 drops of liquid). We propose to revise § 414.902 and define a low volume dose to be a labeled dose (based on FDA-approved labeling) that is contained within no more than 0.4 mL when removed from the vial or container. For example, if a labeled dose is 4 mg and a vial contains a suspension with a concentration of 40 mg/mL, the labeled dose would be contained in 0.1 mL, which would not exceed 0.4 mL and would, therefore, be considered a low volume dose. We propose that this definition of low volume dose apply even if the drug is further diluted after removal from the vial and prior to administration because, even if the dose is further diluted, a dose withdrawn from the vial and diluted would still have the same physical constraints as a dose that was not diluted, and those constraints would necessitate the loss of product as described in the previous paragraph. In addition, we propose that for a drug to meet these unique circumstances, all labeled doses of the drug would be low volume doses. As proposed, this definition would not affect the determination of units as defined at section 1847A(b)(2)(B) of the Act and codified at § 414.802, and we note that the statutory definition of unit is exclusive of any diluent without reference to volume measures pertaining to liquids. The proposed definition of low volume dose would only be applied for the determination of whether a higher applicable percentage is warranted for a drug.

We propose a two-tiered increased applicable percentage for drugs with low volume doses, because the percentage that is unused and discarded for these drugs decreases as the volume of the dose increases. We propose that, for drugs with labeled doses contained within 0.1 mL or less when removed from the vial or container, the applicable percentage be increased to 90 percent. We are proposing 90 percent applicable percentage for this tier because certain drugs with low volume doses of 0.1 mL or less have up to 90 percent of the labeled amount that is unused and discarded and not part of the labeled dose available to be administered.[107] [108] We are not proposing to add an additional 10 percent to this number as we did in the case of hydrogel, as discussed in the CY 2023 final rule (see 87 FR 69729), because, generally, we do not believe it would be appropriate for any product to have an applicable percentage of 100 percent. Such an applicable percentage would, in effect, exclude drugs from the refund liability altogether. We believe it would be inappropriate to effectively expand the list of exclusions described in section 1847A(h)(8)(B) of the Act by proposing an increased applicable percentage of 100 percent to drugs not expressly excluded in statute. However, we considered whether some additional percentage might be appropriate in this case. We solicit comment on whether an additional percentage above 90 percent (but less than 100 percent) is warranted for drugs with low volume doses of 0.1 mL or less.

In the second tier of the low volume dose unique circumstances, we propose that for drugs with labeled doses contained within 0.11–0.4 mL, the applicable percentage be increased to 45 percent. Certain drugs currently marketed that fall into this category have up to 35.6 percent of the labeled amount that is unused and discarded and not part of the labeled dose to be administered. In the same manner as the applicable percentage for the hydrogel finalized in the CY 2023 PFS final rule, we propose to add the discarded amount percentage to the applicable percentage of 10 percent that is used for drugs without unique circumstances (that is, 35.6 percent plus 10 percent), and we propose to round that number to an applicable percentage of 45 percent for this tier.

In summary, we propose to increase the applicable percentages for drugs with a low volume dose (a dose of a drug for which the volume removed from the vial or container containing the labeled dose does not exceed 0.4 mL). Specifically, we propose that:

- Refundable drugs with labeled doses that are contained within 0.1 mL or less when removed from the vial or container have an increased applicable percentage of 90 percent and;
- Refundable drugs with labeled doses that are contained within 0.11—0.4 mL when removed from the vial or container have an increased applicable percentage of 45 percent.

To date, we have identified certain drugs that would meet the proposed criteria for such unique circumstances and would have a proposed increased applicable percentage of 90 percent, including Triesence® (triamcinolone acetonide injection, suspension) and Xipere® (triamcinolone acetonide injection, suspension), along with some other ophthalmic drugs with such low volume doses that do not include all of the target fill volume in the labeled amount (that is, those that are labeled such that the low volume dose is equal to the labeled amount). We also note that, although Susvimo™ (ranibizumab injection, solution) would qualify for the proposed 90 percent applicable percentage, it is excluded from the definition of refundable drug due to filtration requirements as discussed in the 2023 PFS final rule (87 FR 69723 through 69724). To date, we have identified certain drugs that would meet the proposed criteria for such unique circumstances and would have a proposed increased applicable percentage of 45 percent, including Xiaflex® (collagenase clostridium histolyticum) and Kimmtrak® (tebentafusp injection, solution, concentrate).

The second categorical unique circumstances we are proposing is for orphan drugs administered to a low volume of unique beneficiaries, which we propose to be fewer than 100 unique Medicare fee-for-service beneficiaries per calendar year (hereafter referred to as rarely utilized orphan drugs); we propose an increased applicable percentage of 26 percent for drugs with these unique circumstances. There is a higher probability that the percentage of discarded amounts for rarely utilized orphan drugs may not have a normal statistical distribution from quarter to quarter, which could disproportionately affect manufacturers of such drugs by resulting in highly variable refund amounts as compared with the variability of drugs administered to a

[107] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/211950Orig1s000correctedlbl.pdf.*

[108] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/022223,022048lbl.pdf.*

higher number of beneficiaries. This is evidenced by our analysis of quarterly discarded drug data reported using the JW modifier of 30 refundable drugs identified in the 2021 Medicare Part B Discarded Drug Units data with greater than 10 percent units discarded,[109] three of which were orphan drugs furnished to a patient population of less than 100 unique fee-for-service Medicare beneficiaries in CY 2021: J9262 (*omacetaxine mepesuccinate*); J9269 (*tagraxofusp-erzs*); and J0223 (*givosiran*). This analysis of JW modifier data for quarters in 2021 and 2022 showed that the average standard deviation of the percentage of units discarded across quarters for the rarely utilized orphan drugs is 6.21 percent, compared with an average standard deviation for all other refundable drugs (with a percentage of discarded units over 10 percent in 2021) of 2.35 percent. In other words, the standard deviation from the mean discarded drug percentage for rarely utilized orphan drugs is 2.64 times greater than that of the group of refundable drugs with larger patient populations and claims volume. In addition, based on the 2021 Medicare Part B Discarded Drug Units data for the three aforementioned drugs, the most historical public data is associated with J9262, which shows that the percent discarded units for J9262 was 23.65 percent, 19.96 percent, and 30.98 percent in 2019, 2020, and 2021, respectively. Because of this substantial statistical variation from quarter to quarter for such drugs, we believe it would be difficult to optimize the presentation of the drug to consistently minimize the discarded amounts to less than 10 percent given the small number of patients receiving the drug. We consider the higher percentage of unused and discarded amounts from such drugs as unavoidable loss due to both the low volume of unique beneficiaries receiving the drug contributing statistically higher variability in discarded amounts. Also, due to the low numbers of patients available to study for rare disease, it may be more difficult to determine the most efficient vial size for the patient population who receive the drug post-marketing. This is similar to the loss of product due to filtration described in section 1847A(8)(B)(ii) of the Act because the loss is unavoidable in both circumstances. In the case of filtration described in statute, the loss is unavoidable because certain amounts of product will be left within the filter and unavailable for administration; in the case of rarely utilized orphan drugs, the loss is unavoidable because of the variability of potential doses (and low number of patients receiving the drug) leading to an inability to develop a package size that will result in a consistent average percentage of discarded units (as evidenced in the analysis above in this section). In contrast, drugs administered to a larger number of beneficiaries per year do have a more consistent average percentage discarded from quarter to quarter, as evidenced by the lower standard deviation in our analysis, and we believe manufacturers are able to develop availability of the drug accordingly to minimize discarded amounts.

We propose that unique circumstances of rarely utilized orphan drugs have the following characteristics: (1) a drug designated under section 526 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as a drug for a rare disease or condition; and (2) that is furnished to fewer than 100 unique Medicare fee-for-service beneficiaries per calendar year. We propose that the number of beneficiaries receiving such drug in the calendar year would correspond with the refund quarter. For example, for refund quarters in 2023, we would use the number of beneficiaries receiving the drug in the 2023 calendar year to determine if the unique circumstances and increased applicable percentage would apply. Data of number of beneficiaries would be analyzed at the same time as the JW modifier data for the given calendar quarters. To meet these unique circumstances, we propose that the drug be designated an orphan-drug under section 526 of the FD&C Act for a rare disease or condition (or diseases or conditions) and be approved by the FDA-only for one or more indications within such designated rare disease or condition (or diseases or conditions). That is, all FDA-labeled indications for the drug must be orphan indications. In addition, we propose that the drug would meet these unique circumstances and that the increased applicable percentage would apply for as long as the drug meets these conditions, even after any orphan-drug exclusivity end date.

The increased applicable percentage of 26 percent that we are proposing is appropriate because the standard deviation from the mean discarded drug percentage for rarely utilized orphan drugs is 2.64 times greater than that of the larger group of refundable drugs, and multiplying the applicable percentage referenced in paragraph (h)(3)(B)(i)(II) by how many times greater the variance is (in other words, 10 percent times 2.64) equals 26.4 percent, which we propose to round to the nearest percentage.

We propose that CMS would identify drugs that have unique circumstances of low volume doses and rarely utilized orphan drugs in the report sent to manufacturers and apply the proposed increased applicable percentages based on these categorical unique circumstances proposals. If a manufacturer believes that the incorrect applicable percentage was applied to the refund calculation, the manufacturer may submit a dispute regarding the calculation by submitting an error report (see § 414.940(e)).

We propose to codify these applicable percentages at § 414.940(d). Specifically, we propose to add applicable percentages for low volume doses by creating new paragraphs (d)(3) and (4); and we propose to add applicable percentage for orphan drugs administered to fewer than 100 unique beneficiaries per calendar year in new paragraph (d)(5). We propose that these applicable percentages apply beginning with the initial refund report that we propose to be sent no later than December 31, 2024.

We solicit comments on the proposed categorical unique circumstances. Specifically, we solicit comment on the proposed volume (mL) tiers for drugs with low volume doses along with the proposed increased applicable percentages and whether an additional percentage above 90 percent (but less than 100 percent) is warranted for drugs with low volume doses of 0.1 mL or less. We also solicit comment on the increased applicable percentage of 26 percent for rarely utilized orphan drugs.

(4) Proposed Application Process for Individual Drugs

In addition to the two proposed categorical unique circumstances, we propose to establish an application process through which manufacturers may request that we consider an individual drug to have unique circumstances for which an increased applicable percentage is appropriate. We believe manufacturers would benefit from a formal process through which they can provide information, including that which may not be publicly available, and therefore, not known to us, in order to request an increase in their refundable drug's applicable percentage and provide justification for why the drug has unique circumstances for which such an increase is appropriate, including in the case of a drug with an applicable percentage that has already been increased by virtue of

[109] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

its inclusion in categorical unique circumstances.

We propose that, to request CMS consider increasing the applicable percentage of a particular refundable drug, a manufacturer must submit the following: (1) a written request that a drug be considered for an increased applicable percentage based on its unique circumstances; (2) FDA-approved labeling for the drug; (3) justification for the consideration of an increased applicable percentage based on such unique circumstances; and (4) justification for the requested increase in the applicable percentage. Such justification could include documents, such as (but not limited to) a minimum vial fill volume study or a dose preparation study. We propose that in evaluating requests for increased applicable percentages, we would review the documentation referenced above for evidence that amounts of drug identified in the FDA-approved package or labeling has similar loss of product as that described in paragraph section 1847A(8)(B)(ii) of the Act.

Section 1847(h)(3)(B)(ii) of the Act requires that any increase to applicable percentages for refundable drugs to be made through notice-and-comment rulemaking. Therefore, we propose that applications for individual applicable percentage increases be submitted in a form and manner specified by CMS by February 1 of the calendar year prior to the year the increased applicable percentage would apply (for example, applications for increased applicable percentages effective January 1, 2025 would be due to CMS by February 1, 2024). We propose to discuss our analyses of applications in the PFS rulemaking immediately following the application period, and to communicate in the proposed rule whether we consider the drug to have unique circumstances that warrant an increased applicable percentage. We would also include proposals, if any, for increased applicable percentages, along with a summary of any applications for which we determined not to propose an increase in the applicable percentage. We propose to codify this application process for individual unique circumstances in new paragraph § 414.940(e).

We do not consider the following to be unique circumstances warranting an increased applicable percentage at this time: weight-based doses, BSA-based doses, varying surface area of a wound, loading doses, escalation or titration doses, tapering doses, and dose adjustments for toxicity because we believe manufacturers can optimize the availability of products for these circumstances to limit the percentage of discarded units for a drug, unlike the circumstances of manufacturers of drugs that require filtration during the preparation process, as described in section 1847A(h)(8)(B)(ii) of the Act. FDA draft guidance, titled ''Optimizing the Dosage of Human Prescriptions Drugs and Biological Products for the Treatment of Oncologic Diseases'',[110] states: ''Various dose strengths should be available to allow multiple dosages to be evaluated in clinical trials. Perceived difficulty in manufacturing multiple dose strengths is an insufficient rationale for not comparing multiple dosages in clinical trials.'' Although optimization of dosage and available product formulations most often occurs prior to marketing a drug, we also observe several instances where the drug formulation availability has been changed and subsequently resulted in a decreased percentage of discarded amounts. For example, Kyprolis® (carfilzomib), which is cross-walked to the billing and payment code J9047, was available in only one 60-mg single-dose vial size when first approved in 2012.[111] Subsequently, a second 30-mg vial size was approved in 2016,[112] and a third 10-mg vial size was approved in June of 2018.[113] We observe in discarded drug data, based on the JW modifier, that the percentage of discarded units for J9047 was 14.27, 12.68, 5.95, 4, and 3.09 percent in 2017, 2018, 2019, 2020, and 2021, respectively. There is a sharp drop in the percent of discarded units after 2018, which correlates with the introduction of the 10-mg vial. The labeled dose of Kyprolis® is based on the patient's BSA, there is a dose escalation, there are two different dosage schedules (once weekly and twice weekly) each with differing doses, there are dosage modifications for toxicity that involve dose reductions, and there is a dose reduction for patients with hepatic impairment. With these dose variations taken into consideration, the available vial sizes of the drug allow for the percentage of discarded units to remain well below 10 percent after the introduction of the third vial size.

In addition, we observe that, based on the 2021 discarded drug data,[114] as the number of available package sizes increases, the percent discarded decreases (see Table 19). This example is indicative of ways in which manufacturers can optimize package sizes to reduce the percentage of discarded units in the circumstances listed above.

TABLE 19: 2021 Discarded Drug Data for Refundable Drugs and Number of Available Package Sizes

Percent Units Discarded	Number of Refundable Drugs	Percentage of Refundable Drugs with Only One Package Size
> 20%	7	100%
15—19.99%	6	83.33%
10—14.99%	20	75%
5—9.99%	22	45.45%
2—4.99%	47	29.79%

We solicit comments from interested parties on the application process for individual drug unique circumstances. Specifically, we solicit comment on what factors we should use in a framework for considering these

[110] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/optimizing-dosage-human-prescription-drugs-and-biological-products-treatment-oncologic-diseases.*

[111] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202714lbl.pdf.*

[112] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/202714s012lbl.pdf.*

[113] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/202714s019lbl.pdf.*

[114] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

applications, what factors we should use to assess appropriate increases to applicable percentages, as well as what types of additional or alternative documentation may help us analyze justifications for increased applicable circumstances.

e. Clarification for the Definition of Refundable Drug

As discussed in the CY 2023 PFS final rule (87 FR 69650 through 69655), CMS aims to create a consistent coding and payment approach for the suite of products currently referred to as skin substitutes. On January 18, 2023, we held a Town Hall to discuss this issue further and to provide an opportunity to further engage interested parties on this matter and is soliciting additional comments about skin substitutes in this proposed rule. We anticipate addressing coding and payment for skin substitutes in future rulemaking. While we consider making changes to the Medicare Part B payment policies for such products, we propose that billing and payment codes that describe products currently referred to as skin substitutes not be counted for purposes of identifying refundable drugs for calendar quarters during 2023 and 2024. We plan to revisit discarded drug refund obligations for skin substitutes in future rulemaking.

f. Clarification for the Determination of Discarded Amounts and Refund Amounts

Section 1847A(h) of the Act specifies that discarded amounts of refundable drugs are to be determined using a mechanism such as the JW modifier used as of the date of enactment of the Infrastructure Act or any successor modifier that includes such data as determined appropriate by the Secretary. In the CY 2023 PFS final rule (87 FR 69718 through 69719), we finalized our previously existing policy that required billing providers report the JW modifier for all separately payable drugs with discarded drug amounts from single use vials or single use packages payable under Part B, beginning January 1, 2023. Since the JW modifier, the mechanism described in section 1847A(h) of the Act, is not required in Medicare Advantage claims for drugs payable under Medicare Part B and there is not a similar mechanism to identify discarded units of such drugs that are billed to Medicare Advantage plans, we are clarifying that the JW modifier requirement does not apply to units billed to Medicare Advantage plans and that the refund amount calculations under section 1847A(h)(3) of the Act will not include units billed to Medicare Advantage plans.

g. Technical Changes

In the CY 2023 PFS final rule (87 FR 70227) we finalized the regulation text for the calculation of the manufacturer refund requirement. That text contained an error in two places, § 414.940(c)(3) and (d), which incorrectly referenced paragraph (c)(1)(ii) of that section in reference to the applicable percentage, rather than paragraph (c)(2). We propose to correct the textual reference in both paragraphs and make additional technical changes to streamline the text. See section III.A.3.d.(1) of this proposed rule for discussion of additional proposed revisions to these provisions.

h. Use of the JW Modifier and JZ Modifier Policy

In the CY 2023 PFS final rule (87 FR 69723), we discussed the applicability of the JW and JZ modifier policy to drugs that are not administered by the billing supplier, including drugs furnished through a covered item of DME that may be administered by the beneficiary. In such cases, suppliers who dispense drugs payable under Medicare Part B do not actually administer the drug, as the claim is typically submitted prior to the administration of the drug, and the billing provider or supplier is not at the site of administration to measure discarded amounts. We stated that since we do not believe it would be appropriate to collect data about discarded amounts from beneficiaries, the reporting requirement does not apply to drugs that are self-administered by a patient or caregiver in the patient's home. In the updated FAQ for the JW/JZ modifier policy [115] released on January 5, 2023, we reiterated that suppliers who dispense but do not actually administer a separately payable drug are not expected to report the JW modifier.

Beginning October 1, 2023, we will begin editing for correct use of both the JW and JZ modifiers for billing and payment codes for drugs from single-dose containers (87 FR 69719). However, because currently there is no claims modifier to designate that a drug was dispensed, but not administered, by the billing supplier, the policy finalized last year exempting self-administered drugs from the JW/JZ modifier policy may result in claims rejections absent a modification. Therefore, as we continue to believe it is unreasonable to collect discarded drug data from beneficiaries, we propose to require that drugs separately payable under Part B from single-dose containers that are furnished by a supplier who is not administering the drug be billed with the JZ modifier.

B. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background

a. RHC and FQHC Payment Methodologies

As provided in 42 CFR part 405, subpart X of our regulations, RHC and FQHC visits generally are defined as face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, NPs, PAs, 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 in an area verified as having shortage of home health agencies. We note, as discussed in section III.B.2.b. of this proposed rule, effective January 1, 2024 RHC and FQHC practitioners can also be licensed marriage and family therapists or mental health counselors. Transitional Care Management (TCM) services can also be paid by Medicare as an RHC or FQHC visit. In addition, Diabetes Self-Management Training (DSMT) or Medical Nutrition Therapy (MNT) sessions furnished by a certified DSMT or MNT program may also be considered FQHC visits for Medicare payment purposes. 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 generally 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). The AIR is subject to a payment limit, meaning that an RHC will not receive any payment beyond the specified limit amount. As of April 1, 2021, all RHCs are subject to new payment limits on the AIR, and this limit will be determined for each RHC in accordance with section 1833(f) of the Act.

FQHCs were paid under the same AIR methodology until October 1, 2014.

[115] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf.*

Beginning on that date, in accordance with section 1834(o) of the Act (as added by section 10501(i)(3) of the Patient Protection and Affordable Care Act (Pub. L. 111–148), FQHCs began to transition to the 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). The rate is increased by 34 percent when an FQHC furnishes care to a patient that is new to the FQHC, or to a beneficiary receiving an initial preventive physical examination (IPPE) or has an annual wellness visit (AWV).

Both the RHC AIR and FQHC PPS payment rates were designed to reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day. The rates are not adjusted at the individual level for the complexity of individual patient health care needs, the length of an individual visit, or the number or type of practitioners involved in the patient's care. Instead for RHCs, all costs for the facility over the course of the year are aggregated and an AIR is derived from these aggregate expenditures. The FQHC PPS base rate is updated annually by the percentage increase in the FQHC market basket less a productivity adjustment.

2. Implementation of the Consolidated Appropriations Act (CAA), 2023

a. Section 4113 of the Consolidated Appropriations Act, 2023

In the CY 2022 PFS final rule with comment (86 FR 65211), we revised the regulatory requirement that an RHC or FQHC mental health visit must be a face-to-face (that is, in person) encounter between an RHC or FQHC patient and an RHC or FQHC practitioner. We revised the regulations under § 405.2463 to state that an RHC or FQHC mental health visit can also include encounters furnished through interactive, real-time, audio/video telecommunications technology or audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder. We noted that these changes aligned with similar mental health services furnished under the PFS. We also noted that this change allows RHCs and FQHCs to report and be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person. In addition, we revised the regulation under § 405.2463 to state that there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record (86 FR 65210 and 65211).

We also revised the regulation under § 405.2469, FQHC supplemental payments, to state that a supplemental payment required under this section is made to the FQHC when a covered face-to-face (that is, in-person) encounter or an encounter where services are furnished using interactive, real-time, telecommunications technology or audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder occurs between a MA enrollee and a practitioner as set forth in § 405.2463. At § 405.2469, we also revised paragraph (d) to describe the same in-person visit requirement referenced in § 405.2463.

As discussed in the CY 2023 PFS final rule (87 FR 69738), the Consolidated Appropriations Act, 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022) included the extension of a number of Medicare telehealth flexibilities established during the public health emergency (PHE) for COVID–19 for a limited 151-day period beginning on the first day after the end of the PHE for COVID–19. Specifically, Division P, Title III, section 304 of the CAA, 2022, delayed the in-person requirements under Medicare for mental health services furnished through telehealth under the PFS and for mental health visits furnished by RHCs and FQHCs via telecommunications technology until the 152nd day after the end of the PHE for COVID–19. Therefore, in the CY 2023 PFS final rule (87 FR 69737), we revised the regulations under §§ 405.2463 and 405.2469 again to reflect these provisions.

The CAA, 2023 (Pub. L. 117–328, December 29, 2022) extends the Medicare telehealth flexibilities enacted in the CAA, 2022 for a period beginning on the first day after the end of the PHE for COVID–19 and ending on December 31, 2024, if the PHE ends prior to that date. Specifically related to RHCs and FQHCs, section 4113(c) of the CAA, 2023 amends section 1834(m)(8) of the Act to extend payment for telehealth services furnished by FQHCs and RHCs for the period beginning on the first day after the end of the COVID–19 PHE and ending on December 31, 2024 if the PHE ends prior to that date. Payment continues to be made under the methodology established for telehealth services furnished by FQHCs and RHCs during the PHE, which is based on payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS. We do not believe it necessary to conform the regulation to this temporary provision. Rather, we used our authority in section 4113(h) of the CAA, 2023 to issue program instructions or other subregulatory guidance to effectuate this provision to ensure a smooth transition after the PHE.[116]

Section 4113(d) of the CAA, 2023 also continues to delay the in-person requirements under Medicare for mental health services furnished through telehealth under the PFS and for mental health visits furnished by RHCs and FQHCs via telecommunications technology. That is, for RHCs and FQHCs, in-person visits will not be required until January 1, 2025 or, if later, the first day after the end of the PHE for COVID–19. Therefore, we continue to apply the delay of the in-person requirements under Medicare for mental health services furnished by RHCs and FQHCs. We note, the Department of Health and Human Services declared an end to the Federal PHE for COVID–19 under section 319 of the Public Health Service Act on May 11, 2023.[117]

We are proposing to make conforming regulatory text changes based on CAA, 2023 to the applicable RHC and FQHC regulations in 42 CFR part 405, subpart X, specifically, at § 405.2463, ''What constitutes a visit,'' we are proposing to amend paragraph (b)(3) and, at § 405.2469 ''FQHC supplemental payments,'' we are proposing to amend paragraph (d) to include the delay of the in-person requirements for mental

[116] *https://www.cms.gov/files/document/rural-health-clinics-and-federally-qualified-health-centers-cms-flexibilities-fight-covid-19.pdf.*

[117] *https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html.*

health visits furnished by RHCs and FQHCs through telecommunication technology under Medicare beginning January 1, 2025. We note that we are not revising the regulation text to reflect ''or, if later, the first day after the end of the PHE for COVID–19'' as the legislation states since the end of the PHE was May 11, 2023.

In the CY 2023 PFS final rule (87 FR 69738), we listed the several other provisions of the CAA, 2022 that apply to telehealth services (those that are not mental health visits) furnished by RHCs and FQHCs. For details on the other Medicare telehealth provisions in the CAA, 2022, see section II.D. of this proposed rule. The CAA, 2023 extends the telehealth policies mentioned above and enacted in the CAA, 2022 through December 31, 2024 if the PHE ends prior to that date.

b. Direct Supervision via Use of Two-Way Audio/Video Communications Technology

As discussed in section II.D.2.a of this proposed rule, under Medicare Part B, certain types of services are required to be furnished under specific minimum levels of supervision by a physician or practitioner. For RHCs and FQHCs, services and supplies furnished incident to physician's services are limited to situations in which there is direct physician supervision of the person performing the service, except for certain care management services which may be furnished under general supervision (§ 405.2415(a)(5)). The ''incident to'' policy for RHCs and FQHCs is discussed in Pub. 100–02, chapter 13, section 120.1. Similar to physician services paid under the PFS, outside the circumstances of the PHE, direct supervision of RHC and FQHC services does not require the physician to be present in the same room. However, the physician must be in the RHC or FQHC and immediately available to provide assistance and direction throughout the time the incident to service or supply is being furnished to a beneficiary.

During the COVID–19 PHE, the modifications that we made to the regulatory definition of direct supervision for services paid under the PFS were also applicable to RHCs and FQHCs. We explained in the April 6, 2020 IFC that given the circumstances of the PHE for the COVID–19 pandemic, we recognized that in some cases, the physical proximity of the physician or practitioner might present additional exposure risks, especially for high risk patients isolated for their own protection or cases where the practitioner has been exposed to the virus but could otherwise safely supervise from another location using telecommunications technology. We believed that the same concerns existed for RHCs and FQHCs. In the April 6, 2020 IFC, we allowed the supervising professional to be immediately available through virtual presence using two-way, real time audio-visual technology, instead of requiring their physical presence (85 FR 19245 and 19246).[118] When discussing direct supervision in RHCs and FQHCs, we noted that in general, CMS had modified the requirements for direct supervision to include the use of a virtual supervisory presence through the use of interactive audio and video telecommunications technology.[119]

We believe that extending this definition of direct supervision for RHCs and FQHCs through December 31, 2024, would align the timeframe of this policy with many of the previously discussed PHE-related telehealth policies that were extended under provisions of the CAA, 2023 and we are concerned about an abrupt transition to the pre-PHE policy of requiring the physical presence of the supervising practitioner beginning after December 31, 2023, given that RHCs and FQHCs have established new patterns of practice during the PHE for COVID–19. We also believe that RHCs and FQHCs will need time to reorganize their practices established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology. For RHCs and FQHCs, we are proposing to continue to define ''immediate availability'' as including real-time audio and visual interactive telecommunications through December 31, 2024.

In the absence of evidence that patient safety is compromised by virtual direct supervision, we believe that an immediate reversion to the pre-PHE definition of direct supervision may present a barrier to access services, such as those furnished incident-to a physician's service. Therefore, we are soliciting comment on whether we should consider extending the definition of direct supervision to permit virtual presence beyond December 31, 2024. When compared to professionals paid under the PFS, RHCs and FQHCs have a different model of care and payment structure. Therefore, we seek comment from interested parties on potential patient safety or quality concerns when direct supervision occurs virtually in RHCs and FQHCs; for instance, if certain types of services are more or less likely to present patient safety concerns, or if this flexibility would be more appropriate when certain types of auxiliary personnel are performing the supervised service. We are also interested in potential program integrity concerns such as overutilization or fraud and abuse that interested parties may have in regard to this policy.

c. Section 4121 of the CAA, 2023

Section 1861(aa) of the Act provides authority under Medicare Part B to cover and pay for RHC and FQHC services. Section 1861(aa)(1) of the Act defines these services as those furnished by physicians, physician assistants, nurse practitioners, nurse-midwives, qualified clinical psychologists, clinical social workers, and services and supplies furnished incident to professional services of these practitioners. As discussed in section III.B.1.a. of this proposed rule, our conforming regulation text is provided in 42 CFR part 405, subpart X where we define RHC and FQHC visits as face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are furnished.

Before passage of CAA, 2023, there was no separate benefit category under the statute that recognized the professional services of licensed marriage and family therapists (MFTs) or mental health counselors (MHCs). As discussed in the CY 2023 PFS final rule (87 FR 69546), payment for MFTs was only made under the PFS indirectly when an MFT or MHC performed services as auxiliary personnel incident to the services of a physician or other practitioner and under general supervision. This is also true for RHCs and FQHCs, in that MFTs and MHCs were considered auxiliary personnel and the services they provided were considered incident to the services of the RHC or FQHC practitioner (§ 405.2413).

Section 4121 of Division FF, Title IV, Subtitle C of the CAA, 2023, entitled ''Coverage of Marriage and Family Therapist Services and Mental Health Counselor Services under Part B of the Medicare Program'', amended section 1861(s)(2) of the Act to establish coverage of MFT and MHC services (section 1861(s)(2)(II) of the Act). We note that section II.J of this proposed rule provides a detailed discussion of the provisions in section 4121(a) of CAA, 2023 including the authority for coverage of MFT and MHC services, definitions of these professionals and

[118] *https://www.govinfo.gov/content/pkg/FR-2020-04-06/pdf/2020-06990.pdf.*

[119] *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf.*

their services, and payment under the PFS. Section 4121(b) of CAA, 2023 amended section 1861(aa)(1)(B) of the Act by extending the scope of RHC services to include those furnished by MFTs and MHCs as eligible for payment, which is incorporated into FQHC services through section 1861(aa)(3)(A) of the Act. We are proposing to codify payment provisions for MFTs and MHCs under 42 CFR part 405, subpart X beginning January 1, 2024. That is, RHC and FQHCs would be paid under the RHC AIR and FQHC prospective payment system (PPS), respectively, when MFTs and MHCs furnished RHC and FQHC services defined in §§ 405.2411 and 405.2446. As eligible RHC and FQHC practitioners, MFTs and MHCs would follow the same policies and supervision requirements as a PA, NP, CNM, CP, and CSW.

In addition, as discussed in section II.J of this proposed rule, we are proposing to allow addiction counselors that meet all of the applicable requirements of clinical supervised experience in mental health counseling, and that are licensed or certified as MHCs, clinical professional counselors, or professional counselors by the State in which the services are furnished) to enroll in Medicare as MHCs. Therefore, to remain consistent with payment policies for professionals billing Medicare under the PFS, we propose that the definitions established for MFTs and MHCs under the PFS would also apply for RHCs and FQHCs. In the CY 2023 PFS final rule (87 FR 69735 through 69737), we discussed the coding and payment for HCPCS code G0323 which describes general BHI services performed by CPs and CSWs under the PFS. We noted CPs and CSWs are statutorily authorized to furnish services in RHCs and FQHCs under sections 1861(aa)(1) and (3) of the Act, respectively, and as described by § 405.2411(a)(6). We also explained, the payment rate for HCPCS code G0323 is based on the payment rate for the current general BHI code, 99484. Therefore, in the CY 2023 PFS final rule (87 FR 69737) we clarified that when CPs and CSWs provide the services described in HCPCS code G0323 in an RHC or FQHC, the RHC or FQHC can bill HCPCS code G0511. We further stated RHCs and FQHCs that furnish general BHI services are able to bill for this service 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, 2023.

We note that in section II.J of this proposed rule, we are proposing to revise the code descriptor for HCPCS code G0323 in order to allow MFTs and MHCs, as well as CPs and CSWs, to be able to bill for this monthly care integration service. Since MFTs and MHCs are statutorily authorized to furnish services in RHCs and FQHCs effective January 1, 2024, we are proposing to clarify that when MFTs and MHCs provide the services described in HCPCS code G0323 in an RHC or FQHC, the RHC or FQHC can bill HCPCS code G0511. We believe that this policy aligns to our effort to be consistent with the new services that are proposed for practitioners billing under the PFS.

We propose to make several conforming regulatory changes to applicable RHC and FQHC regulations in 42 CFR part 405, subpart X, specifically:

- At § 405.2401, Scope and definitions, we propose to amend the section to add definitions for MFT and MHC;
- At § 405.2411, Scope of benefits, we propose to amend the section to include MFT and MHC where other RHC and FQHC practitioners are stated;
- At § 405.2415, Incident to services and direct supervision, we propose to amend the section to include MFT and MHC where other RHC and FQHC practitioners are stated;
- At § 405.2446, Scope of services, we propose to amend the section to include MFT and MHC services to the scope of services;
- At § 405.2448, Preventive primary services, we propose to amend the section to include MFT and MHC where other RHC and FQHC practitioners are stated;
- At § 405.2450, Clinical psychologist and clinical social worker services, we propose to amend the section title to add MFT and MHC and include MFT and MHC where other RHC and FQHC practitioners are stated;
- At § 405.2452, Services and supplies incident to clinical psychologist and clinical social worker services, we propose to amend the section title to add MFT and MHC and include MFT and MHC where other RHC and FQHC practitioners are stated;
- At § 405.2463, What constitutes a visit, we propose to amend the section to add MFT and MHC to the list of eligible practitioners; and
- At § 405.2468, Allowable costs, we propose to amend the section to add MFTs and MHCs where other RHC and FQHC practitioners are listed.

d. Section 4124 of the Consolidated Appropriations Act, 2023

Section 4124 of Division FF of the CAA, 2023 establishes coverage and payment under Medicare for the Intensive Outpatient Program (IOP) benefit, effective January 1, 2024. IOP may be furnished by hospitals, Community Mental Health Centers (CMHCs), FQHCs and RHCs. Payment for IOP services furnished by RHCs and FQHCs is to be made at the same payment rate as if it were furnished by a hospital.

In addition to existing mental health services furnished by RHCs and FQHCs, this new provision establishes coverage for IOP services furnished in RHCs and FQHCs and includes occupational therapy, family counseling, beneficiary education, diagnostic services and individual and group therapy.

Please see section VIII.F. of the CY 2024 Outpatient Prospective Payment System proposed rule for discussion of the new IOP scope of benefits, requirements, physician certification, and payment policies.

3. Updates to Supervision Requirements for Behavioral Health Services Furnished at RHCs and FQHCs

In the CY 2023 PFS final rule (87 FR 69545 through 69548), we amended the direct supervision requirement under the ''incident to'' regulations for services payable under the PFS to allow behavioral health services to be furnished under the general supervision of a physician or non-physician practitioner (NPP) when these services or supplies are provided by auxiliary personnel incident to the services of a physician or NPP. Several commenters expressed support for CMS allowing behavioral health services to be furnished under general supervision in the RHC and FQHC settings in addition to services paid under the PFS. In response to the public comments, we noted that for CY 2023, the proposed change to the level of supervision for ''incident to'' behavioral health services from direct to general was applicable only to services payable under the PFS, as services furnished in the RHC and FQHC settings were not addressed in the relevant proposal in the CY 2023 PFS proposed rule (87 FR 46062 through 46068). We stated we may consider changes to the regulations regarding services furnished at RHCs and FQHCs in the future.

Currently, behavioral health services furnished in the RHC and FQHC settings require direct supervision. However, in order to be more consistent with applicable policies under the PFS, for CY 2024, we are proposing to change the required level of supervision for behavioral health services furnished ''incident to'' a physician or NPP's services at RHCs and FQHCs to allow

general supervision, rather than direct supervision, consistent with the policies finalized under the PFS for CY 2023. Accordingly, we are proposing to revise the regulations at §§ 405.2413 and 405.2415 to reflect that behavioral health services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided by auxiliary personnel incident to the services of a physician (or another practitioner). Additionally, as discussed in the CY 2023 PFS final rule (87 FR 69547), we note that at § 410.26(a)(1) we define ''auxiliary personnel'' 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), has not been excluded from the Medicare, Medicaid and all other Federally-funded health care programs by the Office of Inspector General or had his or her Medicare enrollment revoked, and meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished.

4. General Care Management Services in RHCs and FQHCs

a. Background

We have been engaged in a multi-year examination of coordinated and collaborative care services in professional settings, and as a result established codes and separate payment in the PFS to independently recognize and pay for these important services. The care coordination included in services, such as office visits, do not always adequately describe the non-face-to-face care management work involved in primary care. Payment for office visits may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries, such as those who are returning to a community setting following discharge from a hospital or skilled nursing facility (SNF) stay.

As we discussed in the CY 2016 PFS final rule (80 FR 71081 through 71088), to address the concern that the non-face-to-face care management work involved in furnishing comprehensive, coordinated care management for certain categories of beneficiaries is not adequately paid for as part of an office visit, beginning on January 1, 2015, practitioners billing under the PFS are paid separately for CCM services when CCM service requirements are met. We explained that RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services and individual practitioners working at RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services while working at the RHC or FQHC. Although many RHCs and FQHCs pay for coordination of services within their own facilities, and may sometimes help to coordinate services outside their facilities, the type of structured care management services that are now payable under the PFS for patients with multiple chronic conditions, particularly for those who are transitioning from a hospital or SNF back into their communities, are generally not included in the RHC or FQHC payment. Therefore, separate payment was established in the CY 2016 PFS final rule (80 FR 71080 through 71088) for RHCs and FQHCs that furnish CCM services. We believe the non-face-to-face time required to coordinate care is not captured in the RHC AIR or the FQHC PPS payment, particularly for the rural and/or low-income populations served by RHCs and FQHCs. Allowing separate payment for CCM services in RHCs and FQHCs is intended to reflect the additional resources necessary for the unique components of CCM services.

In the CY 2018 PFS final rule (82 FR 53169 and 53180), we finalized revisions to the payment methodology for 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, 2018. We also initiated the use of HCPCS code G0511, 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. In the CY 2019 PFS final rule (83 FR 59683), we explained for CY 2018 the payment amount for HCPCS code G0511 was 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. That is, for CY 2018 the 3 codes that comprised HCPCS code G0511 were CPT code 99490 (*20 minutes or more of CCM services*), CPT code 99487 (*60 minutes or more of complex CCM services*), and CPT code 99484 (*20 minutes or more of BHI services*).

We also explained that another CCM code was introduced for practitioners billing under the PFS, CPT code 99491, which would correspond to 30 minutes or more of CCM furnished by a physician or other qualified health care professional and is similar to CPT codes 99490 and 99487 (83 FR 56983). Therefore, for RHCs and FQHCs, we added CPT code 99491 as a general care management service and included it in the calculation of HCPCS code G0511. Starting on January 1, 2019, RHCs and FQHCs were paid for HCPCS code G0511 based on the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 99491 (83 FR 59687).

In the CY 2021 PFS final rule (85 FR 84697 through 84699), we explained that the requirements described by the codes for Principal Care Management (PCM) services were similar to the requirements for the services described by HCPCS code G0511; therefore, we added HCPCS codes G2064 and G2065 to HCPCS code G0511 as general care management services for RHCs and FQHCs. Consequently, effective January 1, 2021, RHCs and FQHCs are paid when a minimum of 30 minutes of qualifying PCM services are furnished during a calendar month. The payment rate for HCPCS code G0511 for CY 2021 was 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 PCM codes (HCPCS codes G2064 and G2065). We note that in the CY 2022 PFS final rule (86 FR 65118), HCPCS codes G2064 and G2065 were replaced by CPT codes 99424 and 99435. Therefore, for CY 2022 the payment rate for HCPCS code G0511 was the average of the national non-facility PFS payment rate for CPT codes 99490, 99487, 99484, 99491, 99424, and 99425).

Most recently, in the CY 2023 PFS final rule (87 FR 69735 through 69737), we included Chronic Pain Management (CPM) services described by HCPCS code G3002 in the general care management HCPCS code G0511 when at least 30 minutes of qualifying non-face-to-face CPM services are furnished during a calendar month. We explained since HCPCS code G3002 is valued using a crosswalk to the PCM CPT code 99424, which is currently one of the CPT codes that comprise HCPCS code G0511, there was no change made to the average used to calculate the HCPCS code G0511 payment rate to reflect CPM services.

Additional information on care management 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.*

b. Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring (RTM) Services Furnished in RHCs and FQHCs

In recent years under the PFS, we have finalized payment for five CPT codes in the RPM code family. RPM services include the collection, analysis, and interpretation of digitally collected physiologic data, followed by the development of a treatment plan, and the managing of a patient under the treatment plan (84 FR 62697). Within the suite of services that comprise RPM, there is a CPT code that describes the initial set-up and patient education on use of the equipment that stores the physiologic data.

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 other practitioner 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.

TABLE 20: RPM HCPCS Codes and Descriptors

HCPCS code	Short Description	Official Long Description
99453	Rem mntr physiol param setup	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
99454	Rem mntr physiol param dev	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
99457	Rem physiol mntr 1st 20 min	Remote physiologic monitoring treatment 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
99458	Rem physiol mntr ea addl 20	Remote physiologic monitoring treatment 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)
99091	Collj & interpj data ea 30 d	Collection and interpretation of physiologic data (e.g. Blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days

Remote Therapeutic Monitoring (RTM) is a family of five codes finalized for Medicare payment in the CY 2022 PFS final rule (86 FR 65114 through 65117). The RTM codes include three practice expense (PE)-only codes and two professional work, treatment management codes. RTM services involve remote monitoring of respiratory system status, musculoskeletal status, therapy adherence, or therapy response. There is also a CPT code that describes the initial set-up and patient education on use of the equipment that stores the physiologic data within the suite of services that comprise RTM.

TABLE 21: RTM HCPCS Codes and Descriptors

HCPCS code	Short Description	Official Long Description
98975	Rem ther mntr 1st setup&edu	Remote therapeutic monitoring (e.g. therapy adherence, therapy response); initial set-up and patient education on use of equipment
98976	Rem ther mntr dev sply resp	Remote therapeutic monitoring (e.g. therapy adherence, therapy response); device(s) supply with scheduled (e.g. daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days
98977	Rem ther mntr dv sply mscskl	Remote therapeutic monitoring (e.g. therapy adherence, therapy response); device(s) supply with scheduled (e.g. daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days
98980	Rem ther mntr 1st 20 min	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes
98981	Rem ther mntr ea addl 20 min	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (list separately in addition to code for primary procedure)

Currently, RPM and RTM services are not stand-alone billable visits in RHCs and FQHCs. When these services are furnished incident to an RHC or FQHC visit, payment is included in the RHC's AIR subject to a payment-limit or the per visit payment under the FQHC PPS which is the lesser of the PPS rate or the FQHC's actual charges.

In recent years, we have updated RHC and FQHC policies to improve payment for care management and coordination. We have provided a separate payment to RHCs and FQHCs in addition to the billable visit in part for monthly care management and behavioral health integration codes, as described in the general care management code, HCPCS code G0511, because these are inherently non-face-to-face services that may not be accounted for in the per-visit payment for an in-person encounter.

RHCs and FQHCs have inquired about receiving a separate payment for RTM and RPM services. They have stated that CMS should expand HCPCS code G0511 to include RPM treatment management services to provide Medicare beneficiaries in rural and underserved areas access to these services or establish G-codes to reimburse RHCs and FQHCs for RPM set-up and patient education on use of equipment (CPT code 99453) and monthly data transmission (CPT code 99554) and do not believe that these services are captured in the RHC AIR or FQHC PPS and as such are impeding access to these services.

Upon further review and in line with our thinking about non-face-to-face services previously, we are proposing to include the CPT codes that are associated with the suite of services that comprise RPM and RTM in the general care management HCPCS code G0511 when these services are furnished by RHCs and FQHCs since the requirements for RPM and RTM services are similar to the non-face-to-face requirements for the general care management services furnished in RHCs and FQHCs. Allowing a separate payment for RPM and RTM services in RHCs and FQHCs is intended to reflect the additional resources necessary for the unique components of these services.

The care coordination included in services, such as office visits, do not always adequately describe the non-face-to-face care management work involved in primary care. Payment for in-person encounters may not reflect all the services and resources required to furnish comprehensive, coordinated care management. As RPM and RTM services are described, particularly, collection and transmission of data and then further analysis and interpretation of the data are happening outside of the face-to-face visit. RPM and RTM also have principles which are consistent with other care management principles, such as, an established patient-physician relationship is required, patient consent is required at the time that RPM services are furnished, and services allow the monitoring of acute conditions and chronic conditions. However, we note that under this proposal, RPM and RTM services must be medically reasonable and necessary, meet all requirements, and not be duplicative of services paid to RHCs and FQHCs under the general care management code for an episode of care in a given calendar month. Therefore, we propose that RHCs and FQHCs that furnish RPM and RTM services would be able to bill these 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, 2024.

c. Services Addressing Health-Related Social Needs: Community Health Integration Services and Principal Illness Navigation Services

(1) Background

As discussed in section II.E.4.(27) of this proposed rule, in recent years, we have sought to recognize significant changes in health care practice and been engaged in an ongoing, incremental effort to identify gaps in appropriate coding and payment for care management/coordination and primary care services under the PFS. In congruence with services paid under the PFS, we have similarly provided separate payment for transitional care management services, chronic care management services, and behavioral health care management services (discussed above in section III.B.4.a. of the proposed rule) to improve payment accuracy to better recognize resources involved in care management and coordination for certain patient populations. In this effort to improve payment accuracy for care coordination in RHCs and FQHCs, we are exploring ways to better identify the resources for

helping patients with serious illnesses navigate the healthcare system or removing health-related social barriers that are interfering with their ability to execute a medically necessary plan of care. RHCs and FQHCs sometimes obtain information about and help address, social determinants of health (SDOH) that significantly impact their ability to diagnose or treat a patient. The CPT E/M Guidelines defined SDOH as, ''Economic and social conditions that influence the health of people and communities. Examples may include food or housing insecurity. Additionally, RHCs and FQHCs sometimes help newly diagnosed cancer patients and other patients with similarly serious, high-risk illnesses navigate their care, such as helping them understand and implement the plan of care, and locate and reach the right practitioners and providers to access recommended treatments and diagnostic services, considering the personal circumstances of each patient. Payment for these activities, to the extent they are reasonable and necessary for the diagnosis and treatment of the patient's illness or injury, is currently included in the RHC AIR or under the FQHC PPS payment amount for visits and some care management services. Medical practice has evolved to increasingly recognize the importance of these activities, and we believe RHCs and FQHCs are performing them more often.

However, this work is not explicitly identified in current coding, and as such, we believe it is underutilized and undervalued. Accordingly, we are proposing to create new coding to expressly identify and value these services for PFS payment, and distinguish them from current care management services. Therefore, we are considering the new coding for purposes of payment to RHCs and FQHCs.

(2) Payment for Community Health Integration (CHI) Services in RHCs and FQHCs

Consistent with the discussion in section II.E.4.(27).b. of this proposed rule, there are two new HCPCS codes proposed to describe CHI services performed by certified or trained auxiliary personnel, which may include a CHW, incident to the professional services and under the general supervision of the billing practitioner. The requirements for the proposed CHI services, as stated in section II.E.4.(27) of this proposed rule, are similar to the requirements for the general care management services furnished by RHCs and FQHCs. As such, we believe the level of care coordination resources required in addressing the particular SDOH need(s) that are interfering with, or presenting a barrier to, diagnosis or treatment of the patient's problem(s) addressed in the CHI initiating visit are not captured in the RHC AIR or the FQHC PPS payment, particularly for the rural and/or low-income populations served by RHCs and FQHCs. Payment for office visits may not reflect all the services and resources involved with CHI as described in the HCPCS code below, for example, coordination of care, facilitation of access to services, communication between settings.

GXXX1 Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit:

- Person-centered assessment, performed to better understand the individualized context of the intersection between the SDOH need(s) and the problem(s) addressed in the initiating
E/M visit.

++ Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors.

++ Facilitating patient-driven goal-setting and establishing an action plan.

++ Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.

- Practitioner, Home-, and Community-Based Care Coordination.

++ Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable).

++ Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.

++ Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.

++ Facilitating access to community-based social services (*e.g.,* housing, utilities, transportation, food assistance) to address the SDOH need(s).

- *Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the SDOH need(s), and educating the patient on how to best participate in medical decision-making.*
- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the SDOH need(s), in ways that are more likely to promote personalized and effective diagnosis or treatment.*
- *Health care access/health system navigation.*

++ Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.

- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*
- *Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*
- *Leveraging lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

GXXX2—Community health integration services, each additional 30 minutes per calendar month (List separately in addition to GXXX1).

(3) Payment for Principal Illness Navigation (PIN) Services in RHCs and FQHCs

Consistent with the discussion in section II.E.4.(27).e. of this proposed rule, there are two new HCPCS codes proposed to describe PIN services. That is when certified or trained auxiliary personnel under the direction of a billing practitioner, which may include a patient navigator or certified peer specialist, are involved in the patient's health care navigation as part of the treatment plan for a serious, high-risk disease expected to last at least 3 months, that places the patient at significant risk of hospitalization or

nursing home placement, acute exacerbation/decompensation, functional decline, or death. The requirements for the proposed PIN services are also similar to the requirements for the general care management services furnished by RHCs and FQHCs.

As such, we believe the resources required to provide the level of care coordination needed for individualized help to the patient (and caregiver, if applicable) to identify appropriate practitioners and providers for care needs and support, and access necessary care timely are not captured in the RHC AIR or the FQHC PPS payment, particularly for the rural and/or low-income populations served by RHCs and FQHCs. Payment for office visits may not reflect all the services and resources involved with PIN as described in the HCPCS code below.

GXXX3 Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities:

- *Person-centered assessment, performed to better understand the individual context of the serious, high-risk condition.*

++ Conducting a person-centered assessment to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors.

++ Facilitating patient-driven goal setting and establishing an action plan.

++ Providing tailored support as needed to accomplish the practitioner's treatment plan.

- *Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.*
- *Practitioner, Home, and Community-Based Care Coordination.*

++ Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; home- and community-based service providers; and caregiver (if applicable).

++ Communication with practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.

++ Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.

++ Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s).

- *Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making.*
- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition.*
- *Health care access/health system navigation.*

++ Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care, and helping secure appointments with them.

++ Providing the patient with information/resources to consider participation in clinical trials or clinical research as applicable.

- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*
- *Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*
- *Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

GXXX4—Principal Illness Navigation services, additional 30 minutes per calendar month (List separately in addition to GXXX3).

Allowing a separate payment for CHI and PIN services in RHCs and FQHCs is intended to reflect the additional time and resources necessary for the unique components of care coordination services. In an effort to be consistent with the new services that are being proposed for practitioners billing under the PFS, we are proposing to include PIN services in the general care management HCPCS code G0511 when these services are provided by RHCs and FQHCs.

We note that under the proposals to expand the billable services under HCPCS code G0511 to include CHI and PIN, each of these services must be medically reasonable and necessary, meet all requirements, and not be duplicative of services paid to RHCs and FQHCs under the general care management code for an episode of care in a given calendar month. We expect that our proposal to add the new codes for CHI and PIN to the general care management code would also support the CMS pillars [120] for equity, inclusion, and access to care for the Medicare population, and improve patient outcomes, including for underserved and low-income populations where there is a disparity in access to quality care.

d. Proposed Revision to the Calculation of the Payment Amount for the General Care Management HCPCS Code G0511

Currently, HCPCS code G0511 is based on the PFS national average non-facility payment rate for each of the services identified as billable general care management services. Then we add each payment rate and divide by the total number of codes to arrive at the payment amount for HCPCS code G0511. This payment amount is a flat rate that is not subsequently adjusted for locality. As we noted in the CY 2023 PFS final rule (87 FR 69735), when determining which services are billable under HCPCS code G0511, we do not include the add-on HCPCS codes payable under the PFS because RHCs and FQHCs do not pay their practitioners based on additional minutes spent by practitioners. Instead we generally include the base codes. In the CY 2023 PFS final rule (87 FR 69736), we mentioned that we may consider other approaches for calculating the payment rate for HCPCS code G0511 as the number of services included in the general care management code is growing each year and provided examples. We thought to consider in the future valuing HCPCS code G0511 using a weighted average of the services that comprise HCPCS code G0511 or using the national average of the top three services comprising HCPCS code G0511. We welcomed comments on potential methodologies, but noted we did not receive any comments.

As we discuss above, we have been engaged in a multi-year examination of coordinated and collaborative care services in professional settings, and as a result established codes and separate

[120] CMS Strategic Plan. *https://www.cms.gov/cms-strategic-plan.*

payment in the PFS to separately recognize and pay for these important services. The care coordination included in services, such as office visits, do not always adequately describe the non-face-to-face care management work involved in primary care. Payment for in-person encounters may not reflect all the services and resources required to furnish comprehensive, coordinated care management. Through the last few payment rules, we have expanded the general care management services billable using the HCPCS code G0511 to be consistent with the policies implemented under the PFS.

In section III.B.4.b and c. of this proposed rule, we are proposing to expand the billable services under HCPCS code G0511 to include RPM, RTM, CHI, and PIN. If we continue to calculate HCPCS code G0511 using our current approach, we believe that the value may no longer be appropriate payment for those services since we are simply dividing by the number of codes that comprise HCPCS code G0511 and as that number of services with lower payment rates increases, the value diminishes. Therefore, we are proposing to revise our method for calculating HCPCS code G0511 so that payment for general care management is more appropriate. Below, we compare our current method to the proposed revised approach.

Based on the current methodology for HCPCS code G0511 as shown in Table 22, general care management services are paid at the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, 99491, 99424 and 99426.

TABLE 22: CY 2023 National Non-Facility PFS Payment Rate for G0511

CPT Code	National Non-Facility PFS Payment Rate
99424	$81.33
99426	$61.34
99484	$43.04
99487	$133.18
99490	$62.69
99491	$85.06
G0511	**$77.94[1]**

[1] Noting when averaging the six codes, the total RVU for HCPCS code G0511 is 2.295. Multiplying that by the conversion factor of 33.8872 results in $77.77. However, RVUs on the PFS file are expressed in two decimal places. Thus, we round the 2.295 average to 2.30 which yields 2.30 * 33.8872, resulting in $77.94, the current payment rate for HCPCS code G0511.

As shown in Table 23, when we include RPM and RTM services in the national non-facility average as discussed above, the payment rate for HCPCS code G0511 is reduced to $64.13 based on the national non-facility PFS payment rates for CY 2023.

TABLE 23: CY 2023 National Non-Facility PFS Payment Rate for G0511 with RPM and RTM Base Codes

CPT Code	National Non-Facility PFS Payment Rate
99454	$50.15
99457	$48.80
99091	$54.22
98976	$50.15
98977	$50.15
98980	$49.48
99424	$81.33
99426	$61.34
99484	$43.04
99487	$133.18
99490	$62.69
99491	$85.06
G0511	**$64.13***

*Noting when averaging the 12 codes, the total RVU for HCPCS code G0511 is 2.30. Multiplying that by the conversion factor of 33.8872 results in $64.13.

As demonstrated by comparing Table 22 to Table 23, using the current method of calculating the average of the non-facility rates but adding in RPM and RTM services base codes would result in a lower payment amount for HCPCS code G0511 compared to the current payment amount. We believe that while the policy may address providing a payment for furnishing non-face-to-face services, the magnitude of the value may not appropriately account for the costs. Therefore, we considered and are proposing a revised methodology for the calculation by looking at the actual utilization of the services. That is, we are proposing to use a weighted average of the services that comprise HCPCS code G0511. In order to use a weighted average, there needs to be data on the utilization of the services. We do not have data on utilization of the services that comprise HCPCS code G0511 for RHCs and FQHCs since HCPCS code G0511 accounts for a variety of services. Therefore, we would use the most recently available utilization data from the services paid under the PFS, that is, in the physician office setting. We believe that the physician office setting provides an appropriate proxy for utilization of these services in the absence of actual data because this setting most closely aligns with the types of services furnished in RHCs and FQHCs since they typically furnish primary care.

In order to analyze utilization for services paid under the PFS and to ensure we accounted for payments accurately, we would use CY 2021 claims data to look at utilization of the base code for the service and any applicable add-on codes used in the same month as well as any base codes reported alone in a month for all of the services encompassing general care management, that is the array of services that make up HCPCS code G0511. We believe we need to account for the payment associated with the base code along with an applicable add-on code in our calculation as this demonstrates a complete encounter. Until actual utilization becomes available, RHCs and FQHCs that furnish CPM, GBHI, CHI and PIN services would report HCPCS code G0511 when those services are furnished; however, they would not be included in the weighted average at this time. Once more data is available, we will revisit the valuation of HCPCS code G0511 to include CPM, GBHI, CHI, and PIN as necessary.

Table 24 shows the payment amount using this calculation. The national non-facility payment rate associated with each code that comprises HCPCS code G0511 can be found in Addendum B of this proposed rule. We note that the revised methodology does reduce the payment rate for HCPCS code G0511 from its current rate for CY 2023, although not significantly.

TABLE 24: Weighted Average Payment Rate for G0511 with RPM, RTM, CHI, and PIN Services Using CY 2023 Rates and Conversion Factor

CPT Code	2021 NF Utilization	Weighted Average
99454	931,411	46,710,262
99457	492,286	24,023,557
99457+99458	398,209	35,221,586
99474	1,581	24,110
99091	55,435	3,005,686
98976	93,141	4,671,028
98977	93,141	4,671,028
98980	14,112	698,243
98980+98981	119,463	10,647,711
99424	13,719	1,115,766
99424+99425	4,573	638,482
99426	28,858	1,770,134
99426+99427	9,619	1,046,382
99484	151,808	6,533,816
99487	26,441	3,521,412
99487+99489	229,004	46,641,245
99490	3,436,429	215,429,734
99490+99439	802,656	88,396,505
99491	29,665	2,523,322
99491+99437	118,661	17,210,562
G0511		**$72.98**

Therefore, we propose to take the weighted average of the base code and add-on code pairs, in addition to the individual base codes for all of the services that comprise HCPCS code G0511 by using the CY 2021 PFS utilization to calculate the payment rate for the general care management services furnished in RHCs and FQHCs on or after January 1, 2024. The number on the right side of Table 24 is a weighted average which grants more relative weight to the codes in proportion to their utilization in 2021 claims data. To calculate the weighted average, we multiple the non-facility payment rate times the non-facility utilization for each code, sum this total, then divide by the summed non-facility utilization for the codes included in the average. In an effort to be consistent with practitioners billing under the PFS and to account for the additional time spent in care coordination, we determined that this approach was more accurate representation of the payment. We would also update HCPCS code

G0511 annually based on current data available in the PFS.

We propose revisions at § 405.2464(c) to reflect the revised methodology for calculating the payment amount for general care management services beginning January 1, 2024 which would be based on a weighted average of the services that comprise HCPCS code G0511 using the most recently available PFS utilization data. We welcome comments on this proposed methodology.

e. Chronic Care Management Services and Virtual Communication Services Requirement for Obtaining Beneficiary Consent

(1) Chronic Care Management Services

RHCs and FQHCs have been authorized to bill for Chronic Care Management (CCM) services since January 1, 2016. The RHC and FQHC requirements for billing CCM services have generally followed the requirements for practitioners billing under the PFS, with some adaptations based on the RHC and FQHC payment methodologies. In fact, in the CY 2017 PFS final rule (81 FR 80256–80257) to assure that CCM requirements for RHCs and FQHCs were not more burdensome than those for practitioners billing under the PFS, we finalized revisions to the requirements for CCM services furnished by RHCs and FQHCs similar to revisions to the requirements for CCM services finalized under the PFS (81 FR 80243 through 80251). Information regarding CCM services is available on the CMS Care Management Site.[121]

In the CY 2022 PFS proposed rule (86 FR 39175), we solicited public comment on the standard practice used by practitioners to obtain beneficiary consent for CCM services. We stated that we have received questions from interested parties regarding the consent requirements for CCM services. We explained that these questions may have arisen because of the many flexibilities allowed in response to the PHE for COVID–19. In particular, during the PHE for COVID–19, we allowed interested parties to obtain beneficiary consent for certain services under general supervision (85 FR 19230, April 6, 2020). We noted that before the PHE for COVID–19, we required that beneficiary consent be obtained either by or under the direct supervision of the primary care practitioner. We noted that this requirement was consistent with the conditions of payment for this service under the PFS. We stated that as we consider what policies implemented during the PHE for COVID–19 should remain in effect beyond the PHE, we were interested in understanding how billing practitioners furnishing CCM at different service sites (for example, physician office settings, RHCs, FQHCs) have been obtaining beneficiary consent over the past year and how different levels of supervision impact this activity. We welcomed public comment on the issue, specifically on what levels of supervision are necessary to obtain beneficiary consent when furnishing CCM services and said that we will consider such comments in future rulemaking.

We received 52 comments regarding the standard practice used by practitioners to obtain beneficiary consent for CCM services from a variety of interested parties. For example, we received comments from hospitals, physicians, RHCs, FQHCs, software companies, care management companies.

All comments received expressed support for obtaining consent for care management under general supervision. Many commenters requested that CMS make this supervision level permanent after the expiration of the COVID–19 PHE. They stated that their practice would be unable to maintain its current CCM program without the assistance of a third-party partner. CCM vendors have trained enrollment staff which are vital to obtaining proper consent from their patients. Their staff are able to educate and inform our patients regarding the CCM program as they have been specifically trained to explain the benefits of CCM. They explained that vendors have the capacity to call patients and receive calls when it is convenient for the patient. They expressed concern that they could not replicate these services using only their employed staff and that allowing a third party to obtain consent from their patients for CCM under general supervision is vital to their CCM program.

One commenter explained that CCM programs are a challenging and heavy lift for all providers, regardless of size and available resources, and the providers that offer CCM services to their patient populations do so because they recognize and value CCM's capacity to improve patient outcomes. The commenter stated that they have seen the administrative burdens of successful and compliant CCM programs fall hardest upon RHCs and FQHCs and noted if CMS were to establish general supervision as the guideline for beneficiary consent, this would ease those burdens. The commenter noted that CCM codes describing clinical staff activities are assigned general supervision and if CMS were to carve out beneficiary consent from the rest of CCM and impose a heightened administrative burden by imposing direct supervisions, RHCs and FQHCs that service the most vulnerable and underserved patient populations, would encounter challenges that could have negative consequence for their existing CCM programs.

Several commenters stated that they believed an efficient Medicare system requires CCM services to leverage the potential of non-face-to-face modalities, such as EHR systems, patient portals, texting/SMS services, chatbot technologies, interactive mobile medical apps, and direct patient calls. The commenters explained that while they understood CMS' concerns, it is long past due that CMS do away with the requirement for a provider to directly obtain consent. Virtual modalities more than adequately enable a patient to gain an understanding of what they are consenting to at the same level or better than an in-person consent process, making the direct consent requirement outdated and overburdensome. The commenters strongly encouraged CMS to permanently allow providers to obtain beneficiary consent under general supervision.

We note that, for the purposes of CCM services furnished under the PFS, we require that practitioners obtain informed consent before furnishing a beneficiary with CCM services. During the COVID–19 PHE, CMS clarified its existing policy about how practitioners could obtain beneficiary consent. We explained that practitioners could obtain beneficiary consent either at the required initiating visit for CCM (many of which Medicare allows to be furnished virtually), or at the same time that the CCM service is initiated by auxiliary staff who work to furnish the CCM services. When the beneficiary's consent is separately obtained, it may be obtained under the general supervision of the billing practitioner and may be verbal as long as it is documented in the medical record and includes notification of the required information. Now that the COVID–19 PHE has ended, we expect that practitioners will continue to appropriately obtain informed consent before they start furnishing CCM services to a beneficiary.

For purposes of CCM services furnished by RHCs and FQHCs, we are proposing to clarify the policy of how RHC and FQHC practitioners can obtain beneficiary consent. That is, while we have stated our intent since allowing

[121] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.*

RHCs and FQHCs to furnish CCM services, is to assure that CCM requirements for RHCs and FQHCs were not more burdensome than those for practitioners billing under the PFS, we believe our guidance could be clearer. After a review of commenters' concerns, we propose to clarify when, how and by whom beneficiary consent for CCM services can be obtained. Specifically, informed consent to receive CCM services must be obtained prior to the start of CCM services. Consent does not have to be obtained at the required initiating visit for CCM that must be performed by the RHC or FQHC practitioner, but it can be obtained at that time. Since the RHC or FQHC practitioner discusses CCM with the beneficiary during the initiating visit, if consent is separately obtained, it may be obtained under general supervision, and can be verbal as long as it is documented in the medical record and includes notification of the required information. That is, beneficiary consent can be obtained at the same time that the CCM service is initiated by auxiliary staff who work to furnish the CCM services. Further, there need not be an employment relationship between the person obtaining the consent and the RHC or FQHC practitioner. That is, the clinical staff obtaining the verbal or written consent can be under contract with the RHC or FQHC.

It is important to reiterate that the importance of obtaining advance beneficiary consent to receive CCM services is to ensure the beneficiary is informed, educated about CCM services, and is aware of applicable cost sharing. In addition, querying the beneficiary about whether another practitioner is already providing CCM services helps to reduce the potential for duplicate provision or billing of the services. We require the beneficiary be informed on the availability of CCM services; that only one practitioner can furnish and be paid for these services during a calendar month; and of the right to stop the CCM services at any time (effective at the end of the calendar month). Again, we believe that it is important that the beneficiary grant the consent at the onset of CCM services to have the opportunity to understand what services are being billed and note it is important for CMS to take a balanced approach between administrative burden and potential program integrity concerns. That being said, we are clarifying that we understand that the sequencing and mode of consent can take various forms since the beneficiary is given notice and verbally consents.

(2) Virtual Communication Services

In the April 6, 2020 IFC (85 FR 19253 through 19254), we implemented on an interim final basis the expansion of services that can be included in the payment for virtual communications in RHCs and FQHCs. We explained that in order to minimize risks associated with exposure to COVID–19, and to provide the best care possible during the PHE for the COVID–19 pandemic, we believed that RHCs and FQHC practitioners, like many other health care providers, should explore the use of interactive communications technology in the place of services that would have otherwise been furnished in person and reported and paid under the established methodologies.

In order to ensure these services would be available to beneficiaries who otherwise would not have access to clinically appropriate in-person treatment, we placed in our interim final rule a provision stating that all virtual communication services billed by HCPCS code G0071 would be available to new patients not seen by the RHC or FQHC within the previous months and modified requirements regarding when patient consent was required for these services, in order to promote timely provision of care. Specifically, we allowed consent to be obtained when the services were furnished instead of prior to the service being furnished and before the services were billed. Consent could also be acquired by staff under the general supervision of the RHC or FQHC practitioner for the virtual communication codes during the COVID–19 PHE.

We received several comments on these policies and subsequently finalized the provisions of the April 6, 2020 IFC without modification. However, we stated that when the COVID–19 PHE ended, beneficiary consent for these services would revert back to direct supervision and clarified this in the CY 2023 PFS final rule with comment period (87 FR 70127 through 70128).

Similar to the discussion above regarding obtaining consent for CCM, we believe the same philosophy applies to consent for virtual communications. In an effort to continue promoting access to timely, quality care for Medicare beneficiaries and to align with the PFS, we propose to clarify that the consent from the beneficiary to receive virtual communication 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 do not believe that the timing or manner in which beneficiary consent is acquired should interfere with the provision of one of these services.

C. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) Conditions for Certification or Coverage (CfCs)

1. Summary of the Provisions

Section III.C. of this proposed rule outlines changes to the RHC and FQHC CfCs as required in section 4121 of division FF of the Consolidated Appropriations Act (Pub. L. 117–328, December 29, 2022) (CAA 2023). Specifically, we must implement provisions that would modify the existing RHC and FQHC CfCs at § 491.8(a)(3) to include marriage and family therapists (MFTs) and mental health counselors (MHCs) as part of the collaborative team approach to provide services under Medicare Part B. We also propose to include definitions of other healthcare professionals who are already eligible to provide services at RHCs and FQHCs.

2. Proposed Changes to the RHC Conditions for Certification and FQHC Conditions for Coverage

a. Definitions (§ 491.2)

According to House Report No. 95–548 (Vol. I), the Rural Health Clinic Services Act of 1977 was established to address an inadequate supply of physicians available to serve Medicare and Medicaid beneficiaries in rural and shortage areas. The establishment of RHCs addressed this problem by allowing physicians and certain other practitioners in qualifying clinics in rural, medically underserved communities to furnish outpatient services to Medicare and Medicaid beneficiaries. The Rural Health Clinic Services Act of 1977 (Pub. L. 95–210, enacted December 13, 1977) enacted section 1861(aa) of the Act to extend Medicare entitlement and payment for primary care services furnished at an RHC by physicians and certain other practitioners and for services and supplies incidental to their services. Other practitioners included nurse practitioners (NPs) and physician assistants (PAs). Subsequent legislation extended the definition of covered RHC services to include the services of clinical psychologists (CPs), clinical social workers (CSWs), and certified nurse midwives (CNMs).

Section 4161(a)(2) of the Omnibus Budget Reconciliation Act (OBRA) of

1990 added the definition of ''FQHC services'' to section 1861(aa) of the Act as ''services described in section 1861(aa)(l)(A) through (C) of the Act,'' which, are RHC services generally provided by physicians, NPs, PAs, CPs, CSWs, and CNMs. FQHCs were established to provide primary care and preventive services in underserved rural or urban areas designated as either a shortage area or an area with a medically underserved population, regardless of the patient's ability to pay.

Section 4121 of division FF of the CAA, 2023 amended section 1861 of the Act to add a new subsection (lll) and corresponding revisions to subsection (s)(2) of such section that establish a new benefit category for MFT services and MHC services. Section 4121(b)(1) of the CAA, 2023 amended section 1861(aa)(1)(B) of the Act to add MFT and MHC services as services that can be furnished by RHCs, which is incorporated into FQHC services through section 1861(aa)(3) of the Act.

Section 1861 of the Act authorizes the Secretary to establish the requirements that an RHC and FQHC must meet to participate in the Medicare Program. These requirements are codified in regulations at 42 CFR part 491. For an RHC and FQHC to receive Medicare payment for services, it must meet the requirements at part 491, which are intended to promote the health and safety of care provided to RHC and FQHC patients.

In order to reflect the statute, we propose adding conforming changes to the CfCs to include MFT and MHC services as proposed in section III.B. of this proposed rule to indicate that RHC and FQHCs can offer these services under their Medicare certification. At § 491.2, *Definitions,* we propose adding a definition of MFTs and MHCs by cross-referencing the definitions proposed at §§ 410.53 and 410.54.

Previously enacted laws extended the definition of covered RHC services to include the services of CPs (section 4077(a) of OBRA '87), CNMs (section 6213(a) of OBRA '89), and CSWs (section 6213(b) of OBRA '89). Note that the CfCs do not currently define CPs, CSWs, or CNMs whose services are covered when furnished in an RHC and FQHC, so we also propose to add these professionals to § 491.2, *Definitions,* and cross-reference the definitions established in the payment requirements at § 410.77(a), § 410.71(d), § 410.73(a) respectively.

We propose revising the existing ''nurse practitioner'' (NP) definition at § 491.2. The current definition sets forth education and certification requirements. The current requirement at § 491.2(1) states that an NP must be certified as a primary care NP by the American Nurses Association and the National Board of Pediatric Nurse Practitioners and Associates. The National Board of Pediatric Nurse Practitioners and Associates has changed the organization's name since this requirement was first implemented. The American Association of Nurse Practitioners (AANP), examined NP graduates from 2019 to 2020 by certification exam and discovered that 88 percent of licensed NPs in the U.S. are educated and prepared in primary care.[122] The AANP considers primary care providers with a population focus on family, adult gerontology primary care, psych mental health, pediatric primary care, and women's health. We believe that removing specific certifying boards from § 491.2(1) will ensure that the requirements reflect the breadth of currently available certifications. For awareness, examples of certifying boards that focus on an area the AANP considers primary care are the American Academy of Nurse Practitioners Certification Board (AANPCB), American Nurses Credentialing Center (ANCC) Certification Program, Pediatric Nursing Certification Board (PNCB), and the National Certification Corporation (NCC).[123] We propose revising the definition of NP at § 491.2(1) to require that an NP, be certified as a primary care nurse practitioner at the time of provision of services by a recognized national certifying body that has established standards for nurse practitioners and possess a master's degree in nursing or a Doctor of Nursing Practice (DNP) doctoral degree. We have proposed adding the education requirement to clause (1) of the definition because the American Nurses Association has stated that for someone to become an NP, one must be a registered nurse or have a bachelor of science in nursing (BSN), complete an NP-focused master's or doctoral nursing program, and pass the National NP Certification Board Exam.[124] We propose to retain paragraphs (2) and (3) of the current NP definition, which provides alternative certification and education requirements an NP can meet to furnish services in an RHC or FQHC if (1) is not met.

We are soliciting comments regarding the current definition of NPs at § 491.2(1). Specifically, we are interested in feedback on whether the definition of NPs should specify that an NP's certification be in the area of primary care, or whether this distinction should be removed. This would allow all NPs who are certified by a national certifying body and meet other applicable requirements to furnish services in an RHC or FQHC. We recognize that NPs are one of the fastest-growing provider groups to provide primary care, and the number of Medicare beneficiaries who receive primary care services from NPs is increasing.[125] [126] According to the March 2023 Medicare Payment Policy report, a larger percentage of Medicare beneficiaries and privately insured persons living in rural or low-income areas have revealed that they rely on NPs or PAs for most, if not all, of their healthcare needs. This indicates that NPs and PAs play a crucial role in ensuring that underserved populations have access to quality healthcare services, despite the challenges of living in areas with limited healthcare professionals and resources. The latest report from AANP indicates that a significant proportion of NP graduates are currently certified in primary care; however, during the 2019–2020 academic year, approximately 12.9 percent or 45,795 NP graduates received certification in non-primary care specialties, including Adult Acute Care, Neonatal, and Pediatric Acute Care.[122] The precise number of non-primary care-certified NPs who would furnish their services at RHCs and FQHCs if the primary care certification requirement was removed remains uncertain at this time.

With the increasing number of NPs and their crucial role in providing quality care, the Consensus Model was developed to tackle the issue of inconsistent standards in education, regulation, and practice for advanced practice RNs (APRNs) by providing guidance for states to adopt uniformity in the regulation of APRN roles, licensure, accreditation, certification and education. The aim of the Consensus Model is to promote patient safety while providing greater access to

[122] *https://www.aanp.org/advocacy/advocacy-resource/position-statements/nurse-practitioners-in-primary-care#:~:text=Millions%20of%20Americans%20choose%20a,of%20all%20ages%20and%20backgrounds.*

[123] *https://www.aanp.org/student-resources/np-certification.*

[124] *American Association of Nurse Practitioners (2020). The Path to Becoming a Nurse Practitioner (NP). https://www.aanp.org/news-feed/explore-the-variety-of-career-paths-for-nurse-practitioners#:~:text=To%20become%20an%20NP%2C%20one,national%20NP%20board%20certification%20exam.*

[125] *https://www.bls.gov/careeroutlook/2020/article/careers-for-nurses-opportunities-and-options.htm.*

[126] *https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch4_v2_SEC.pdf.*

care by standardizing education, certification, accreditation and licensure requirements for APRNs, including NPs.[127] In order to practice in specialized nursing roles, individuals must possess specialized knowledge and skills. Therefore, the Consensus Model mandates that Advanced Practice Registered Nurses (APRNs) have congruent education, certification, and licensure in terms of population foci. NPs are required to select between two population foci tracks: adult-gerontology and pediatric foci. These foci are further distinguished as either primary care or acute care. Although the focus of practice centers around the patient's needs rather than the setting, NPs possess comprehensive educational training and practical experience to cater to patients in primary or acute care.[128] Primary care NPs are trained to offer comprehensive, continuous care for patients with most health needs, including chronic conditions. In contrast, acute care NPs are equipped to provide restorative care, which involves addressing rapidly changing clinical conditions in patients with unstable, chronic, and complex acute and critical conditions.

The NP scope of practice allows them to provide care to patients based on the acuity of the patient's needs, rather than the setting in which the services are administered. This implies that an acute care NP can offer their services to patients within their scope of practice in RHCs and FQHCs, and other settings. NPs increasingly provide services to Medicare beneficiaries; however, the scope of benefits between primary care and acute care may be different. We seek comments on whether the specification of requiring NPs to be certified in primary care should remain in the definition at § 491.2.

b. Staffing and Staff Responsibilities (§ 491.8)

Section 1861(aa) of the Act extends Medicare and Medicaid entitlement and payment for primary and emergency care services furnished at an RHC by physicians and other practitioners and for services and supplies incidental to their services. Other practitioners include NPs, PAs, CPs, CSWs, and CNMs. Section 4121(b)(1) of the CAA, 2023, *Coverage of Certain Mental Health Services Provided in Certain Settings Rural Health Clinics and Federally Qualified Health Centers* amends section 1861(aa)(1)(B) of the Act by including MFT and MHCs to the list of other practitioners whose services, when provided in RHCs and FQHCs, are entitled to payment under the Medicare program. To implement these changes, we propose modifying our CfCs to include MFT and MHCs as recognized staff for RHC and FQHCs.

The current requirements at § 491.8, *Staffing and staff responsibilities,* establish staffing requirements for RHC and FQHCs, details of physician responsibilities, PA and NP responsibilities, and COVID–19 vaccination requirements for staff. We propose revising the requirements at § 491.8, *Staffing and staff responsibilities.* Currently, at § 491.8(a)(3), the PA, NP, CNM, CSW, or CP may be the owner, employee, or furnish services under contract with the clinic (RHC) or center (FQHC). In the case of a clinic, at least one PA or NP must be an employee of the clinic. At § 491.8(a)(3), we propose to add MFT and MHC to the list, allowing them to be the owner, employee, or furnish services under contract to the clinic or center. Additionally, § 491.8(a)(6) requires that a physician, PA, NP, CNM, CSW, or CP is available to furnish patient care services at all times the clinic or center operates. Furthermore, for RHCs, an NP, PA, or CNM is available to furnish patient care services at least 50 percent of the time the RHC operates. We propose adding MFTs and MHCs to the list of other practitioners who can provide services when the clinic or center is open and operating. We are also proposing to update § 491.8(a)(6) to include MFTs and MHCs to the list of other practitioners who are eligible to furnish services and who can provide services, within the scope of practice, when the clinic or center is open and operating.

Section 1861(aa)(2) and (4) of the Act require that RHC and FQHC staff include one or more physicians, and RHCs are also required to employ at least one PA or NP. There are no requirements for an RHC or FQHC to employ a CNM, CSW, CP, MHC, or MFT; however, we expect clinics and centers to ensure that the needs of the patient population they serve are met. We acknowledge that there are similarities and differences between CSWs, MHCs, and MFTs, ranging from offered services to experience to scope of practice. CSWs, MHCs, and MFTs have similar roles and responsibilities as they relate to counseling and can assist patients with the challenges they are facing; however, MHCs and MFTs may have a larger emphasis on human development and psychological approaches, whereas CSWs often focus on a person's overall social and socioeconomic circumstance. Some other services social workers can provide are psychosocial assessments, identifying and providing community resources to patients, and assisting with communicating with other members of their healthcare team. As rural areas are increasingly diverse, have significant strengths and unique challenges, and are essential in providing care to residents of medically underserved communities, RHCs and FQHCs play a key role in identifying the needs of their patients and employing mental health professionals. In November 2022, we published a framework for advancing health care in rural, tribal, and geographically isolated communities.[129] Priorities related to rural health included in the framework are advancing health equity by addressing health disparities, expanding access to care, and engaging with partners and communities. To reduce health disparities and achieve positive physical, mental, and behavioral health outcomes, providers must address access to affordable and quality food, education, employment, housing, and access to the physical and mental care they need.[130] People living in rural areas have less access to healthcare and social services, higher unemployment rates, and higher poverty rates than urban areas, which impacts a person's physical and mental well-being.[131] [132] [133] To meet an individual's medical, behavioral, and social service needs, it's important to have high-quality staff to address those issues.[134] A team of diverse professionals can address a patient's physical and mental health through counseling, case management, and provide resources and information to address social determinants of health.[135]

Individuals living in rural areas face multiple barriers that prevent people from accessing physical and mental health services, including but not limited to provider shortages and

[127] *https://www.ncbi.nlm.nih.gov/books/NBK209870/.*

[128] *https://www.aacn.org/~/media/aacn-website/certification/advanced-practice/adultgeroacnpcompetencies.pdf.*

[129] *https://www.cms.gov/files/document/cms-geographic-framework.pdf.*

[130] *https://www.jstor.org/stable/pdf/26554276.pdf?refreqid=excelsior%3A3437750e2633ee53aa5c0afe8caae6ea&ab_segments=&origin=&initiator=&acceptTC=1.*

[131] *https://apps.who.int/iris/bitstream/handle/10665/112828/9789241506809_eng.pdf.*

[132] *https://onlinelibrary.wiley.com/doi/10.1111/jmft.12202.*

[133] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4102288/.*

[134] *https://www.chcs.org/media/INSIDE_ICTs_for_Medicare-Medicaid_Enrollees-012216.pdf.*

[135] *https://www.jstor.org/stable/pdf/26554276.pdf?refreqid=excelsior%3A3437750e2633ee53aa5c0afe8caae6ea&ab_segments=&origin=&initiator=&acceptTC=1.*

transportation difficulties.[136] A study from 2015 surveyed mental health specialists in nonmetropolitan areas and found that rural counties had less than half as many mental health professionals as proportional to the population compared to urban areas.[137] The shortage of mental health providers in rural areas also puts a strain on generalist providers to diagnose and care for patients seeking care for mental health.[138] In 2017, general practice physicians (including NPs and PAs) were the predominant source for treating depression in adults living in rural communities.[139] Of the same population, less than 20 percent received treatment from mental health professionals, and 32 percent received no treatment. If MFTs and MHCs can provide reimbursable services under the Medicare program, the pool of mental health professionals who can help address practitioner shortages in rural communities can expand.

D. Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-In of Payment Reductions

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) 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 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 for failure to report applicable information with respect to the initial data reporting period.[140]

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, 35855 through 35862). First, we excluded Medicare Advantage plan payments under Part C from the denominator of the Medicare revenues threshold calculation to broaden the types of laboratories qualifying as an applicable laboratory. 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 original provisions enacted by section 216(a) of PAMA, for the first 3 years after implementation (CY 2018 through CY 2020), the reduction could not be more than 10 percent per year. For the next 3 years after implementation (CY 2021 through CY 2023), section 216(a) of PAMA stated that the reduction could not be more than 15 percent per year. Under sections 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 were to 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 originally scheduled to take place from January 1, 2020, through March 31, 2020, with the next update to the Medicare payment rates for those tests based on that reported applicable information scheduled to take effect on 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. The definition of an ADLT is set forth in section 1834A(d)(5) of the Act and implemented at § 414.502. 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

[136] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1851736/.*

[137] *https://aspe.hhs.gov/sites/default/files/2021-07/rural-health-rr.pdf.*

[138] *https://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1013&context=ruhrc_reports.*

[139] *https://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1013&context=ruhrc_reports.*

[140] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf.*

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.[141]

3. Previous Statutory Revisions to the Data Reporting Period and Phase-In of Payment Reductions

Beginning in 2019, Congress passed a series of legislation to modify the statutory requirements for the data reporting period and phase-in of payment reductions under the CLFS. First, section 105(a)(1) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116–94, December 20, 2019) (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, instead of January 1, 2020, through March 30, 2020. 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 applied 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 was 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 at § 414.507(d) (81 FR 41036).

Subsequently, section 3718 of the Coronavirus Aid, Relief, and Economic Security Act, 2020 (CARES Act) (Pub. L. 116–136, March 27, 2020) 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. The CARES Act did not modify the data collection period that applied 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 would have been based on the data collection period of January 1, 2019 through June 30, 2019.

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 instead of CY 2023. 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 would apply for CYs 2022 through 2024, instead of CYs 2021 through 2023. In the CY 2021 PFS rulemaking (85 FR 50210 through 50211; 85 FR 84693 through 84694), in accordance with section 105(a) of the FCAA and section 3718 of the CARES Act, we proposed and finalized conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G.

Section 4 of the Protecting Medicare and American Farmers from Sequester Cuts Act (PMAFSCA) (Pub. L. 117–71, December 10, 2021) made additional revisions to the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs and to the phase-in of payment reductions under section 1834A of the Act. Specifically, section 4(b) of PMAFSCA 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, 2023, through March 31, 2023. The 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. As amended by section 4 of PMAFSCA, section 1834A(a)(1)(B) of the Act provided 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, 2022; (ii) reporting is required during the period beginning January 1, 2023, and ending March 31, 2023; and (iii) reporting is required every 3 years after the period described in clause (ii).

Section 4 of PMAFSCA 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, 2023, through March 31, 2023) would continue to be based on the data collection period of January 1, 2019, through June 30, 2019, as defined in § 414.502.

Section 4 of PMAFSCA 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 2025. It further amended section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for each of CY 2021 and 2022 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2021 and 2022 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2020. Section 4(a) of PMAFSCA further amended section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent would apply for CYs 2023 through 2025, instead of CYs 2022 through 2024.

In the CY 2023 PFS rulemaking (87 FR 46068 through 46070; 87 FR 69741 through 69744, 70225), in accordance with section 4 of PMAFSCA, we proposed and finalized conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G. Specifically, we finalized revisions to § 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, 2023, through March 31, 2023, the data collection period is January 1, 2019, through June 30, 2019. We also revised

[141] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.*

§ 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning January 1, 2023. In addition, we finalized conforming changes to our requirements for the phase-in of payment reductions to reflect the PMAFSCA amendments. Specifically, we finalized revisions to § 414.507(d) to indicate that for CY 2022, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2021, and for CYs 2023 through 2025, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

As a result of the statutory revisions under the FCAA, CARES Act, and PMAFSCA, there have only been two data collection periods for CDLTs that are not ADLTs to date. The first data collection period for these tests occurred from January 1, 2016, through June 30, 2016, and the second occurred from January 1, 2019, through June 30, 2019. Thus far, there has been only one data reporting period for these tests, which took place from January 1, 2017, through March 31, 2017. We have established CLFS payment rates for these tests using the methodology established in PAMA only one time, effective January 1, 2018, based on the applicable information collected by applicable laboratories during the 2016 data collection period and reported to CMS during the 2017 data reporting period.

Additionally, we have applied the phase-in of payment reductions for the first 3 years of PAMA implementation, CY 2018 through CY 2020, whereby reduction of payment rates could not be more than 10 percent per year as compared to the amount established the prior year. However, the phase-in of payment reductions set forth in PAMA for years 4 through 6 of PAMA implementation, whereby payment cannot exceed 15 percent per year as compared to the amount established the prior year, has not yet occurred.

4. Additional Statutory Revisions to the Data Reporting Period and Phase-In of Payment Reductions

Section 4114 of the Consolidated Appropriations Act of 2023 (CAA, 2023) (Pub. L. 117–328, enacted December 29th, 2022) made further revisions to the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs and to the phase-in of payment reductions under section 1834A of the Act. Specifically, section 4114(b) of the CAA, 2023 amended the data reporting requirements in section 1834A(a)(1)(B) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by one year, so that data reporting would be required during the period of January 1, 2024, through March 31, 2024, instead of the data reporting period of January 1, 2023 through March 31, 2023 established under the PMAFSCA. The 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. As amended by section 4114(b) of the CAA, 2023, 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, 2023; (ii) reporting is required during the period beginning January 1, 2024, and ending March 31, 2024; and (iii) reporting is required every 3 years after the period described in clause (ii).

Section 4114 of the CAA, 2023 does 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, 2024, through March 31, 2024) will continue to be based on the data collection period of January 1, 2019, through June 30, 2019, as defined in § 414.502.

Section 4114(a) of the CAA, 2023 further amends the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extends the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2026. It further amends section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2023 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2023 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2022. Section 4114(a) of the CAA, 2023 further amends section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent will apply for CYs 2024 through 2026.

5. Proposed Conforming Regulatory Changes

In accordance with section 4114 of the CAA, 2023, we are proposing to make certain conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G. Specifically, we are proposing 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, 2024, through March 31, 2024, the data collection period is January 1, 2019, through June 30, 2019. We are also proposing to revise § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning January 2024. In addition, we are proposing to make conforming changes to our requirements for the phase-in of payment reductions to reflect the amendments in section 4114(a) of the CAA, 2023. Specifically, we are proposing to revise § 414.507(d) to indicate that for CY 2023, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2022, and for CYs 2024 through 2026, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We note that the CYs 2023 and 2024 CLFS payment rates for CDLTs that are not ADLTs are based on applicable information collected in the data collection period of January 1, 2016, through June 30, 2016. Under current law, the CLFS payment rates for CY 2025 through CY 2027 will be based on applicable information collected during the data collection period of January 1, 2019, through June 30, 2019, and reported to CMS during the data reporting period of January 1, 2024, through March 31, 2024.

E. Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation Expansion of Supervising Practitioners

Conditions of coverage for pulmonary rehabilitation (PR), cardiac rehabilitation (CR) and intensive cardiac rehabilitation (ICR) are codified at 42 CFR 410.47 and 410.49. We are proposing revisions to the PR and CR/ICR regulations to codify the statutory changes made in section 51008 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018) (BBA of 2018) which permit other specific practitioners to supervise the items and services effective January 1, 2024.

1. Statutory Authority

Section 144(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275, July 15, 2008) (MIPPA) amended title XVIII to add new section 1861(eee) of the Act to provide coverage of CR and ICR under Medicare part B, as well as new section 1861(fff) of the Act to provide coverage of PR under Medicare

part B. The statute specified certain conditions for coverage of these services and an effective date of January 1, 2010. Conditions of coverage for PR, CR and ICR consistent with the statutory provisions of section 144(a) of the MIPPA were codified in §§ 410.47 and 410.49 respectively through the CY 2010 PFS final rule with comment period (74 FR 61872 through 61886 and 62002 through 62003 (PR) 62004 through 62005 (CR/ICR)). Section 51008 of the BBA of 2018, entitled ''Allowing Physician Assistants, Nurse Practitioners, and Clinical Nurse Specialists to Supervise Cardiac, Intensive Cardiac and Pulmonary Rehabilitation Programs,'' amended sections 1861(eee) and (fff) of the Act, effective January 1, 2024. The amendment directs us to add to the types of practitioners who may supervise PR, CR and ICR programs to also include a physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS).

2. Background

Under § 410.47(b), Medicare part B covers PR for beneficiaries with moderate to very severe chronic obstructive pulmonary disease (COPD) (defined as GOLD classification II, III and IV), when referred by the physician treating the chronic respiratory disease and allows additional medical indications to be established through a national coverage determination (NCD). We have not added additional medical indications for PR using the NCD process; however, we used notice and comment rulemaking through the CY 2022 PFS final rule (86 FR 64996) to establish coverage of PR for beneficiaries who have had confirmed or suspected COVID–19 and experience persistent symptoms that include respiratory dysfunction for at least 4 weeks. In the same final rule, we also updated language to improve consistency and accuracy across PR and CR/ICR conditions of coverage and removed a PR requirement for direct physician-patient contact.

Under § 410.49(b), Medicare part B covers CR and ICR for beneficiaries who have experienced one or more of the following: (1) an acute myocardial infarction within the preceding 12 months; (2) a coronary artery bypass surgery; (3) current stable angina pectoris; (4) heart valve repair or replacement; (5) percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; (6) a heart or heart-lung transplant; (7) stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks, on or after February 18, 2014, for cardiac rehabilitation and on or after February 9, 2018, for intensive cardiac rehabilitation; or (8) other cardiac conditions as specified through an NCD. The NCD process may also be used to specify non-coverage of a cardiac condition for ICR if coverage is not supported by clinical evidence.

In 2014, we established coverage of CR through the NCD process (NCD 20.10.1, Cardiac Rehabilitation Programs for Chronic Heart Failure (Pub. 100–03) to beneficiaries with stable, chronic heart failure. Section 51004 of the BBA of 2018, amended section 1861(eee)(4)(B) of the Act to expand coverage of ICR to include patients with stable, chronic heart failure. Section 410.49 was updated to codify this expansion through the CY 2020 PFS final rule (84 FR 62897 through 62899 and 63188). The CY 2022 PFS final rule (86 FR 64996) updated language in § 410.49 to improve consistency and accuracy across PR and CR/ICR conditions of coverage.

3. Proposals for Implementation

Consistent with the amendments made by section 51008 of the BBA of 2018 to section 1861(eee) and (fff) of the Act, we propose additions and revisions to language in §§ 410.47 and 410.49 as described below.

a. Definitions

We are proposing to add a new term, nonphysician practitioner (NPP), to §§ 410.47(a) and 410.49(a), which would be defined as a PA, NP, CNS as those terms are defined in section 1861(aa)(5)(A) of the Act.

We are proposing to amend the term supervising physician at §§ 410.47(a) and 410.49(a) to supervising practitioner and amend the definition to mean a physician or NPP.

Finally, we are proposing to amend the definition for pulmonary rehabilitation at § 410.47(a) and the definitions for cardiac rehabilitation and intensive cardiac rehabilitation (ICR) program at § 410.49(a) to specify that these are physician- or NPP-supervised programs.

b. Setting

We are proposing to amend § 410.47(b)(3)(ii)(A) and § 410.49(b)(3)(ii) to specify that all settings must have a physician or NPP immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the programs.

c. Supervising Practitioner Standards

We are proposing to amend language at §§ 410.47(d) and 410.49(e) by specifying that these sections include supervising practitioner standards, rather than just supervising physician standards. We are also removing the third standard in each section (§§ 410.47(d)(3) and 410.49(e)(3)) because specifying that a physician or NPP is licensed to practice medicine in the state where a PR/CR/ICR program is offered, or any corresponding reference to a NPP being licensed or authorized to practice, is redundant to the definition for each practitioner type in the Act. Since the physicians and NPPs that may supervise PR/CR/ICR are defined at §§ 410.47(a) and 410.49(a) by cross-reference to the Act, we believe repeating part of that definition in these sections is unnecessary.

4. Summary

We are proposing additions and revisions that are necessary to implement the amendments to section 1861(eee) and (fff) of the Act set forth in section 51008 of the BBA of 2018, which expand the types of practitioners that may supervise PR, CR and ICR. This includes changes to the regulatory language in the definitions, settings and supervising practitioner standards sections under §§ 410.47 and 410.49. We believe these proposed amendments to §§ 410.47 and 410.49 would serve to implement the provisions in the BBA of 2018 regarding the types of practitioners that may supervise PR, CR and ICR beginning January 1, 2024. All other provisions of these regulations would remain unchanged.

F. 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 (SUPPORT) for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, October 24, 2018) established a new Medicare Part B benefit 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 and 84 FR 62919 through 62926), we implemented Medicare coverage and provider enrollment requirements and established a methodology for determining the bundled payments for episodes of care for the treatment of OUD furnished by OTPs. We also

established in the CY 2020 PFS final rule new codes 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. In the CY 2021 PFS final rule (85 FR 84683 through 84692), we adopted new add-on codes for take home supplies of nasal naloxone and injectable naloxone. In the CY 2022 PFS final rule (86 FR 65340 and 65341), we established a new add-on code and payment for a higher dose of nasal naloxone. We also revised paragraphs (iii) and (iv) in the definition of ''Opioid disorder treatment service'' at § 410.67(b) to allow OTPs to furnish individual and group therapy and substance use counseling using audio-only telephone calls rather than two-way interactive audio/video communication technology after the conclusion of the public health emergency (PHE) for COVID–19 in cases where audio/video communication technology is not available to the beneficiary, provided all other applicable requirements are met (86 FR 65342).

More recently, CMS made further modifications and expansions to covered services for the treatment of OUD by OTPs in the CY 2023 PFS final rule (87 FR 69768 through 69777). Specifically, we revised our methodology for pricing the drug component of the methadone weekly bundle and the add-on code for take-home supplies of methadone by using the payment amount for methadone for CY 2021 updated by the PPI for Pharmaceuticals for Human Use (Prescription) to better reflect the changes in methadone costs for OTPs over time. Additionally, we finalized a modification to the payment rate for individual therapy in the non-drug component of the bundled payment for an episode of care to base the payment rate on the rate for longer therapy sessions that better account for the greater severity of needs for patients with an OUD and receiving treatment in the OTP setting. Moreover, for the purposes of the geographic adjustment, we clarified that services furnished via OTP mobile units will be treated as if the services were furnished in the physical location of the OTP for purposes of determining payments to OTPs under the Medicare OTP bundled payment codes and/or add-on codes to the extent that the services are medically reasonable and necessary and are furnished in accordance with Substance Abuse and Mental Health Services Administration (SAMHSA) and Drug Enforcement Administration (DEA) guidance. We believe that this policy enables OTPs to better serve Medicare beneficiaries living in underserved areas by providing access to many of the same OUD treatment services offered at the brick and mortar location of the OTP. We are continuing to monitor utilization of OUD treatment services furnished by OTPs to ensure that Medicare beneficiaries have appropriate access to care. For CY 2024, we are proposing several modifications to the policies governing Medicare coverage and payment for OUD treatment services furnished by OTPs.

2. Additional Flexibilities for Periodic Assessments Furnished via Audio-Only Telecommunications

We have finalized several flexibilities for OTPs regarding the use of telecommunications, both during the PHE for COVID–19 and outside of the PHE. In the CY 2020 PFS final rule, we finalized a policy allowing OTPs to furnish substance use counseling and individual and group therapy via two-way interactive audio-video communication technology. In the IFC entitled ''Medicare and Medicaid Programs: Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' which appeared in the April 6, 2020 **Federal Register** (85 FR 19258), we revised paragraphs (iii) and (iv) in the definition of opioid use disorder treatment service at § 410.67(b) on an interim final basis to allow the therapy and counseling portions of the weekly bundles, as well as the add-on code for additional counseling or therapy, to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology during the PHE for the COVID–19 if beneficiaries do not have access to two-way audio-video communications technology, provided all other applicable requirements are met. In the CY 2022 PFS final rule (86 FR 65341 through 65343), we finalized that after the conclusion of the PHE for COVID–19, OTPs are permitted to furnish substance use counseling and individual and group therapy via audio-only telephone calls when audio and video communication technology is not available to the beneficiary. As we explained in the CY 2022 PFS final rule (86 FR 65342), we interpret the requirement that audio/video technology is ''not available to the beneficiary'' to include circumstances in which the beneficiary is not capable of or has not consented to the use of devices that permit a two-way, audio/video interaction because in each of these instances audio/video communication technology is not able to be used in furnishing services to the beneficiary. More recently in the CY 2023 PFS final rule (87 FR 69775 through 69777), we further extended telecommunication flexibilities for the initiation of treatment with buprenorphine outside of the COVID–19 PHE. Specifically, we allowed the OTP intake add-on code to be furnished via two-way, audio-video communications technology when billed for the initiation of treatment with buprenorphine, to the extent that the use of audio-video telecommunications technology to initiate treatment with buprenorphine is authorized by DEA and SAMHSA at the time the service is furnished. We also permitted the use of audio-only communication technology to initiate treatment with buprenorphine in cases where audio-video technology is not available to the beneficiary, provided all other applicable requirements are met.

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 appeared in the May 8, 2020 **Federal Register** (85 FR 27558), we revised paragraph (vii) in the definition of ''Opioid use disorder treatment service'' at § 410.67(b) on an interim final basis to allow periodic assessments to be furnished during the PHE for COVID–19 via two-way interactive audio-video telecommunication 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. In the CY 2021 PFS final rule (85 FR 84690), we finalized our proposal to revise paragraph (vii) in the definition of ''Opioid use disorder treatment service'' at § 410.67(b) to provide that periodic assessments (HCPCS code G2077) must be furnished during a face-to-face encounter, which includes services furnished via two-way interactive audio-video communication technology, as clinically appropriate, provided all other applicable

requirements are met, on a permanent basis.

Furthermore, in the CY 2023 PFS proposed rule (87 FR 46093), we sought comment on whether we should allow periodic assessments to continue to be furnished using audio-only communication technology following the end of the PHE for COVID–19 for patients who are receiving treatment via buprenorphine, and if this flexibility should also continue to apply to patients receiving methadone or naltrexone. In response, several commenters advocated for CMS to continue to allow periodic assessments to be furnished audio-only when video is not available after the end of the PHE. Commenters highlighted that making audio-only flexibilities permanent would further promote equity for individuals who are economically disadvantaged, live in rural areas, are racial and ethnic minorities, lack access to reliable broadband or internet access, or do not possess devices with video capability. Additionally, a commenter cited a 2020 HHS Issue Brief indicating higher utilization of audio-only visits for older adults. Specifically, evidence suggests that the proportion of telephonic audio-only visits increases with the age of the patient, with ''17 percent of visits delivered via audio-only interaction for patients 41–60 years of age, 30 percent for patients 61–80 years of age, and 47 percent of visits for patients over 81.'' [142] One commenter stated that periodic assessments are no less complex than intake/initial assessments, and thus are equally appropriate for audio-video and audio-only care. Lastly, several commenters expressed support for the use of telecommunications in circumstances when the provider and patient have together determined that the patient would individually benefit from telehealth services and a high quality of care is maintained. They encouraged CMS to expand flexibilities to furnish substance use disorder (SUD) services via telecommunications to allow providers and patients to decide collaboratively the best modality for individualized care. After considering these comments, CMS determined that it would be appropriate to allow periodic assessments to be furnished audio-only when video is not available through the end of CY 2023, to the extent that it is authorized by SAMHSA and DEA at the time the service is furnished and, in a manner consistent with all applicable requirements. We stated our belief that this modification would allow continued beneficiary access to these services for the duration of CY 2023 in the event the PHE terminated before the end of 2023 and that it would also grant additional time for CMS to further consider telecommunication flexibilities associated with periodic assessments. Accordingly, we revised the requirements related to the periodic assessment services in paragraph (vii) in the definition of ''Opioid use disorder treatment services'' at § 410.67(b) of the regulations to reflect these changes.

Section 4113 of Division FF, Title IV, Subtitle A of the Consolidated Appropriations Act of 2023 (CAA, 2023) (Pub. L. 117–328, December 29, 2022) extended the telehealth flexibilities enacted in the Consolidated Appropriations Act of 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022). Specifically, it amended sections 1834(m), 1834(o), and 1834(y) of the Act to delay the requirement for an in-person visit prior to furnishing certain mental health services via telecommunications technology by physicians and other practitioners, Rural Health Clinics (RHCs), and Federally Qualified Health Centers (FQHCs) until dates of service on or after January 1, 2025 if the COVID–19 PHE ends prior to that date. Additionally, it extended the flexibilities available during the PHE that allow for certain Medicare telehealth services defined in section 1834(m)(4)(F)(i) of the Act to be furnished via an audio-only telecommunications system through December 31, 2024 if the PHE for COVID–19 ends prior to that date. The PHE for COVID–19, which was declared under section 319 of the Public Health Service Act, expired at the end of the day on May 11, 2023, so the aforementioned flexibilities will be extended through the end of CY 2024 or CY 2025, as applicable.

To better align coverage for periodic assessments furnished by OTPs with the telehealth flexibilities described in section 4113 of the CAA, 2023, we are proposing to extend the audio-only flexibilities for periodic assessments furnished by OTPs through the end of CY 2024. Under this proposal, we would allow periodic assessments to be furnished audio-only when video is not available to the extent that use of audio-only communications technology is permitted under the applicable SAMHSA and DEA requirements at the time the service is furnished and all other applicable requirements are met. We believe extending this flexibility would promote continued beneficiary access to these services following the end of the PHE and for the duration of CY 2024. During the COVID–19 pandemic, substance use disorder treatment facilities increased telemedicine offerings by 143 percent, and as of 2021, almost 60 percent of SUD treatment facilities offer telehealth.[143] Notably, telephone-based (that is, audio-only) therapy and recovery support services provided by SUD programs have been found to be one of the most common modes of telehealth for treatment of opioid use disorder.[144] Therefore, extending these audio-only flexibilities for an additional year may minimize disruptions associated with the conclusion of the PHE. Additionally, evidence has shown that Medicare beneficiaries who are older than 65 years-old, racial/ethnic minorities, dual-enrollees, or living in rural areas, or who experience low broadband access, low-income, and/or not speaking English as their primary language, are more likely to be offered and use audio-only telemedicine services than audio-video services.[145] Other evidence also suggests that while Tribal populations, including American Indian and Alaska Natives, have the highest rates of OUD prevalence among Medicare beneficiaries, one-third of these populations do not have adequate access to high-speed broadband and continue to rely on audio-only visits.[146] Therefore, minimizing disruptions to care for beneficiaries currently receiving audio-only periodic assessments may further promote health equity and minimize disparities in access to care. Lastly, extending these flexibilities another year will allow CMS time to further consider this issue, including whether periodic assessments should continue to be furnished using audio-only communication technology following the end of CY 2024 for patients who are receiving treatment via buprenorphine, methadone, and/or naltrexone at OTPs.

Accordingly, we are proposing to revise paragraph (vii) of the definition of

[142] HHS ASPE Issue Brief: Medicare beneficiary use of telehealth visits: Early Data from the Start of the COVID–19 Pandemic (July 27, 2020). *https://aspe.hhs.gov/reports/medicare-beneficiary-use-telehealth-visits-early-data-start-covid-19-pandemic.*

[143] *https://pubmed.ncbi.nlm.nih.gov/34407631/.*

[144] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8250742/.*

[145] *https://pubmed.ncbi.nlm.nih.gov/33471458/*; *https://www.kff.org/medicare/issue-brief/medicare-and-telehealth-coverage-and-use-during-the-covid-19-pandemic-and-options-for-the-future/*; *https://journals.lww.com/lww-medicalcare/Fulltext/2021/11000/Disparities_in_Audio_only_Telemedicine_Use_Among.10.aspx.*

[146] *https://docs.fcc.gov/public/attachments/FCC-20-50A1.pdf*; *https://www.cms.gov/files/document/aian-telehealthwebinar.pdf*; *https://www.sciencedirect.com/science/article/pii/S0749379721000921?via%3Dihub.*

''Opioid treatment services'' at § 410.67(b) of the regulations to state that through the end of CY 2024, 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.

3. Intensive Outpatient Program (IOP) Services Provided by OTPs

In the CY 2023 PFS proposed rule, we solicited comments on intensive outpatient mental health treatment (87 FR 45943 through 45944). Commenters emphasized the importance of ensuring access to intensive outpatient program (IOP) services in OTP settings and that these services are valuable to those with SUDs (for example, OUD), including individuals who cannot stabilize at a lower level of care or require more care than can be provided in office settings and individuals who have stabilized biomedical conditions and the need for close monitoring but no longer require a higher level of care for SUD treatment, such as partial hospitalization or inpatient care.

Please see the CY 2024 Outpatient Prospective Payment System proposed rule for the full policy discussion and additional details regarding Medicare payment for IOP services provided by OTPs.

G. Medicare Shared Savings Program

1. Executive Summary and Background

a. Purpose

Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare providers, may participate in the Medicare Shared Savings Program (Shared Savings Program) by forming or joining an accountable care organization (ACO) and in so doing agree to become accountable for the total cost and quality of care provided under Traditional Medicare to an assigned population of Medicare fee-for-service (FFS) beneficiaries. Under the Shared Savings Program, providers and suppliers that participate in an ACO continue to receive traditional Medicare FFS payments under Parts A and B, and the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements, and in some instances may be required to share in losses if it increases health care spending.

As of January 1, 2023, 10.9 million people with Medicare receive care from one of the 573,126 health care providers in the 456 ACOs participating in the Shared Savings Program, the largest value-based care program in the country.[147] While the Shared Savings Program experienced a decrease in the number of ACOs and assigned beneficiaries for 2023, the policies finalized in the CY 2023 PFS final rule (87 FR 69777 through 69968) are expected to grow participation in the program for 2024 and beyond, when many of the new policies are set to go into effect. These policies are expected to drive growth in participation, particularly in rural and underserved areas, promote equity, advance alignment across accountable care initiatives, and increase the number of beneficiaries assigned to ACOs participating in the program by up to four million over the next several years.[148] Accordingly, we expect these recently finalized changes will support CMS in achieving its goal of having 100 percent of people with Original Medicare in a care relationship with accountability for quality and total cost of care by 2030.[149]

Section III.G. of this proposed rule addresses changes to the Shared Savings Program regulations to further advance Medicare's overall value-based care strategy of growth, alignment, and equity, and to respond to concerns raised by ACOs and other interested parties. We propose changes to the quality performance standard and reporting requirements under the Alternative Payment Model (APM) Performance Pathway (APP) within the Quality Payment Program (QPP) that would continue to move ACOs toward digital measurement of quality and align with the QPP. Further, the policy proposals would add a third step to the step-wise beneficiary assignment methodology under which we would use an expanded period of time to identify whether a beneficiary has met the requirement for having received a primary care service from a physician who is an ACO professional in the ACO to allow additional beneficiaries to be eligible for assignment, as well as to propose related changes to how we identify assignable beneficiaries used in certain Shared Savings Program calculations. Additionally, we are proposing updates to the definition of primary care services used for purposes of beneficiary assignment to remain consistent with billing and coding guidelines. We also propose refinements to the financial benchmarking methodology for ACOs in agreement periods beginning on January 1, 2024, and in subsequent years to cap the risk score growth in an ACO's regional service area when calculating regional trends used to update the historical benchmark at the time of financial reconciliation for symmetry with the cap on ACO risk score growth; apply the same CMS–HCC risk adjustment methodology applicable to the calendar year corresponding to the performance year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year; further mitigate the impact of the negative regional adjustment on the benchmark to encourage participation by ACOs caring for medically complex, high-cost beneficiaries; and specify the circumstances in which CMS would recalculate the prior savings adjustment for changes in values used in benchmark calculations due to compliance action taken to address avoidance of at-risk beneficiaries, or as a result of the issuance of a revised initial determination of financial performance for a previous performance year following a reopening of ACO shared savings and shared losses calculations. We are also proposing to refine our policies for the newly established advance investment payments (AIP) and make updates to other programmatic areas including the program's eligibility requirements and make timely technical changes to the regulations for clarity and consistency. Lastly, we seek comment on potential future developments to Shared Savings Program policies, including with respect to incorporating a new track that would offer a higher level of risk and potential reward than currently available under the ENHANCED track, refining the three-way blended benchmark update factor and the prior savings adjustment, and promoting ACO and community-based organization (CBO) collaboration.

b. Statutory and Regulatory Background on the 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

[147] Refer to CMS, Shared Savings Program Fast Facts—As of January 1, 2023, available at *https://www.cms.gov/files/document/2023-shared-savings-program-fast-facts.pdf*.

[148] See CMS Press Release, ''CMS Announces Increase in 2023 in Organizations and Beneficiaries Benefiting from Coordinated Care in Accountable Care Relationship'', January 17, 2023, available at *https://www.cms.gov/newsroom/press-releases/cms-announces-increase-2023-organizations-and-beneficiaries-benefiting-coordinated-care-accountable*.

[149] Ibid. See also, Seshamani M, Fowler E, Brooks-LaSure C. Building On The CMS Strategic Vision: Working Together For A Stronger Medicare. Health Affairs. January 11, 2022. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20220110.198444*. CMS, Innovation Center Strategy Refresh, available at *https://innovation.cms.gov/strategic-direction-whitepaper* (Innovation Center Strategic Objective 1: Drive Accountable Care, pages 13–17).

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 of 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 FFS beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. (See 42 U.S.C. 1395jjj.)

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 (the CURES Act) (Pub. L. 114–255, December 13, 2016). The Bipartisan Budget Act of 2018 (Pub. L. 115–123, 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) (hereinafter 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 31, 2020 date of display and appeared in the April 6, 2020 **Federal Register** (85 FR 19230) (hereinafter referred to as the ''March 31, 2020 COVID–19 IFC''), we removed the restriction that 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 8, 2020, and appeared in the May 8, 2020 **Federal Register** (85 FR 27573 through 27587) (hereinafter referred to as the ''May 8, 2020 COVID–19 IFC''), we modified Shared Savings Program policies to: (1) allow ACOs whose agreement periods expired 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. For summaries of certain policies finalized in prior PFS rules, refer to the CY 2020 PFS proposed rule (84 FR 40705), the CY 2021 PFS final rule (85 FR 84717), the CY 2022 PFS final rule (86 FR 65253 and 65254), and the CY 2023 PFS final rule (87 FR 69779 and 69780). In the CY 2023 PFS final rule (87 FR 69777 through 69968), we finalized changes to Shared Savings Program policies, including to: provide advance shared savings payments in the form of advance investment payments to certain new, low revenue ACOs that can be used to support their participation in the Shared Savings Program; provide greater flexibility in the progression to performance-based risk; establish a health equity adjustment to an ACO's Merit-based Incentive Payment System (MIPS) quality performance category score used to determine shared savings and losses to recognize high quality performance by ACOs serving a higher proportion of underserved populations; incorporate a sliding scale reflecting an ACO's quality performance for use in determining shared savings for ACOs, and revise the approach for determining shared losses for ENHANCED track ACOs; modify the benchmarking methodology to strengthen financial incentives for long term participation by reducing the impact of ACOs' performance and market penetration on their benchmarks, and to support the business case for ACOs serving high risk and high dually eligible populations to participate, as well as mitigate bias in regional expenditure calculations for ACOs electing prospective assignment; expand opportunities for certain low revenue ACOs participating in the BASIC track to share in savings; make changes to policies within other programmatic areas, including the program's beneficiary assignment methodology, requirements related to marketing material review and beneficiary notifications, the SNF 3-day rule waiver application, and data sharing requirements.

Policies applicable to Shared Savings Program ACOs for purposes of reporting for other programs have also continued to evolve based on changes in the statute. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015) 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 MIPS and Advanced APMs and related policies applicable to eligible clinicians who participate in APMs, including the Shared Savings Program. We have also made updates to policies under the Quality Payment Program through the annual CY PFS rules.

c. Summary of Shared Savings Program Proposals

In sections III.G.2. through III.G.7. of this proposed rule, we propose modifications to the Shared Savings Program's policies, and describe comment solicitations. As a general summary, we are proposing the following changes to Shared Savings Program policies to:

- Revise the quality reporting and the quality performance requirements (section III.G.2. of this proposed rule), including the following:

++ Allow Shared Savings Program ACOs the option to report quality measures under the APP on only their Medicare beneficiaries through Medicare CQMs (section III.G.2.b. of this proposed rule).

++ Update the APP measure set for Shared Savings Program ACOs (section III.G.2.c. of this proposed rule).

++ Revise the calculation of the health equity adjustment underserved multiplier (section III.G.2.d. of this proposed rule).

++ Use historical data to establish the 40th percentile MIPS Quality performance category score used for the quality performance standard (section III.G.2.e. of this proposed rule).

++ Apply a Shared Savings Program scoring policy for suppressed APP measures (section III.G.2.f. of this proposed rule).

++ Require Spanish language administration of the CAHPS for MIPS survey (section III.G.2.g. of this proposed rule).

++ Align CEHRT requirements for Shared Savings Program ACOs with MIPS (section III.G.2.h. of this proposed rule).

++ Solicit comments on MIPS Value Pathway reporting for specialists in Shared Savings Program ACOs (section III.G.2.i. of this proposed rule).

++ Revise the requirement to meet the case minimum requirement for quality performance standard determinations (section III.G.2.j. of this proposed rule).

- Revise the policies for determining beneficiary assignment (section III.G.3 of this proposed rule).

++ Modify the step-wise beneficiary assignment methodology and approach to identifying the assignable beneficiary population (section III.G.3.a of this proposed rule).

++ Update the definition of primary care services used in beneficiary assignment at § 425.400(c) (section III.G.3.b of this proposed rule).

- Revise the policies on the Shared Savings Program's benchmarking methodology (section III.G.4 of this proposed rule).

++ Modify the calculation of the regional update factor used to update the historical benchmark between benchmark year (BY) 3 and the performance year by capping an ACO's regional service area risk score growth through use of an adjustment factor to provide more equitable treatment for ACOs and for symmetry with the cap on ACO risk score growth (section III.G.4.b of this proposed rule).

++ Further mitigate the impact of the negative regional adjustment on the benchmark to encourage participation by ACOs caring for medically complex, high-cost beneficiaries (section III.G.4.c of this proposed rule).

++ Specify the circumstances in which CMS would recalculate the prior savings adjustment for changes in values used in benchmark calculations due to compliance action taken to address avoidance of at-risk beneficiaries, or as a result of the issuance of a revised initial determination of financial performance for a previous performance year (section III.G.4.d of this proposed rule).

++ Specify use of the CMS–HCC risk adjustment methodology applicable to the calendar year corresponding to the performance year in calculating prospective HCC risk scores for Medicare FFS beneficiaries for the performance year, and for each benchmark year of the ACO's agreement period (section III.G.4.e. of this proposed rule).

- Refine AIP policies, including the following (section III.G.5 of this proposed rule):

++ Modify AIP eligibility requirements to allow an ACO to elect to advance to a two-sided model level of the BASIC track's glide path beginning with the third performance year of the 5-year agreement period in which the ACO receives advance investment payments.

++ Modify AIP recoupment and recovery polices to forgo immediate collection of advance investment payments from an ACO that terminates its participation agreement early in order to early renew under a new participation agreement to continue their participation in the Shared Savings Program.

++ Modify termination policies to specify that CMS would immediately terminate advance investment payments

to an ACO for future quarters if the ACO voluntarily terminates from the Shared Savings Program.

++ Modify ACO reporting requirements to require ACOs to submit spend plan updates to CMS in addition to publicly reporting spend plan updates.

++ Modify AIP requirements to permit ACOs to seek reconsideration review of all quarterly payment calculations.

• Update Shared Savings Program eligibility requirements, including the following (section III.G.6 of this proposed rule):

++ Remove the option for ACOs to request an exception to the shared governance requirement that 75 percent control of an ACO's governing body must be held by ACO participants.

++ Codify the existing Shared Savings Program operational approach to specify that CMS determines that an ACO participant TIN participated in a performance-based risk Medicare ACO initiative if it was included on a participant list used in financial reconciliation for a performance year under performance-based risk during the five most recent performance years.

• Make technical changes to references in Shared Savings Program regulations (section III.G.7 of this proposed rule), including to update assignment selection references to either § 425.226(a)(1) or § 425.400(a)(4)(ii) in subpart G of the regulations, correct typographical errors in the definitions in § 425.20, and update certain terminology used in § 425.702.

In addition, we are soliciting comment on potential future developments to Shared Savings Program policies (section III.G.8. of this proposed rule), including: incorporating a track with higher risk and potential reward than the ENHANCED track; modifying the amount of the prior savings adjustment through potential changes to the 50 percent scaling factor used in determining the adjustment, as well as considerations for potential modifications to the positive regional adjustment to reduce the possibility of inflating the benchmark; potential refinements to the ACPT and the three-way blended benchmark update factor over time to further mitigate potential ratchet effects within the update factor; and policies to promote ACO and CBO collaboration.

In combination, the Shared Savings Program proposals are anticipated to improve the incentive for ACOs to sustainably participate and earn shared savings in the program. On net, total program spending is estimated to decrease by $330 million over the 10-year period 2024 through 2033. These changes are anticipated to support the goals outlined in the CY 2023 PFS final rule for growing the program with a particular focus on including underserved beneficiaries.

Certain policies, including both existing policies and the proposed new policies described in this proposed rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following proposals require the use of our authority under section 1899(i) of the Act: the proposed modifications to the calculation of regional component of the three-way blended update factor to cap regional service area risk score growth for symmetry with the ACO risk score growth cap, as described in section III.G.4.b of this proposed rule and the refinements to AIP policies as described in section III.G.5. of this proposed rule. Further, certain existing policies adopted under the authority of section 1899(i)(3) of the Act that depend on use of the assigned population and assignable beneficiary populations would be affected by the proposed addition of a new third step of the beneficiary assignment methodology and the proposed revisions to the definition of assignable beneficiary described in section III.G.3. of this proposed rule, including the following: the amount of advance investment payments; factors used in determining shared losses for ACOs under two-sided models (including calculation of the variable MSR/MLR based on the ACO's number of assigned beneficiaries, and the applicability of the extreme and uncontrollable circumstances policy for mitigating shared losses for two-sided model ACOs); and calculation of the ACPT, regional and national components of the three-way blended benchmark update factor. As described in the Regulatory Impact Analysis in section VII. and elsewhere in this proposed rule, these proposed changes to our payment methodology are expected to improve the quality and efficiency of care and are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act. We will continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

2. Quality Performance Standard 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 for purposes of assessing such quality of care. As we stated in the November 2011 final rule establishing the Shared Savings Program (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality health care at the individual and population levels. In the November 2011 final rule, we established 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). We have subsequently updated the measures that comprise the quality performance measure set for the Shared Savings Program through rulemaking in the CY 2015, 2016, 2017, 2019, and 2023 PFS final rules (79 FR 67907 through 67921, 80 FR 71263 through 71269, 81 FR 80484 through 80488, 83 FR 59707 through 59715, 87 FR 69860 through 69763, respectively).

b. Proposal for Shared Savings Program ACOs To Report Medicare CQMs

(1) Background

In the CY 2021 PFS final rule, CMS finalized modifications to the Shared Savings Program quality reporting requirements and quality performance standard for performance year 2021 and subsequent performance years (85 FR 84720). For performance year 2021 and subsequent years, ACOs are required to report quality data via the Alternative Payment Model (APM) Performance Pathway (APP). Pursuant to policies

finalized under the CY 2022 and CY 2023 PFS (86 FR 65685; 87 FR 69858), to meet the quality performance standard under the Shared Savings Program through performance year 2024, ACOs must report the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs, and the CAHPS for MIPS survey. In performance year 2025 and subsequent performance years, ACOs must report the three eCQMs/MIPS CQMs and the CAHPS for MIPS survey.

Since the CY 2021 PFS final rule was issued, interested parties have continued to express concerns about requiring ACOs to report all payer/all patient eCQMs/MIPS CQMs via the APP due to the cost of purchasing and implementing a system wide infrastructure to aggregate data from multiple ACO participant TINs and varying EHR systems (86 FR 65257). In the CY 2022 PFS, commenters supported our acknowledgement of the complexity of the transition to all payer/all patient eCQM/MIPS CQMs (86 FR 65259). Additionally, one commenter questioned how data completeness standards could be met, given the issues of de-duplication and patients adding or moving insurance coverage (87 FR 65260). In public comment to the CY 2023 PFS proposed rule, some commenters expressed multiple concerns regarding the requirement to report all payer/all patient eCQMs/MIPS CQMS beginning in performance year 2025, such as issues related to meeting all payer data requirements, data completeness requirements, data aggregation and deduplication issues, and interoperability issues among different EHRs (87 FR 69837). In the CY 2023 PFS final rule, we explained these comments went beyond the scope of our proposals. These comment letters included details of the commenters' concerns. Specifically, some commenters, which included ACOs, noted the financial burden of aggregating, deduplicating, and exporting eCQM data across multiple TINs and EHRs. Commenters, including ACOs, expressed concerns that the requirement to report all payer measures ties performance to patients that the ACO does not actively manage, increases the difficulty of meeting data completeness, and may negatively impact an ACO's performance by including patients seen by specialists. We also acknowledged that as the transition to reporting all-payer eCQMs/MIPS CQMs continues, the health equity adjustment which we finalized in the CY 2023 PFS final rule (87 FR 69842) will support ACOs that may experience challenges with the new quality reporting requirement and will provide an incentive for ACOs to serve underserved populations during the transition to reporting eCQMs/MIPS CQMs. In the CY 2023 PFS final rule, we stated that we are continuing to monitor the impact of these policies as we gain more experience with ACOs reporting all payer/all patient eCQMs/MIPS CQMs and, further, that we are exploring how to address some of the concerns related to data aggregation and the all payer requirement and may revisit these and related issues in future rulemaking based on lessons learned (87 FR 69833).

Consistent with our goal to support ACOs in the transition to all payer/all patient eCQMs/MIPS CQMs, in the CY 2023 final rule we extended the eCQM/MIPS CQM reporting incentive through PY 2024 to provide an incentive to ACOs to report the eCQMs/MIPS CQMs, while allowing them time to gauge their performance on the eCQMs/MIPS CQMs before full reporting of these measures is required beginning in performance year 2025 (87 FR 69835). Building on our goal to provide technical support to ACOs and to help ACOs build the skills necessary to aggregate and match patient data to report all payer/all patient eCQMs/MIPS CQMS, in December 2022, we hosted a webinar to support ACOs in the transition to reporting all payer/all patient eCQMs/MIPS CQMs and released a guidance document on the topic. Resources from the ''Reporting MIPS CQMs and eCQMs in the APM Performance Pathway'' webinar are available at *https://qpp.cms.gov/resources/webinars.* The guidance document, entitled ''Medicare Shared Savings Program: Reporting MIPS CQMs and eCQMs in the Alternative Payment Model Performance Pathway (APP)'' is available in the Quality Payment Program Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2179/APP%20Guidance%20Document%20for%20ACOs.pdf.* We are committed to continuing to support ACOs in the transition to all payer/all patient eCQMs/MIPS CQMs and in the transition to digital quality measurement reporting.

(2) Reporting the Medicare CQMs

In light of the concerns raised by ACOs and other interested parties and our commitment to supporting ACOs in the transition to digital quality measure reporting, for performance year 2024 and subsequent performance years as determined by CMS, we are proposing in section IV.A.4.f.(1)(b) of this proposed rule to establish the Medicare CQMs for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs) as a new collection type for Shared Savings Program ACOs reporting on the Medicare CQMs (reporting quality data on beneficiaries eligible for Medicare CQMs as defined at § 425.20) within the APP measure set and administering the CAHPS for MIPS Survey as required under the APP. Medicare CQMs would serve as a transition collection type to help some ACOs build the infrastructure, skills, knowledge, and expertise necessary to report all payer/all patient MIPS CQMs and eCQMs by defining a population of beneficiaries that exist within the all payer/all patient MIPS CQM Specifications and tethering that population to claims encounters with ACO professionals with specialties used in assignment. Specifically, we believe that Medicare CQMs would address the concern raised by ACOs that—for ACOs with a higher proportion of specialty practices and/or multiple EHR systems—the broader all payer/all patient eligible population would capture beneficiaries with no primary care relationship to the ACO. Further, we believe that ACOs, particularly ACOs with a higher proportion of specialty practices and/or multiple EHRs, would be able utilize Medicare Part A and B claims data to help identify the ACO's eligible population and to validate the ACO's patient matching and deduplication efforts. For these reasons, we believe that it is appropriate to establish Medicare CQMs as a new collection type for Shared Savings Program ACOs only.

We recognize that Medicare CQMs might not be the suitable collection type for some ACOs, particularly ACOs with a single-EHR platform, a high proportion of primary care practices, and/or ACOs composed of participants with experience reporting all payer/all patient measures in traditional MIPS. We encourage ACOs to evaluate all quality reporting options to determine which collection type is most appropriate based on the ACO's unique composition and technical infrastructure. In addition to this proposal to report quality data utilizing the Medicare CQMs collection type, in performance year 2024, ACOs would have the option to report quality data utilizing the CMS Web Interface measures, eCQMs, and/or MIPS CQMs collection types. Under this proposal, in performance year 2025 and subsequent performance years as determined by CMS, ACOs would have the option to

report quality data utilizing the eCQMs, MIPS CQMs, and/or Medicare CQMs collection types.

Our long-term goal continues to be to support ACOs in the adoption of all payer/all patient measures. We would monitor the reporting of quality data utilizing the Medicare CQMs collection type. For example, one indicator to evaluate Medicare CQMs would be to assess if there are any Medicare CQMs topped out as described at § 414.1380(b)(1)(iv). Therefore, in the 4th year the measure could be removed and would no longer be available for reporting during the performance period (83 FR 59761). Once the measure has reached an extremely topped out status (for example, a measure with an average mean performance within the 98th to 100th percentile range), we may propose the measure for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped out measure lifecycle, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, after taking into account any other relevant factors (83 FR 59763). Separately, we may specify higher standards, new measures, or both—up to and including proposing to sunset the Medicare CQM collection type in future rulemaking—to ensure that Medicare CQMs conform to the intent of section 1899(b)(3)(C) of the Act and the priorities established in the CMS National Quality Strategy.

We also remain steadfast in our commitment to support providers in the transition from traditional MIPS to APMs and Advanced APMs. As mentioned above, we acknowledge that Medicare CQMs may not be the preferred collection type for all ACOs. ACOs that are composed of participants with experience reporting all payer/all patient measures in traditional MIPS would continue to have the option to report all payer/all patient measures under this proposal. In supporting providers in the transition from traditional MIPS to APMs and Advanced APMs we also recognize the corresponding need to support ACOs in the transition to all payer/all patient reporting. In addition to the technical support we would continue to provide ACOs, we believe that the Medicare CQM collection type would aid some ACOs in the transition to all payer/all patient measures by allowing ACOs to focus patient matching and data aggregation efforts on ACO professionals with specialties used in assignment while the ACO builds the infrastructure necessary to report on a broader eligible population.

To facilitate the reporting of Medicare CQMs, we are proposing to amend the definition of ''Collection Type'' in section IV.A.4.f.(1)(b) of this proposed rule to include the Medicare CQM as an available collection type in MIPS for ACOs that participate in the Shared Savings Program. We note that the Medicare CQMs collection type would serve as a transition collection type and be available as determined by CMS. Additionally, we are proposing to establish data submission and completeness criteria pertaining to the Medicare CQMs for the MIPS quality performance category as discussed in sections IV.A.4.f.(1)(c)(i) and IV.A.4.f.(1)(d)(ii) of this proposed rule.

A Medicare CQM for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQM) is essentially a MIPS CQM reported by an ACO under the APP on only the ACO's Medicare fee-for-service beneficiaries, instead of its all payer/all patient population. We are proposing to define a beneficiary eligible for Medicare CQM at § 425.20 as a beneficiary identified for purposes of reporting Medicare CQMs for ACOs participating in the Medicare Shared Savings Program (Medicare CQMs) who is either of the following:

- A Medicare fee-for-service beneficiary (as defined at § 425.20) who—

++ Meets the criteria for a beneficiary to be assigned to an ACO described at § 425.401(a); and

++ Had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a PA, NP, or CNS.

- A Medicare fee-for-service beneficiary who is assigned to an ACO in accordance with § 425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

While this definition refers to beneficiaries that have been assigned to an ACO, it nonetheless differs from our basic assignment methodology described under subpart E and from the concept of assignable beneficiary defined at § 425.20. Specifically, the use of the terms of ''claim'' (instead of primary care services) and ''measurement period'' (instead of assignment window) in the definition are synchronous with the application of all payer/all patient MIPS CQM Specifications in reporting Medicare CQMs. For example, we define primary care services as the set of services identified by the HCPCS and revenue center codes designated under § 425.400(c). Each all payer/all patient MIPS CQM Specification identifies eligible encounters that, in part, identify patients that should be included in the measure's eligible population.

Our proposed definition for beneficiary eligible for Medicare CQMs is intended to create alignment with the all payer/all patient MIPS CQM Specifications. The HCPCS and revenue center codes designated under § 425.400(c) as primary care services for purposes of assignment under the Shared Savings Program only partially over-lap with the codes designated as eligible encounters used to identify the eligible population in all payer/all patient MIPS CQM Specifications. Applying primary care service codes or deferring to the basic assignment methodology under subpart E to identify the beneficiaries eligible for Medicare CQMs would have the unintended result of limiting the codes used to identify eligible encounters in the Medicare CQM Specification to only the codes that overlap with primary care services. Similarly, we define the assignment window as the 12-month period used to assign beneficiaries to the ACO. In a manner that is identical to the all payer/all patient MIPS CQM Specifications, the Medicare CQM Specifications would identify the measurement period applicable to each measure. Applying the 12-month period used in assignment or deferring to the basic assignment methodology under Subpart E to identify the beneficiaries eligible for Medicare CQMs would have the unintended result of reducing the beneficiaries eligible for Medicare CQMs to only patients that had an eligible encounter during the overlap of the assignment window as defined at § 425.20 and the measurement period as defined in the Medicare CQM Specifications.

In section IV.A.4.f.(1)(d)(ii)of this proposed rule, we are proposing to establish the data completeness criteria threshold for the Medicare CQM collection type, in which a Shared Savings Program ACO that meets the reporting requirements under the APP would submit quality measure data for Medicare CQMs on the APM Entity's applicable beneficiaries eligible for the Medicare CQM, as proposed at § 425.20, who meet the measure's denominator criteria. In section IV.A.4.f.(1)(d)(ii) of this proposed rule, we are proposing the following data completeness criteria thresholds for Medicare CQMs:

- At least 75 percent for the CY 2024, CY 2025, and CY 2026 performance periods/2026, 2027, and 2028 MIPS payment years.
- At least 80 percent for the CY 2027 performance period/2029 MIPS payment year.

With the Medicare CQMs collection type serving as a transition collection type under the APP and would be available as determined by CMS, we are proposing to establish the aforementioned data completeness criteria thresholds in advance of the applicable performance periods. We recognize that it is advantageous to delineate the expectations for ACOs as they prepare to meet the quality reporting requirements for the Medicare CQMs collection type under the APP. We will assess the availability of the Medicare CQM as a collection type under the APP during the initial years of implementation and determine the timeframe to sunset the Medicare CQM as a collection type in future rulemaking.

An ACO that reports Medicare CQMs in an applicable performance year would aggregate patient data for beneficiaries who are eligible for Medicare CQMs, as proposed at § 425.20, across all ACO participants. The ACO would then match the aggregated patient data with each Medicare CQM Specification to identify the eligible population for each measure. The ACO's aggregated ACO submission must account for 100 percent of the eligible and matched patient population across all ACO participants. Data completeness is calculated based on submitted data. We believe that the proposal to establish the Medicare CQM collection type would address the concerns from ACOs regarding the capability of meeting the data completeness requirement for all payer data. Specifically, our proposal to define Beneficiaries eligible for Medicare CQMs aims to focus ACOs' reporting efforts on beneficiaries with an encounter with an ACO professional with a specialty used in assignment and thereby reduce the potential for missing or un-matched patient data. It is important to note that ACOs that include or are composed solely of FQHCs or RHCs must report quality data on behalf of the FQHCs or RHCs that participate in the ACO. To clarify, while FQHCs and RHCs that provide services that are billed exclusively under FQHC or RHC payment methodologies are exempt from reporting traditional MIPS, FQHCs and RHCs that participate in APMs, such as the Shared Savings Program, are considered APM Entity groups described at § 414.1370.

To facilitate population-based activities related to improving health through quality measurement of Medicare CQMs and to aid ACOs in the process of patient matching and data aggregation necessary to report Medicare CQMs, we would provide ACOs a list of beneficiaries who are eligible for Medicare CQMs within the ACO. As set forth in our regulations at § 425.702, we share certain aggregate reports with ACOs under specific conditions, and this information includes demographic data that represents the minimum data necessary for ACOs to conduct health care operations work, which includes demographic and diagnostic information necessary to report quality data. We anticipate the list of beneficiaries eligible for Medicare CQMs to be shared once annually, at the beginning of the quality data submission period. Since we would not have full run-out on performance year claims data prior to the start of the quality data submission period, the list of beneficiaries eligible for Medicare CQMs would not be a complete list of beneficiaries that should be included on an ACO's Medicare CQMs reporting. ACOs would have to ensure that all beneficiaries that meet the applicable Medicare CQM Specification and also meet the definition of a beneficiary eligible for Medicare CQMs proposed under § 425.20 are included in the ACO's eligible population/denominator for reporting each Medicare CQM. We are proposing to add new paragraph (c)(1)(iii) to § 425.702 as follows:

For performance year 2024 and subsequent performance years, at the beginning of the quality submission period, CMS, upon the ACO's request for the data for purposes of population-based activities relating to improving health or reducing growth in health care costs, protocol development, case management, and care coordination, provides the ACO with information about its fee-for-service population.

- The following information is made available to ACOs regarding beneficiaries eligible for Medicare CQMs as defined at § 425.20:
  - ++ Beneficiary name.
  - ++ Date of birth.
  - ++ Beneficiary identifier.
  - ++ Sex.
- Information in the following categories, which represents the minimum data necessary for ACOs to conduct health care operations work, is made available to ACOs regarding beneficiaries eligible for Medicare CQMs as defined at § 425.20:
  - ++ Demographic data such as enrollment status.
  - ++ Health status information such as risk profile and chronic condition subgroup.
  - ++ Utilization rates of Medicare services such as the use of evaluation and management, hospital, emergency, and post-acute services, including the dates and place of service.

The list of beneficiaries eligible for Medicare CQMs shared by CMS would aim to help ACOs aggregate, and match and deduplicate patient data. We anticipate including the minimum data necessary to facilitate the reporting of Medicare CQMs including beneficiary identifier, gender, date of birth and death (if applicable), chronic condition subgroup, and the NPIs of the top three frequented providers in the ACO. We propose to include health status information such as risk profile and chronic condition subgroup to the extent that such data would aid ACOs in identifying patients that meet the denominator criteria for the Medicare CQM Specifications. We would also provide technical assistance to ACOs when reporting the Medicare CQMs, including providing technical resource documents. Our proposal to create Medicare CQMs is intended to support ACOs through the transition to reporting the all payer/all patient eCQMs/MIPS CQMs and to facilitate quality assessment improvement activities (as described in the definition of health care operations at 45 CFR 164.501) since we would provide ACOs with a list of beneficiaries eligible for Medicare CQM reporting to aid in patient matching and data deduplication.

In the CY 2021 PFS final rule (85 FR 84733), we finalized the following 3 all payer/all patient eCQMs/MIPS CQMs under the APP for performance year 2021 and subsequent performance years:

- Quality ID#: 001 Diabetes: Hemoglobin A1c (HbA1c) Poor Control;
- Quality ID#: 134 Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and
- Quality ID#: 236 Controlling High Blood Pressure.

In section IV.A.4. e. of this proposed rule, we are proposing to add these measures as Medicare CQMs to the APP measure set for Shared Savings Program ACOs beginning with performance year 2024 and subsequent performance years. ACOs may report the 3 Medicare CQMs, or a combination of eCQMs/MIPS CQMs/Medicare CQMs, to meet the Shared Savings Program quality reporting requirement at § 425.510(b) and the quality performance standard at § 425.512(a)(5).

As a result, in order to meet the Shared Savings Program reporting requirements:

• For performance year 2024, an ACO would be required to report the 10 measures under the CMS web interface measures, or the 3 eCQMs/MIPS CQMs/Medicare CQMs. In addition, an ACO would be required to administer the CAHPS for MIPS Survey, and CMS will calculate the two claims-based measures.

• For performance year 2025 and subsequent performance years, an ACO would be required to report the 3 eCQMs/MIPS CQMs/Medicare CQMs. In addition, an ACO would be required to administer the CAHPS for MIPS Survey, and CMS will calculate the two claims-based measures.

ACOs may still report via the APP using the all payer/all patient eCQM/MIPS CQM collection types and may report different collection types for each measure.

In conjunction with the proposed changes to § 425.512(a)(2), as described in section III.G.2.j. of this proposed rule, we propose to incorporate Medicare CQMs into the existing quality performance standard policies for new ACOs at § 425.512(a)(2)(i), (ii), and (iii). Accordingly, we propose that for the first performance year of an ACO's first agreement period under the Shared Savings Program, if the ACO reports data via the APP and meets MIPS data completeness requirement at § 414.1340 and receives a MIPS Quality performance category score under § 414.1380(b)(1), the ACO will meet the quality performance standard under the Shared Savings Program, if:

• For performance year 2024. The ACO reports the 10 CMS Web Interface measures or the 3 eCQMs/MIPS CQMs/Medicare CQMs, and administers a CAHPS for MIPS survey under the APP.

• For performance year 2025 and subsequent performance years. The ACO reports the 3 eCQMs/MIPS CQMs/Medicare CQMs and administers a CAHPS for MIPS survey under the APP.

Additionally, we propose to incorporate Medicare CQMs into the existing policies at § 425.512(a)(5)(iii) for when an ACO would not meet the quality performance standard or the alternative quality performance standard. Accordingly, we propose that an ACO would not meet the quality performance standard or the alternative quality performance standard if:

• For performance year 2024, if an ACO (1) does not report any of the 10 CMS Web Interface measures or any of the three eCQMs/MIPS CQMs/Medicare CQMs and (2) does not administer a CAHPS for MIPS survey under the APP.

• For performance year 2025 and subsequent performance years, if an ACO (1) does not report any of the three eCQMs/MIPS CQMs/Medicare CQMs and (2) does not administer a CAHPS for MIPS survey under the APP.

We are not proposing to add Medicare CQMs to the eCQM/MIPS CQM reporting incentive described at § 425.512(a)(5)(i)(A)(*2*) for performance year 2024. The eCQM/MIPS CQM reporting incentive intends to provide an incentive to ACOs to report the all payer/all patient eCQMs/MIPS CQMs while allowing them time to gauge their performance on the all payer/all patient eCQMs/MIPS CQMs before full reporting of these measures is required beginning in performance year 2025.

Under the goals of the CMS National Quality Strategy, CMS is moving towards a building-block approach to streamline quality measure across CMS quality programs for the adult and pediatric populations. This ''Universal Foundation'' of quality measure will focus provider attention, reduce burden, identify disparities in care, prioritize development of interoperable, digital quality measures, allow for cross-comparisons across programs, and help identify measurement gaps. Following in the proposals under MIPS, we intend to propose future policies aligning the APP measure set for Sharing Savings Program ACOs with the quality measures under the ''Universal Foundation'' beginning in performance year 2025. These Universal Foundation measures are proposed to be adopted into the existing the Value in Primary Care MVP as discussed in Table B.11 of Appendix 3: MVP Inventory to this proposed rule. By creating alignment with the Universal Foundation in the Value in Primary Care MVP and the APP measure set by 2025, primary care clinicians would develop familiarity with the same quality measures that are reported in the APP while in MIPS. We expect this alignment would reduce the barriers to participation in the Shared Savings Program.

(3) Benchmarking Policy for Medicare CQMs

As the Shared Savings Program adopted the APP (see, for example, § 425.512(a)(3)(i)), benchmarks for quality measures used by the program are those established under the MIPS policies at § 414.1380(b)(1)(ii). We propose that new benchmarks for scoring ACOs on the Medicare CQMs under MIPS would be developed in alignment with MIPS benchmarking policies. As historical Medicare CQM data would not be available at the time this proposal is finalized (if this proposal is finalized), we propose for performance year 2024 and 2025 to score Medicare CQMs using performance period benchmarks. Similarly, as quality performance data are submitted via Medicare CQM and baseline period data become available to establish historical benchmarks, we propose for performance year 2026 and for subsequent performance years to transition to using historical benchmarks for Medicare CQMs when baseline period data are available to establish historical benchmarks in a manner that is consistent with the MIPS benchmarking policies at § 414.1380(b)(1)(ii).

(4) Expanding the Health Equity Adjustment to Medicare CQMs

In the CY 2023 PFS final rule (87 FR 69838 through 69858), for performance year 2023 and subsequent performance years, we finalized a health equity adjustment to upwardly adjust the MIPS Quality performance score for ACOs that report eCQMs/MIPS CQMs, are high performing on quality, and serve a higher proportion of underserved beneficiaries. As we stated in the CY 2023 PFS final rule, the goals of the health equity adjustment include rewarding ACOs serving a high proportion of underserved beneficiaries and supporting ACOs with the transition to eCQMs/MIPS CQMs (87 FR 69841).

Consistent with the goal of supporting ACOs in their transition to all payer/all patient eCQMs/MIPS CQMs, we are proposing that ACOs that report Medicare CQMs would be eligible for the health equity adjustment to their quality performance category score when calculating shared savings payments. We are proposing to revise § 425.512(b) to specify that, for performance years 2024 and subsequent performance years, we would calculate a health equity adjusted quality performance score for an ACO that reports the three Medicare CQMs or a combination of eCQMs/MIPS CQMs/Medicare CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 for each measure, and administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)). This proposal would advance equity within the Shared Savings Program by supporting ACOs that deliver high quality care and serve a high proportion of underserved individuals. Applying the health equity adjustment to an ACO's quality performance category score when reporting Medicare CQMs would encourage ACOs to treat underserved populations.

(5) Summary of Proposals

In Table 25 of this proposed rule we summarize the proposed changes to the regulation at § 425.512(a)(4) and (5) to reflect the proposed changes to the quality reporting requirements and quality performance standard for performance year 2024 and subsequent performance years. Performance benchmarks for performance year 2024 used to determine the 10th, 30th, and 40th percentiles for purposes of evaluating the eCQM/MIPS CQM reporting incentive described at § 425.512(a)(5)(i)(A)(*2*) will be posted on the Quality Payment Program Resource Library website at *https://qpp.cms.gov/resources/resource-library*. We direct readers to the MIPS measure benchmarking policies described at § 414.1380(b)(1)(ii) and to both the quality benchmark and performance period benchmark documentation posted on the Quality Payment Program Resource Library website at *https://qpp.cms.gov/resources/resource-library* for more details. Performance benchmarks differ by collection type (that is, eCQM, MIPS CQM, Medicare CQM (as proposed), CMS Web Interface) and are updated for each performance year.

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TABLE 25: Proposed APP Reporting Requirements and Quality Performance Standard for Performance Year 2024 and Subsequent Performance Years

	Performance Year 2024	Performance year 2025 and Subsequent Performance Years*
Shared Savings Program ACO Quality Reporting requirements	ACOs are required to report the 10 measures under the CMS Web Interface or the 3 eCQMs/MIPS CQMs/Medicare CQMs and administer the CAHPS for MIPS survey. CMS will calculate the two claims-based measures.	ACOs are required to report on the 3 eCQMs/MIPS CQMs/Medicare CQMs and administer the CAHPS for MIPS survey. CMS will calculate the two claims-based measures.
Shared Savings Program ACO Quality Performance Standard	Achieving a health equity adjusted 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, or Reporting the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 for all three eCQMs/MIPS CQMs and receives a MIPS Quality performance category score under § 414.1380(b)(1), achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set, or An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure would share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality performance score. If an ACO (1) does not report any of the ten CMS Web Interface measures or any of the three eCQMs/MIPS CQMs/Medicare CQMs and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.	Achieving a health equity adjusted 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, or An ACO that fails to meet the criterion above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set would share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality performance score. If an ACO (1) does not report any of the three eCQMs/MIPS CQMs/Medicare CQMs and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.

*The CMS Web Interface reporting option sunsets after performance year 2024 and is no longer available beginning with performance year 2025.

c. Proposed APP Measure Set

(1) Background

We refer readers to Table 26, which lists the measures included in the final APP measure set that will be reported by Shared Savings Program ACOs for performance year 2023 and subsequent performance years. These are the same measures finalized in the CY 2023 PFS final rule (87 FR 69862); however, we note that the Collection Type for each measure has been updated. As finalized in the CY 2023 PFS final rule (87 FR 69863), we included the measure type in Table 26 for each measure in the measure set to provide ACOs a list of the outcome measures for purposes of meeting the quality performance incentive for reporting eCQMs/MIPS CQMs. This information is also relevant to the alternative quality performance standard under which ACOs that fail to meet the quality performance standard to qualify for the maximum sharing rate, but that achieve a quality performance score at the 10th percentile on 1 of the 4 outcome measures in the APP measure set, may be eligible to share in savings on a sliding scale (87 FR 69861). We noted inclusion of this information does not change any of the measures in the measure set.

(2) Proposed Revisions

TABLE 26: Measures included in the APP Measure Set for Performance Year 2024 and Subsequent Performance Years [a]

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
Quality ID#: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	PRO-PM*
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
Measure # 484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/Medicare CQM/CMS Web Interface**	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Medicare CQM/CMS Web Interface**	APM Entity/Third Party Intermediary	Behavioral Health	Process
Quality ID#: 236	Controlling High Blood Pressure	eCQM/MIPS CQM/Medicare CQM/CMS Web Interface**	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
Quality ID#: 318	Falls: Screening for Future Fall Risk	CMS Web Interface**	APM Entity/Third Party Intermediary	Safety	Process
Quality ID#: 110	Preventive Care and Screening: Influenza Immunization	CMS Web Interface**	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
Quality ID#: 226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	CMS Web Interface**	APM Entity/Third Party Intermediary	Behavioral Health	Process
Quality ID#: 113	Colorectal Cancer Screening	CMS Web Interface**	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
Quality ID#: 112	Breast Cancer Screening	CMS Web Interface**	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
Quality ID#: 438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	CMS Web Interface**	APM Entity/Third Party Intermediary	Chronic Conditions	Process
Quality ID#: 370	Depression Remission at Twelve Months***	CMS Web Interface**	APM Entity/Third Party Intermediary	Behavioral Health	Outcome^

[a] We note that the CMS Web Interface measures: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID#: 438) and Depression Remission at Twelve Months (Quality ID: # 370) do not have benchmarks; and therefore, are not scored for performance year 2024; they are however required to be reported in order to complete the Web Interface data set.

^ Indicates this is an outcome measure.

* Patient-reported outcome-based performance measure (PRO-PM) is a performance measure that is based on patient-reported outcome measure (PROM) data aggregated for an accountable healthcare entity.

**ACOs will have the option to report via the CMS Web Interface for performance year 2024 only.

*** This measure is not included as one of the four outcome measures for purposes of the Quality Reporting Standard as this measure is not scored.

Table 27 includes the proposed eCQM/MIPS CQM measure set for performance year 2024 for the Shared Savings Program and outlines the measure types, which is relevant for ACOs that may elect to report on eCQM/

MIPS CQMs in order to qualify for the incentive under § 425.512(a)(4)(i)(B).

TABLE 27: APP Measure Set for eCQM/MIPS CQM Reporting for Performance Year 2024*

Measure #	Measure Title	Measure Type	SSP Quality Performance Standard	
			MIPS Comparable Measure	Outcome Measure
Quality ID#: 321	CAHPS for MIPS	Patient-Reported Outcome	Yes	No
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Outcome	Yes	Yes
Measure # 484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Outcome	Yes	Yes
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	Intermediate Outcome	Yes	Yes
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	Process	Yes	No
Quality ID#: 236	Controlling High Blood Pressure	Intermediate Outcome	Yes	Yes

* We note that Medicare CQM is not one of the collection types included in the eCQM/MIPS CQM incentive under § 425.512(a)(4)(i)(B).

Table 28 identifies the preliminary measures for the Universal Foundation's adult component.

TABLE 28: Preliminary Adult Universal Foundational Measures [a]^

Domain	Identification Number and Name
Wellness and prevention	139: Colorectal cancer screening 93: Breast cancer screening 26: Adult immunization status
Chronic conditions	167: Controlling high blood pressure 204: Hemoglobin A1c poor control (>9%)
Behavioral health	672: Screening for depression and follow-up plan 394: Initiation and engagement of substance use disorder treatment
Seamless care coordination	561 or 44: Plan all-cause readmissions or all- cause hospital readmissions
Person-centered care	158 (varies by program): Consumer Assessment of Healthcare Providers and Systems overall rating measures
Equity	Identification number undetermined: Screening for social drivers of health

[a] Domains are from Meaningful Measures 2.0. Identification numbers are CMS Measures Inventory Tool measure family identification numbers; names reflect the descriptions associated with those numbers.

^ Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher L. Aligning Quality Measures across CMS – The Universal Foundation. New England Journal of Medicine, March 2, 2023, available at *https://www.nejm.org/doi/full/10.1056/NEJMp2215539.*

* Quality ID #487 Screening for social drivers of health is an available MIPS CQM for PY 2023; the MIPS CQM Specification is available at *https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2023_Measure_487_MIPSCQM.pdf.*

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The CMS Web Interface collection type under the APP includes 10 measures. We refer readers to Table Group E of Appendix 1 of this proposed rule for the proposed substantive changes to measure specifications for 9 out of 10 CMS Web Interface measures starting with performance year 2024. As proposed, the changes would update measures and align the CMS Web Interface measures with the practice

workflows of the MIPS CQM collection type.

d. Proposals To Modify the Health Equity Adjustment Underserved Multiplier

(1) Background

Consistent with our goal of rewarding ACOs that include a higher proportion of underserved beneficiaries while delivering high quality care, we finalized in the CY 2023 PFS final rule (87 FR 69836 through 69857) the application of a health equity adjustment that adds up to 10 bonus points to an ACO's MIPS Quality performance category score based on certain criteria. The health equity adjustment is applied to an ACO's MIPS quality performance category score when the ACO reports the three all-payer eCQMs/MIPS CQMs in performance year 2023 and, as proposed in section III.G.2.b.(2) of this proposed rule, the three eCQMs/MIPS CQMs/Medicare CQMs starting in performance year 2024. To qualify for the health equity adjustment, the ACO must also meet the data completeness requirement at § 414.1340 and administer the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)). The health equity adjustment is conditional on (1) high quality measure performance and (2) providing care for a proportion of underserved populations greater than or equal to a predetermined floor.

The goal of the health equity adjustment is to reward ACOs with high performance scores on quality measures and that serve a high proportion of underserved beneficiaries. Correspondingly, the health equity adjustment bonus points are calculated by multiplying the ACO's performance scaler by the ACO's underserved multiplier. An ACO's performance scaler is designed to identify top performance among ACOs reporting all-payer eCQMs/MIPS CQMs in performance year 2023 and, as proposed in section III.G.2.b.(2) of this proposed rule, eCQMs/MIPS CQMs/Medicare CQMs in performance year 2024. The performance scaler is an aggregated value across all eCQM/MIPS CQM measures and is determined based on if the ACO's measure performance was in the top, middle, or bottom third of ACO performance for that performance year. We refer readers to section III.G.4.b.(7).c of the CY 2023 PFS final (87 FR 69843 through 69845) for more details on the performance scaler calculation. The underserved multiplier is designed to identify ACOs serving high proportions of underserved beneficiaries. As described in the CY 2023 PFS final rule (87 FR 69845 through 69849), the underserved multiplier is a proportion ranging from zero to one of the ACO's assigned beneficiary population for the performance year that is considered underserved based on the highest of: (1) the proportion of the ACO's assigned beneficiaries residing in a census block group with an Area Deprivation Index (ADI) national percentile rank of at least 85; or (2) the proportion of the ACO's assigned beneficiaries who are enrolled in Medicare Part D low-income subsidy (LIS) or are dually eligible for Medicare and Medicaid. The use of both the ADI and Medicare and Medicaid dual eligibility or LIS status to assess underserved populations in the health equity adjustment allows CMS to consider both broader neighborhood level characteristics and individual characteristics among CMS beneficiaries.

The CY 2023 PFS final rule did not state how CMS intended to compute the proportion of beneficiaries with an ADI national percentile rank of at least 85 with respect to beneficiaries for whom a numeric national percentile rank value is not available. We do not believe it is appropriate to assign a zero to the beneficiaries without an ADI national percentile rank in the calculation. Doing so would unfairly disadvantage ACOs with such beneficiaries vis-à-vis those ACOs with beneficiaries that all have an ADI national percentile rank by lowering their scores. The CY 2023 PFS final rule (87 FR 69846) stated that the proportion of the ACO's assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85 is computed using the number of assigned beneficiaries. A footnote stated that in computing the proportion of beneficiaries dually eligible for Medicare and Medicaid, we would use for each beneficiary the fraction of the year (referred to as person years) in which they were eligible for the aged/dual eligible enrollment type or for which they were eligible for the ESRD or disabled enrollment type and dually eligible for Medicare and Medicaid. In response to public comment, we finalized the proposal to include LIS as a modification to the calculation of the underserved multiplier (87 FR 69849). In calculating the LIS proportion, CMS uses the same methodology it adopted for calculating dually eligible beneficiaries: person years.

(2) Proposed Revisions

We propose to revise the underserved multiplier calculation to specify the calculations in more detail and bring greater consistency between the calculation of the proportion of ACOs' assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85 and the proportion of ACOs' assigned beneficiaries who are enrolled in Medicare Part D LIS or are dually eligible for Medicare and Medicaid. Specifically, we propose to remove beneficiaries who do not have a numeric national percentile rank available for ADI from the health equity adjustment calculation for performance year 2023 and subsequent performance years. Beneficiaries without a national percentile ADI rank would appear neither in the numerator nor in the denominator of the proportion.

While we established a policy for the treatment of aligned beneficiaries for whom an ADI national percentile rank could not reasonably be calculated for use in the advance investment payments risk factors-based score (87 FR 69796 through 69797), we neither proposed nor finalized a policy for such beneficiaries with respect to the calculation of the health equity adjustment underserved multiplier—nor do we believe the policy we finalized for AIP is appropriate for calculating the health equity adjustment. In the CY 2023 PFS final rule (87 FR 69800), we finalized the use of imputing a value of 50 for the ADI national percentile rank if there is insufficient data to match a beneficiary to an ADI national percentile rank for calculating AIP risk factors-based scores. There are important differences in the implications of using an imputed value of 50 for calculating the AIP risk factors-based scores and for calculating the underserved multiplier. The imputed ADI ranking of 50 corresponds to the average national ADI ranking and would be the most neutral imputed value and would avoid biasing an ACO's payments in either direction for risk factor-based scores in the AIP calculation. The use of an ADI ranking of 50 in the underserved multiplier, however, would result in that beneficiary not counting in the numerator of the underserved multiplier proportion because only beneficiaries with an ADI of at least 85 are counted in the numerator. Therefore, we are proposing to exclude beneficiaries without a national percentile ADI rank from the health equity adjustment underserved multiplier. This approach is more equitable because it will remove a beneficiary without an ADI rank from the denominator and the numerator of the calculation of an ACO's underserved multiplier instead of penalizing ACOs that have such beneficiaries.

It is in the public interest to apply this change starting with performance period

2023. Section 1871(e)(1)(A)(ii) of the Act authorizes the Secretary to retroactively apply a substantive change in Medicare regulations if the Secretary determines that failure to apply the change retroactively would be contrary to the public interest. Here, applying this change starting with performance period 2023 is in the public interest because, absent further specification of how to treat beneficiaries without a national percentile ADI rank current policy may unfairly penalize ACOs for reasons beyond their control. Current policy counts beneficiaries with missing ADI ranks in the underserved multiplier denominator and contributes zero to the numerator, thereby reducing the health equity adjustment for ACOs with such beneficiaries and harming their ability to meet the quality performance standard and receive shared savings.

Separately, we propose to modify the calculation of the proportion of assigned beneficiaries dually eligible for Medicare and Medicaid and the calculation of the proportion of assigned beneficiaries enrolled in LIS to use the number of beneficiaries rather than person years for calculating the proportion of the ACO's assigned beneficiaries who are enrolled in LIS or who are dually eligible for Medicare and Medicaid starting in performance year 2024. For example, when calculating the underserved multiplier component of the health equity adjustment to an ACO's quality performance score for ACOs that report the three eCQMs/MIPS CQMs/Medicare CQMs, the proportion would be equal to the number of assigned beneficiaries with any months enrolled in LIS or dually eligible for Medicare and Medicaid divided by total number of assigned beneficiaries. We are not proposing to alter the calculation of the proportion of beneficiaries residing in a census block group with an ADI national percentile rank of at least 85, which is already based on the number of assigned beneficiaries. Person years would continue to be used in financial calculations where beneficiary experience is stratified into by Medicare enrollment type (ESRD, disabled, aged/dual eligible, and aged non/dual eligible) and it is important to account for partial year enrollment to ensure accuracy. The proposed policy change would bring greater consistency between the two proportions used in determining the underserved multiplier. It also acknowledges that beneficiaries with partial year as compared to full year LIS enrollment or dual eligibility are also socioeconomically vulnerable and strengthens incentives for ACOs to serve this population. Further, inclusion of beneficiaries with partial year LIS enrollment in the underserved multiplier provides increased incentive for ACOs to help facilitate LIS enrollment for beneficiaries who meet eligibility criteria.

We seek comment on these proposals.

e. Proposal To Use Historical Data To Establish the 40th Percentile MIPS Quality Performance Category Score

(1) Background

In the CY 2023 PFS final rule (87 FR 69858), we finalized that beginning performance year 2024, one of the ways for an ACO to meet the Shared Savings Program quality performance standard and share in savings at the maximum rate under its track (or payment model within a track) is for the ACO to achieve a health equity adjusted 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 the CY 2022 PFS proposed and final rules (86 FR 39274 and 86 FR 65271), we stated that, for a given performance year, the 30th or 40th percentile across all MIPS Quality performance category scores would be calculated after MIPS final scoring is complete based on the distribution across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. Therefore, we are not able to provide performance rate information prior to or during the performance year. Nevertheless, we stated that we believe that publicly displaying prior year performance scores that equate to the 30th and 40th percentile across all MIPS Quality performance category scores for the applicable performance year would still provide helpful information for ACOs to determine what level of quality performance they would need to meet in order to satisfy the quality performance standard under the Shared Savings Program. We stated that we would release this historical information on the Shared Savings Program website when it becomes available.

In the CY 2022 PFS proposed rule (86 FR 39274), we also explained that interested parties have expressed concerns regarding the lack of information on the level of quality performance that would equate to the 30th or 40th percentile MIPS Quality performance category score and that would enable an ACO to be eligible to share in savings or to avoid maximum shared losses, if applicable. We noted that interested parties have expressed concern that these data are not publicly available prior to the start of a performance year and that they do not believe that ACOs have a way of determining what quality score they would need to achieve to meet the quality performance standard.

In the CY 2022 PFS proposed rule (86 FR 39274), we also solicited comment on whether publicly displaying prior year performance scores that equate to the 30th or 40th MIPS Quality performance category scores would help to address ACOs' concerns regarding the lack of advance information regarding the quality performance score they must meet in order to satisfy the quality performance standard under the Shared Savings Program. Several commenters supported publicly displaying prior year performance scores that equate to the 30th or 40th percentile across all MIPS Quality category performance scores, and one commenter expressed concern that publicly displaying prior year performance scores is not the optimal way to address concerns of interested parties and indicated that performance is volatile and the 30th (or 40th) percentile may change significantly from year to year depending upon changes in quality performance in MIPS (86 FR 65271).

We clarified in the CY 2023 PFS proposed rule (87 FR 46148) and final rule (87 FR 69867) that we use the submission-level MIPS Quality performance category scores (unweighted distribution of scores) to determine the 30th percentile and 40th percentile MIPS Quality performance category scores for purposes of establishing the applicable quality performance standard under the Shared Savings Program. In light of public comments and concerns about the predictability of the 40th percentile MIPS Quality performance category score due to changes in MIPS scoring policies over time—including MIPS scoring changes impacting measures that lack a benchmark or case minimum as described at § 414.1380(b)(1)(i)(A), measure achievement points as described at paragraph (b)(1)(i), new measures (years 1 and 2 of a measure's use) as described at paragraph (b)(1)(i)(C), new sub-group reporting option as described at § 414.1318(a), and MIPS High Priority and End to End Bonus Points as described at § 414.1380(b)(1)(v)—and as a result of the concerns expressed by ACOs and other interested parties and as we gain experience with aligning Shared Savings Program reporting and scoring policies with MIPS, we believe that a revised methodology is needed to calculate the 40th percentile MIPS Quality performance category score for

the quality performance standard for performance year 2024 and subsequent performance years.

As MIPS scoring policies evolve over time, changes in MIPS scoring policy have the potential to adjust the year-to-year comparability of MIPS Quality performance category scores. Between performance years 2022 and 2023, there were MIPS policy changes to measures that lack a benchmark or case minimum as described at § 414.1380(b)(1)(i)(A), measure achievement points as described at paragraph (b)(1)(i), new measures (years 1 and 2 of a measure's use) as described at paragraph (b)(1)(i)(C), and a new sub-group reporting option as described at § 414.1318(a). Additionally, MIPS High Priority and End to End Bonus Points were sunset in performance year 2022 as described at § 414.1380(b)(1)(v). The projected 40th percentile MIPS Quality performance category score for performance year 2023 does not reflect these proposed methodological changes. To minimize reliance on a single year of performance data, the use of multiple years of historical data could be used to ''smooth'' out the impact of MIPS scoring policy changes on the quality performance standard in any one year. At the same time, using too many years of data to average scores might include a greater number of years that don't reflect current policies.

(2) Proposed Revisions

For performance year 2024 and subsequent performance years, we propose to use historical submission-level MIPS Quality performance category scores to calculate the 40th percentile MIPS Quality performance category score. Specifically, we propose to use a rolling 3-performance year average with a lag of 1 performance year (for example, the 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2024 would be based on averaging the 40th percentile MIPS Quality performance category scores from performance years 2020 through 2022). We believe that our proposal to use a 3-year historical average is consistent with the proposal under section IV.A.4.h.(2) of this proposed rule that would permit, for purposes of establishing a performance threshold as identified in § 414.1405(b), a time span of up to three consecutive performance periods for performance year 2024 and subsequent performance years.

We would provide ACOs with the performance score that equates to the 40th percentile MIPS Quality performance category score that would be used as the quality performance standard for a given performance year prior to the start of the performance year (for example, the 40th percentile MIPS Quality performance category score based on historical data and applicable for performance year 2024 would be released on the Shared Savings Program website in December 2023).

The use of 3 historical base years would mitigate issues that may arise from using a single year historical reference such as scoring, policy, and/or performance anomalies, such as a pandemic, specific to the historical base year. Additionally, the use of historical data would allow additional time for data availability and limit the potential impact of MIPS Targeted Review as described at § 414.1385 and other MIPS scoring corrections. This approach is also responsive to the concerns ACOs, and other interested parties have with the predictability of the current method of calculating the 40th percentile MIPS Quality performance category score. However, we acknowledge that by using historical benchmarks, the benchmark would not reflect the most recent policies, measure specifications, and scores. For example, the historical base years are 2–4 years removed from the performance year and could reflect data that may have anomalies specific to the base year that would render those data inconsistent with the performance year's quality performance. Additionally, changes to measure specifications for measures included in the APP measure set may result in the historical base period including measures that are different than the corresponding measures that were applicable during the performance year. This could further reduce the comparability of historic base year data with the performance year's quality performance data.

Table 29 shows the 40th percentile MIPS Quality performance category scores for performance years 2018 through 2021 based on the current methodology as published in the CY 2023 PFS final rule (87 FR 69868). The proposed methodology would be effective for performance year 2024 and subsequent performance years. We have added to Table 29 the projected 40th percentile MIPS Quality performance category scores for performance years 2022 and 2023 based on the proposed methodology for illustrative purposes. The projected 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2022 is based on the average of the 40th percentile MIPS Quality performance category scores from performance years 2018 through 2020, and the projected 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2023 is based on the average of the 40th percentile MIPS Quality performance category scores from performance years 2019 through 2021. The years are averaged at equal weights. For example, we would calculate the projected 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2022 by first summing the 2018 (70.80), 2019 (70.82), and 2020 (75.59) 40th percentile Quality performance category score values to arrive at a value of 217.21 [70.80 + 70.82 + 75.59 = 217.21]. We would then divide the value of 217.21 by three (the number of years included in the historical reference period) to arrive at a projected 40th percentile MIPS Quality performance category score of 72.40 for 2022 [217.21 ÷ 3 = 72.40]. Note that this example illustrates averaging the 2018, 2019, and 2020 40th percentile MIPS Quality performance category score values.

TABLE 29: 40th Percentile MIPS Quality Performance Category Scores Using Current and Proposed Methodology

Performance Year	40th percentile MIPS Quality performance category score*
2018	70.80*
2019	70.82*
2020	75.59*
2021	77.83*
2022 (projected)	72.40^
2023 (projected)	74.75^

* As published in Table 64 of the CY 2023 PFS final rule (87 FR 69868). The 40th percentile MIPS Quality performance category score was calculated by taking the 40th percentile of all submission-level MIPS Quality performance category scores (the unweighted distribution of scores), excluding entities/providers eligible for facility-based scoring.

^ As projected based on the proposed methodology. The performance year 2022 projected 40th percentile MIPS Quality performance category score for the quality performance standard is based on the average of the 2018, 2019, and 2020 40th percentile MIPS Quality performance category scores. The performance year 2023 projected 40th percentile MIPS Quality performance category score for the quality performance standard is based on the average of the 2019, 2020, and 2021 40th percentile MIPS Quality performance category scores.

We seek comment on our proposal to use a 3-performance year rolling average with a lag of 1-performance year to calculate the 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2024 and subsequent performance years. Using a 1-year lag would help ensure the availability of base period data by limiting the possibility that data availability is negatively impacted by scoring, policy, and/or performance anomalies from the prior performance year. In the development of our proposal to use a 3-performance year rolling average with a lag of 1-performance year to calculate the 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2024 and subsequent performance years, we considered another alternative methodology, which was to establish a historical quality performance standard based on the year immediately prior to the performance year's quality performance score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. We also seek comment on other alternative methodologies we should consider to calculate the 40th percentile MIPS Quality performance category score for the quality performance standard.

f. Proposal To Apply a Shared Savings Program Scoring Policy for Excluded APP Measures

(1) Background

In the CY 2021 PFS final rule (85 FR 84720 through 84734), we finalized an approach that aligns the Shared Savings Program quality performance scoring methodology with the MIPS scoring methodology. We also stated 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)) (85 FR 84725)). In the CY 2021 PFS final rule (85 FR 84901), we finalized policies at § 414.1380(b)(1)(vii)(A) to provide that for each measure under MIPS 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. We stated that ''significant changes'' means changes to a measure that are outside the control of the clinician and its agents and 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. As described at § 414.1380(b)(1)(vii)(A), measures that are excluded due to significant changes are excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points.

In performance year 2022, two of the eCQMs/MIPS CQMs that are part of the APP measure set were excluded from MIPS measure achievement points and total available measure achievement points for the MIPS Quality performance category under § 414.1380(b)(1)(vii)(A). Specifically, the eCQM version of the Preventive Care and Screening: Screening for Depression and Follow-up Plan measure (Quality ID #134) and the Controlling High Blood Pressure measure (Quality ID #236) were excluded. Thus, under MIPS scoring policies, ACOs reporting one or both of these measures had their total measure achievement points and total available measure achievement points reduced by 10 (for reporting one measure) or 20 (for reporting both measures) points, respectively. Under the APP, these ACOs were still required to report all 6 measures; however, their performance year 2022 MIPS Quality performance category score was based on the 4 or 5 non-excluded measures (depending on whether the ACO reported one or both excluded measures) in the APP measure set. Consequently, the resulting MIPS Quality performance category score for an ACO that would have performed well on the excluded quality measures would be lower than it otherwise would have been if those measures were not excluded. Alternatively, if an ACO would have performed poorly on the excluded quality measures, then the resulting MIPS Quality performance category score would be higher than it otherwise would have been if those measures were not excluded. In either scenario, an ACO is required to report quality performance for all measures under the APP and has no control over

whether and which measures are excluded.

(2) Proposed Revisions

Given that the Shared Savings Program does not determine which quality measures are excluded and that ACOs do not have a choice of measures they can report under the APP, we do not want to adversely impact shared savings determinations for events outside the ACOs' control, such as in the event a measure is excluded. Therefore, we are proposing that, for performance year 2024 and subsequent performance years, if (1) an ACO reports all required measures under the APP and meets the data completeness requirement at § 414.1340 for all required measures and receives a MIPS Quality performance category score under § 414.1380(b)(1), and (2) the ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score for the performance year is reduced due to measure exclusion under § 414.1380(b)(1)(vii)(A), then we would use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, to determine whether the ACO meets the quality performance standard required to share in savings at the maximum rate under its track (or payment model within a track), for the relevant performance year. This policy aims to alleviate the potential adverse impacts to shared savings determinations that may arise in the event that one or more of the quality measures required under the APP is excluded. We are also proposing to make conforming changes to the regulation text § 425.512 by revising paragraph (a)(5)(i) and adding paragraph (a)(7).

We finalized in the CY 2023 PFS final rule (87 FR 69845) that unscored measures are removed from the calculation of an ACO's health equity adjustment, effectively receiving a performance scaler of 0 for those measures. However, we inadvertently did not codify this policy in the Code of Federal Regulations. Therefore, in this proposed rule, we are proposing to codify this policy by revising § 425.512(b)(3)(ii)(B) to state that CMS assigns a value of 0 for each measure that CMS does not evaluate because the measure is unscored. We propose that the regulation text changes would be effective for performance year 2023 and subsequent performance years as the policy was finalized in the CY 2023 PFS final rule to calculate the health equity adjustment for performance year 2023 and subsequent performance years.

We are also proposing that quality measures impacted by the MIPS policy at § 414.1380(b)(1)(vii)(A) are unscored measures for the purposes of calculating the health equity adjustment; therefore, excluded measures would not render an ACO ineligible for the health equity adjustment as long as the ACO reports all required measures under the APP and meets the data completeness requirement at § 414.1340 for all required measures and receives a MIPS Quality performance category score under § 414.1380(b)(1).

As discussed in section IV.A.4.g.(1)(c)(i) of this proposed rule, we are proposing a change to the MIPS policy to remove the 10 percent threshold for changes to codes, clinical guidelines, or measure specifications for all measure types. We believe that our proposal to apply a floor to an ACO's Quality performance category score in determining the ACO's quality performance standard in the event that the ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score for the performance year is reduced under § 414.1380(b)(1)(vii)(A) functions in concert with our proposal under section IV.A.4.g.(1)(c)(i) of this proposed rule. We refer readers to section IV.A.4.g.(1)(c)(i) of this proposed rule for further discussion of our proposal to change the MIPS scoring policy.

g. Proposal To Require Spanish Language Administration of the CAHPS for MIPS Survey

(1) Background

CMS has created official translations of the CAHPS for MIPS survey in 7 languages, including Spanish, Cantonese, Korean, Mandarin, Portuguese, Russian, and Vietnamese (81 FR 77386), in addition to the required administration of English survey. However, use of these translations is mostly voluntary, with the exception of a requirement to administer the Spanish translation of the CAHPS for MIPS Survey for patients residing in Puerto Rico. Organizations (groups, virtual groups, subgroups, and APM entities) that elect CAHPS for MIPS must contract with a CMS-approved survey vendor to administer the survey and must request survey translations for the vendor to administer the survey in an optional language. Generally, the use of survey translations adds additional survey administration cost to the organization.

(2) Proposed Revisions

As discussed in section IV.A.4.f.(1)(c)(ii) of this proposed rule, we are proposing to require Spanish language administration of the CAHPS for MIPS survey for MIPS eligible clinicians reporting MIPS. Specifically, we are proposing to require MIPS eligible clinicians to contract with a CMS-approved survey vendor that, in addition to administering the survey in English, will administer the Spanish survey translation to Spanish-preferring patients using the procedures detailed in the CAHPS for MIPS Quality Assurance Guidelines beginning with 2024 survey administration. This should better ensure that we are assessing the experience of patients who are Spanish-speaking and with limited English proficiency, and is part of our efforts to advance health equity. We refer readers to section IV.A.4.f.(1)(c)(ii) of this proposed rule for further discussion of our proposal related to the CAHPS for MIPS survey. In addition, we are interested in gathering information directly from organizations that administer the CAHPS for MIPS Survey on whether they consider to request the vendor to administer the survey in one or more of the available survey translations based on the language preferences of patients. We are also interested in learning about the factors that more or less likely affect the administration of survey translations where there is need for one or more of the available translations.

h. Proposals To Align CEHRT Requirements for Shared Savings Program ACOs With MIPS

(1) Background

Many of our programs require the use of certified electronic health record (EHR) technology (CEHRT), including the Quality Payment Program, Shared Savings Program, and other value-based payment initiatives. With respect to the Shared Savings Program, section 1899(b)(2)(G) of the Act requires participating ACOs to define processes to report on quality measures and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies. In addition, section 1899(b)(3)(D) of the Act authorizes the Secretary to incorporate reporting requirements and incentive payments from section 1848 of the Act into the Shared Savings Program, such as requirements and payments related to electronic prescribing and electronic health

records, including using alternative criteria for determining whether to make such incentive payments. Pursuant to these authorities, we have incorporated reporting requirements related to the adoption and use of CEHRT in our regulations, including specifically cross-referencing the Quality Payment Program's definition of CEHRT (42 CFR 414.1305) in our regulatory definition of CEHRT at § 425.20. For the Shared Savings Program and Quality Payment Program, CEHRT currently is defined at § 414.1305 as EHR technology (which could include multiple technologies) certified by the Office of the National Coordinator for Health Information Technology (ONC) under the ONC Health IT Certification Program as meeting the 2015 Edition Base EHR definition, set forth at 45 CFR 170.102, and a designated set of the 2015 Edition health information technology (IT) certification criteria as further provided therein.

The Health Information Technology for Economic and Clinical Health Act (HITECH Act), sections 13001 through 13424 of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5, February 17, 2009), established ONC under the Department of Health and Human Services, authorizing ONC to adopt standards for certifying health IT. ONC has codified its standards, implementation specifications, certification criteria, and certification program for health IT under 45 CFR part 170. Specifically, ONC has codified its certification criteria for health IT, including EHRs, at 45 CFR 170.315. Currently referred to as the ''2015 Edition health IT certification criteria.'' For more information regarding ONC's current policies, standards, and certification requirements for health IT, please refer to 45 CFR part 170, particularly § 170.315, and the ONC Certification of Health IT website at: *https://www.healthit.gov/topic/certification-ehrs/certification-health-it*.

In the CY 2019 PFS final rule (83 FR 59982 through 59988), we adopted three key requirements related to ACOs use of CEHRT, beginning with the performance years starting on January 1, 2019.

First, ACOs must certify annually, at the end of each performance year, that the percentage of eligible clinicians participating in the ACO who use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage during the current performance year. The ACO's eligible clinicians must use CEHRT that meets the definition in our regulation at § 425.20, which provides that CEHRT has the same meaning as under the Quality Payment Program at § 414.1305. Specifically, we updated our regulations at § 425.506(f) to reflect that, beginning with the performance years starting on January 1, 2019:

- ACOs in a track that does not meet the financial risk standard to be an Advanced APM, which includes ACOs participating under BASIC track Levels A through D, must certify annually that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT to document and communicate clinical care to their patients or other health care providers.
- ACOs in a track that meets the financial risk standard to be an Advanced APM, which includes ACOs participating under BASIC track Level E or the ENCHANCED track, must certify annually that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold established under the Quality Payment Program at § 414.1415(a)(1)(i). Under this requirement, for Performance Periods beginning in 2019, 75 percent of eligible clinicians must use CEHRT to document and communicate clinical care to their patients or health care providers.

Second, we also revised the Shared Savings Program requirements for data submission and certifications at § 425.302(a)(3)(iii) to require the ACO to certify at the end of each performance year, that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage specified by CMS at § 425.506(f).

Finally, we updated our regulations at § 425.20 to incorporate the definition of CEHRT at § 414.1305 that applies under the Quality Payment Program. The Quality Payment Program's regulation at § 414.1305 defines CEHRT as EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition at 45 CFR 170.102 and has been certified as meeting certain other criteria set forth in ONC's 2015 Edition health IT certification criteria at 45 CFR 170.315 as further described in § 414.1305. Applying the Shared Savings Program's definition at § 425.20, ACOs under the Shared Savings Program must use EHR technology meeting the Quality Payment Program's definition of CEHRT at § 414.1305to meet the requirements set forth in our regulation at § 425.506(f). As discussed in section III.R. of this proposed rule, in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing proposed rule (88 FR 23758), which appeared in the April 18, 2023 **Federal Register**, ONC has proposed to discontinue the year-themed ''editions,'' which ONC first adopted in 2012, to distinguish between sets of health IT certification criteria finalized in different rules. ONC is proposing to instead maintain a single set of ''ONC Certification Criteria for Health IT,'' which would be updated in an incremental fashion in closer alignment to standards development cycles and regular health information technology (IT) development timelines (88 FR 23750). As further discussed in section III.R. of this proposed rule, we are proposing to modify the Quality Payment Program's definition of CEHRT at § 414.1305 to flexibly incorporate any changes by ONC to its definition of Base EHR and its certification criteria for Health IT.

(2) Removing CEHRT Use Threshold Requirements and Requiring Reporting of the MIPS Promoting Interoperability Performance Category

In order to streamline CEHRT threshold requirements for ACOs and align with the Quality Reporting Program's Merit-Based Incentive Payment System (MIPS), we propose to sunset the Shared Savings Program CEHRT threshold requirements and modify our regulations at § 425.506(f) to indicate that they will be applicable only through performance year 2023. We further propose, for performance years beginning on or after January 1, 2024, unless otherwise excluded, to require that all MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305 of this subchapter) participating in the ACO, regardless of track, satisfy all of the following:

- Report the MIPS Promoting Interoperability (PI) performance category measures and requirements to MIPS according to 42 CFR part 414 subpart O as either of the following—

++ All MIPS eligible clinicians, QPs, and partial QPs participating in the ACO as an individual, group, or virtual group; or

++ The ACO as an APM entity.

- Earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level.

A MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity may be excluded from the requirements proposed at § 425.507(a) if the MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity—

- Does not exceed the low volume threshold set forth at § 414.1310(b)(1)(iii);
- Is an eligible clinician as defined at § 414.1305 who is not a MIPS eligible clinician and has opted to voluntarily report measures and activities for MIPS as set forth in § 414.1310(b)(2); or
- Has not earned a performance category score for the MIPS Promoting Interoperability performance category because the MIPS Promoting Interoperability performance category has been reweighted in accordance with applicable policies set forth at § 414.1380(c)(2).

We propose to codify this new requirement at § 425.507.

Specifically, we propose that any requirements applicable to MIPS eligible clinicians reporting on objectives and measures specified by CMS for the MIPS PI category would apply to MIPS eligible clinicians, QPs, and Partial QPs participating in an ACO at § 425.507(a). We further propose that if any of these requirements for a MIPS eligible clinician reporting for the MIPS PI category, including objectives and measures, are amended through rulemaking (such as adoption, modification, or removal of an objective or measure), then the new or modified requirements will also be applicable to MIPS eligible clinicians, QPs, and Partial QPs participating in an ACO under § 425.507. For instance, in section IV.A.4.f.(4) of this proposed rule, we are proposing several modifications to the MIPS PI performance category's requirements, including modifying the performance period at § 414.1320 as well as specific measures such as the High Priority Safety Assurance Factors for EHR Resilience (SAFER) Guides measure. To the extent these or other policies are finalized through rulemaking, then these requirements would also be applicable to ACO participants as provided by our proposal here.

To further align with applicable requirements for the MIPS Promoting Interoperability performance category, we are proposing that MIPS eligible clinicians, QPs, Partial QPs, and ACOs as APM entities may be exempt from our proposed regulation at § 425.507(a) if the MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity: (1) does not exceed the low volume threshold set forth at § 414.1310(b)(1)(iii); (2) is an eligible clinician as defined at § 414.1305 who is not a MIPS eligible clinician and has opted to voluntarily report measures and activities for MIPS as set forth in § 414.1310(b)(2); or (3) has not earned a performance category score for the MIPS Promoting Interoperability performance category because the MIPS Promoting Interoperability performance category has been reweighted in accordance with applicable policies set forth at § 414.1380(c)(2). However, if such MIPS eligible clinicians, QPs, and Partial QPs do report the MIPS PI performance category as an individual, group, or virtual group or the ACO reports MIPS PI performance category as an APM entity, the MIPS eligible clinicians, QPs, and Partial QP the exemption would not apply for purposes of satisfying our proposed regulation at § 425.507.

Exclusions to MIPS eligible clinicians described at § 414.1310(b)(1)(iii) include eligible clinicians who do not exceed the MIPS low volume threshold. Eligible clinicians who are not MIPS eligible clinicians have the option to voluntarily report measures and activities for MIPS as described at § 414.1310(b)(2). Federally Qualified Health Centers (FQHC) or Rural Health Clinics (RHC) who provide services that are billed exclusively under the FQHC or RHC payment methodologies may voluntarily report the MIPS PI performance category as a group, virtual group, or APM entity. MIPS eligible clinicians, QPs, and Partial QPs practicing in FQHCs or RHCs who provide services that are billed exclusively under FQHC or RHC payment methodologies may voluntarily report the MIPS PI performance category as an individual, group, virtual group, or APM entity. It is important to note that exclusions to MIPS eligible clinicians as described at § 414.1310(b)(1)(i) and (ii) are not applicable to our proposal at § 425.507 because QPs and Partial QPs are required to report MIPS PI performance category for purposes of satisfying the Shared Savings Program proposal at § 425.507. Examples of applicable exclusions under § 414.1380(c)(2) for reweighting of the MIPS PI performance category include, but are not limited to, the following:

- MIPS eligible clinicians, QPs, and Partial QPs participating in the ACO who are granted a hardship exception under § 414.1380(c)(2)(i)(C) at the individual, group, virtual group, or APM entity level.
- MIPS eligible clinicians, QPs, and Partial QPs that are eligible for reweighting of the PI performance category at the individual, group, virtual group, or APM entity level as described at § 414.1380(c)(2)(i)(A)(4).
- MIPS eligible clinicians, QPs, and Partial QPs that are eligible for reweighting of the PI performance category as described at § 414.1380(c)(2)(i)(A)(*4*).

We believe that incorporating MIPS PI performance category's requirements into the Shared Savings Program will alleviate the burden that the current policy creates for ACOs. Because the Shared Savings Program CEHRT attestation requirement and the MIPS PI category requirements are not the same, ACOs have the burden of managing compliance with two different CEHRT program requirements. In finalizing the Shared Savings Program CEHRT attestation in the CY 2019 PFS, we stated our desire to continue to promote and encourage CEHRT use by ACOs and their ACO participants and ACO providers/suppliers, and our desire to better align with the goals of the Quality Payment Program and the criteria for participation in certain alternative payment models tested by the Innovation Center (83 FR 59983). Given our unified goal and vision for the use of CEHRT, we believe our proposal at § 425.507 will allow ACOs to focus on a unified set of program requirements for the use of CEHRT and reduce the administrative burden of managing compliance with a different set of program requirements with the same aim.

While ACOs would be able to report the MIPS PI category at the individual, group, virtual group, or APM entity level for purposes of satisfy our proposal at § 425.507, we encourage ACOs to evaluate reporting the MIPS PI performance category at the APM entity level for purposes of satisfying the Shared Savings Program regulation proposed at § 425.507. In the CY 2023 PFS final rule, we finalized a policy to introduce a voluntary reporting option for APM entities to report the MIPS PI performance category at the APM entity level beginning with the CY 2023 performance period (87 FR 70033). For purposes of MIPS scoring and payment adjustments, if the ACO reports the MIPS PI performance category at the APM entity level, the APM entity PI performance category score would be used to generate the APM entity level score for purposes of scoring the MIPS PI performance category. If the ACO does not report PI at APM entity level, the ACO's individual and group scores would be calculated as a weighted average up to the APM entity level to generate the APM entity level score for purposes of scoring the MIPS PI performance category. If an eligible clinician reports PI at the individual or group level under traditional MIPS or

the APM Performance Pathway (APP) in addition to reporting the MIPS PI performance at the APM entity level via the APP, for purposes of MIPS scoring and payment adjustments, that eligible clinician would receive the higher of their individual, group, or APM entity PI performance category score. For more information about reporting the PI performance category at the APM entity level, we direct readers to the MIPS Promoting Interoperability User Guide, which is updated each performance year, in the QPP Resource library *https://qpp.cms.gov/resources/resource-library*. We anticipate releasing sub-regulatory guidance for ACOs that participate in the Shared Savings Program about voluntarily reporting the MIPS PI performance category at the APM entity level in future performance years.

We are seeking public comment on our proposal that, for performance years beginning on or after January 1, 2024, unless otherwise excluded, to require that all MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305) participating in the ACO, regardless of track, satisfy all of the following:

- Report the MIPS Promoting Interoperability (PI) performance category measures and requirements to MIPS according to 42 CFR part 414 subpart O as either of the following—

++ All MIPS eligible clinicians, QPs, and partial QPs participating in the ACO as an individual, group, or virtual group; or

++ The ACO as an APM entity.

- Earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level.

A MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity may be excluded from the requirements proposed at § 425.507(a) if the MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity—

- Does not exceed the low volume threshold set forth at § 414.1310(b)(1)(iii);
- Is an eligible clinician as defined at § 414.1305 who is not a MIPS eligible clinician and has opted to voluntarily report measures and activities for MIPS as set forth in § 414.1310(b)(2); or
- Has not earned a performance category score for the MIPS Promoting Interoperability performance category because the MIPS Promoting Interoperability performance category has been reweighted in accordance with applicable policies set forth at § 414.1380(c)(2).

We propose to codify this new requirement at § 425.507.

We are also seeking public comment on an alternative proposal to narrow the proposal to require that ACOs to report the measures and requirements under the MIPS PI performance category, in accordance with our regulations at 42 CFR part 414 subpart O, at the APM entity level. This alternative proposal would remove the option for MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305) participating in the ACO to report the MIPS PI performance category at the individual, group, or virtual group level for purposes of satisfying our proposal at § 425.507.

(3) Updating Public Reporting Requirements

As described in the CY 2019 final rule (80 FR 32813 through 32815), we believe that one important aspect of patient-centered care is patient engagement and transparency, which can be achieved by the public reporting of ACO quality and cost performance. Public reporting helps to hold ACOs accountable and may improve a beneficiary's ability to make informed health care choices as well as facilitate an ACO's ability to improve the quality and efficiency of its care. To ensure our public reporting requirements reflect our proposal to require reporting of objectives, measures, and activities under the MIPS PI performance category as discussed above, we also are proposing to require ACOs to publicly report the number of MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305) participating in the ACO that earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level as proposed at § 425.507. We are proposing to codify this requirement at § 425.308(b)(9).

We are proposing that MIPS eligible clinicians, QPs, and Partial QPs who would be excluded from reporting under the proposed regulation at § 425.507(b) as discussed previously may be excluded from the number of MIPS eligible clinicians, QPs, or Partial QPs that the ACO publicly reports under our proposed regulation at § 425.308(b)(9). However, if such MIPS eligible clinicians, QPs, and Partial QPs do report the MIPS PI performance category as an individual, group, or virtual group or the ACO reports the MIPS PI performance category as an APM entity, the MIPS eligible clinicians, QPs, and Partial QPs should be included in the number of MIPS eligible clinicians, QPs, and Partial QPs that the ACO publicly reports under our proposed regulation at § 425.308(b)(9).

(4) Updating Annual Certification Requirements

As noted in section III.G.2.h.(2) of this proposed rule, we believe that incorporating MIPS PI performance category's requirements will alleviate confusion for ACOs and the use of CEHRT under the Shared Savings Program. Additionally, we find that the MIPS PI performance category's reporting requirements are more comprehensive and better address the key functions that facilitate better care coordination and quality measurement for ACOs. This change would further align the Shared Savings Program with the MIPS program and allow for greater insight into CEHRT use among ACO clinicians.

Currently, under § 425.302(a)(3)(iii), at the end of each performance year, ACOs must certify that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable CEHRT threshold percentage specified at § 425.506(f). As discussed in section III.G.2.h.(4). of this proposed rule, we are proposing to sunset the Shared Savings Program CEHRT threshold requirements and modify § 425.506(f) to indicate that they will end with performance year 2023.

To ensure our certification requirements align with our proposal in section III.G.2.h.(2) of this proposed rule, we also propose to revise our regulation at § 425.302(a)(3)(iii) to make the current Shared Savings Program Annual Certification requirement applicable for only performance years 2019 through 2023. That is, we are proposing to sunset the CEHRT certification requirement in the Shared Savings Program by amending regulations to no longer require ACO clinicians to report the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage specified at § 425.506(f).

We are seeking public comment on our proposal to sunset the CEHRT certification requirement in the Shared Savings Program at §§ 425.302(a)(3)(iii) and 425.506(f) and to add new

requirements at § 425.507, for performance years beginning on or after January 1, 2024, unless otherwise excluded, to require that all MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305) participating in the ACO, regardless of track, satisfy all of the following:

- Report the MIPS Promoting Interoperability (PI) performance category measures and requirements to MIPS according to 42 CFR part 414 subpart O as either of the following—

++ All MIPS eligible clinicians, QPs, and partial QPs participating in the ACO as an individual, group, or virtual group; or

++ The ACO as an APM entity.

- Earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level.

A MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity may be excluded from the requirements proposed at § 425.507(a) if the MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity—

- Does not exceed the low volume threshold set forth at § 414.1310(b)(1)(iii);
- Is an eligible clinician as defined at § 414.1305 who is not a MIPS eligible clinician and has opted to voluntarily report measures and activities for MIPS as set forth in § 414.1310(b)(2); or
- Has not earned a performance category score for the MIPS Promoting Interoperability performance category because the MIPS Promoting Interoperability performance category has been reweighted in accordance with applicable policies set forth at § 414.1380(c)(2).

We also seek comment on our proposal to add a new requirement for public reporting in § 425.308(b)(9), requiring that the ACO must publicly report the number of MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305) participating in the ACO that earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level as proposed at § 425.507.

i. MIPS Value Pathway (MVP) Reporting for Specialists in Shared Savings Program ACOs—Request for Information (RFI)

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 measure set under the APP for Shared Savings Program ACOs. As part of finalizing the APP measure set (85 FR 34727), we stated that the transition to the APP measure set was 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 stated that we selected the measures to be included because they are broadly applicable for the primary care population and population health goals that are associated with the Shared Savings Program.

We received public comments raising concerns about the challenges and applicability of these measures to specialists that are part of their ACOs (85 FR 34727). Commenters provided feedback that: reducing the number of ACO quality measures would make specialists less likely to participate in the Shared Savings Program; 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; CMS should work with interested parties 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; 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.

In the CY 2022 PFS proposed rule (86 FR 39270), we solicited comments on reporting options for specialist providers within an ACO. Specifically, we stated that we have heard from interested parties that the population health/primary care focused measures in the APP are not applicable for specialist providers within an ACO. We noted in the final rule that we may consider feedback we received to inform future rulemaking (86 FR 65264).

In the CY 2022 PFS final rule (86 FR 65376), MVPs were finalized to be available for reporting beginning with the CY 2023 performance period of MIPS, with the notion that MVPs will be implemented through notice and comment rulemaking over the next few years to offer clinically relevant quality reporting for specialists and more granular specialty data (through subgroup reporting) for patients to make informed decisions about the care they receive. In the CY 2022 PFS final rule (86 FR 65376), MVPs were finalized to be available for reporting beginning with the CY 2023 performance period of MIPS, with the notion that MVPs will be implemented through notice and comment rulemaking over the next few years to offer clinically relevant quality reporting for specialists and more granular specialty data (through subgroup reporting) for patients to make informed decisions about the care they receive. Building upon our commitment to align quality measures across CMS,[150] we direct readers to section IV.A.4.a. of this proposed rule where we propose to create a primary care MVP. We note that the primary care MVP would create continuity between the primary care measures assessed under MIPS and the measures providers would be accountable for in the Medicare Shared Savings Program.

In light of the public comments described above and the finalization and continued development of the MVPs, we believe we need incentives for specialists in Shared Savings Program ACOs to report clinically relevant quality measures and to allow patients, referring clinicians, and ACOs to have more information regarding specialists involved in patient care. We believe that encouraging specialists to report on MVPs will lead to increased specialty engagement in the Shared Savings Program, thereby holding specialists accountable for quality improvement.

Beginning in CY 2023, specialists that report under MIPS, including specialists that participate in Shared Savings Program ACOs, have the option to register to report MVPs for the applicable CY performance period as described at § 414.1365(b) as a group, subgroup, or individual and to report on relevant MVP quality measures as described at § 414.1365(c). In this proposed rule, we are soliciting comments on scoring incentives that would be applied to an ACO's health equity adjusted quality performance score beginning in performance year 2025 when specialists who participate

[150] Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher L. Aligning Quality Measures across CMS—The Universal Foundation. New England Journal of Medicine, March 2, 2023, available at *https://www.nejm.org/doi/full/10.1056/NEJMp2215539*.

in the ACO report quality MVPs as described at § 414.1365(c)(1).

Similar to the health equity adjustment finalized in the CY 2023 PFS final rule (87 FR 69838), we are considering bonus points for ACOs with specialists reporting quality MVPs as described at § 414.1365(c)(1) that would be applied after MIPS scoring is complete. ACOs may receive up to a maximum of 10 additional points added to their ACO's health equity adjusted quality performance score if they meet the data completeness requirement at § 414.1340 and receives a MIPS Quality performance category score under § 414.1380(b)(1), in addition to administering the CAHPS for MIPS survey. In addition to specialists that participate in the ACO reporting quality MVPs described at § 414.1365(c)(1), an ACO would be required to report all measures in the APP measure set, meet the data completeness requirement at § 414.1340 and receives a MIPS Quality performance category score under § 414.1380(b)(1) to be eligible for bonus points.

Our overarching intent is to have specialists participate in ACOs in a meaningful way and to collect quality data that is comparable to data reported by other specialty providers in quality MVPs. We are seeking feedback on our overall approach to align quality measures in the Adult Universal Foundation with measures used for evaluation in the Medicare Shared Savings Program. We are also seeking feedback on the following aspects of MVP reporting for specialists in Shared Savings Program ACOs:

- In order to highlight specialty clinical practice within ACOs, how should we encourage specialist reporting of MVPs?
- How should we encourage the reporting of MVPs to collect quality data that is comparable to data reported by other specialty providers in quality MVPs and to address clinician concerns over measure appropriateness?
- How should we consider encouraging specialists to report the MVP that is most relevant to their clinical practice?
- How should we distinguish bonus points for ACOs that report on a larger volume of patients through MVPs?
- How should we provide ACOs with bonus points to their health equity adjusted quality performance score when an ACO's specialty clinicians report MVPs?
- What concerns and considerations should we be aware of when assessing ACOs for quality performance based on reporting quality measures within MVPs?
- Would incentivizing specialty MVPs create a disincentive for ACOs to report primary care focused APP and/or MVP measures?
- In the event that MIPS quality measures in MVPs are excluded under § 414.1380(b)(1)(vii)(A), should we apply the proposed Shared Savings Program scoring policy for excluded APP measures as described in section III.G.2.f. of this proposed rule?
- As noted above, providing ACOs with bonus points to their health equity adjusted quality performance score when ACOs' specialty clinicians report MVPs serves to encourage reporting of MVPs. Therefore, we do not intend to establish bonus points as a permanent policy. We seek comment on how long we should have bonus points in place in order to incentivize MVP reporting.
- Once specialists are reporting MVPs, overall aggregate specialty performance within an ACO could be assessed. We seek comment on if and how CMS should consider assessing overall specialty performance as part of the APP in the future.

We note that in section IV.A.1.b.(2) of this proposed rule, we included an RFI on how we can leverage MIPS policies to enable more Medicare beneficiaries to benefit from accountable care relationships within APMs and provide rigorous performance standards for those clinicians who report MVPs and remain in MIPS.

j. Proposal To Revise the Requirement To Meet the Case Minimum Requirement for Quality Performance Standard Determinations

(1) Background

We require ACOs to meet the case minimum requirement at § 414.1380 to determine the quality performance standard for ACOs in the first performance year of their first agreement period, for the eCQM/MIPS CQM incentive for performance year 2024, and for the extreme and uncontrollable circumstances policy (§ 425.512(a)(2), (a)(5)(i)(A)(2), (c)(3)).

Section 414.1380 includes policies related to all of MIPS scoring and is not specific to the Quality performance category. Further, the phrase ''case minimum'' is mentioned in multiple paragraphs at § 414.1380. The broad reference to § 414.1380 under § 425.512(a)(2), (a)(5)(i)(A)(2), and (c)(3) does not specify which paragraph at § 414.1380 is applicable when applying case minimum for purposes of determining an ACO's quality performance standard. We believe that the references to meeting the case minimum requirement at § 414.1380 in the context of determining an ACO's quality performance standard under § 425.512(a)(2), (a)(5)(i)(A)(2), and (c)(3) is not sufficient in describing our policy's intent, which is to apply the MIPS Quality performance category scoring policies as described at § 414.1380(b)(1) in determining the ACO quality performance standard.

(2) Proposed Revisions

In order to alleviate confusion regarding the reference to case minimum in determining the ACO quality performance standard, for performance year 2024 and subsequent performance years, we propose to replace the references to meeting the case minimum requirement at § 414.1380 from § 425.512(a)(2), (a)(5)(i)(A)(2), and (c)(3) with the requirement that the ACO must receive a MIPS Quality performance category score under § 414.1380(b)(1) in order to meet the quality performance standard. This proposal would correct the purpose of our reference to case minimums by incorporating all of the applications of case minimums in the MIPS Quality performance category scoring policies in our policies to determine an ACO's quality performance standard under the Shared Savings Program. For example, under current policy at § 414.1380(b)(1)(i)(A)(2)(ii) in performance year 2024, if an ACO does not meet the case minimum requirement on an administrative claims-based measure, that measure would be excluded from the ACO's MIPS Quality performance category measure achievement points (numerator) and total available measure achievement points (denominator). If the ACO in this example meets the data completeness requirement at § 414.1340 for the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs/Medicare CQMs and administers a CAHPS for MIPS survey, the ACO would receive a MIPS Quality performance category score. The resulting MIPS Quality performance category score in this example would be used to determine the ACO's quality performance standard under the Shared Savings Program.

All ACOs that participated in the Shared Savings Program were affected by an extreme and uncontrollable circumstance as described at § 425.512(c)(1) for performance years 2021, 2022, and 2023 due to the COVID–19 public health emergency. We believe that any unintended impact of meeting the case minimum requirement at § 414.1380 in evaluating an ACO's quality performance standard for performance years 2021, 2022, and 2023

was mitigated by the application of the extreme and uncontrollable circumstance policy. Specifically, it is not our intent to exclude an ACO who received a MIPS Quality performance category score, but reported less than 20 cases on any measure(s) in the APP measure set from achieving the quality performance standard under § 425.512(a)(2), (a)(5)(i)(A)(2), and (c)(3), if that ACO is otherwise eligible to meet the quality performance standard.

Separately, we propose to address a gap in the current rule regarding the ''minimum beneficiary sampling requirement'' at § 414.1380(b)(1)(vii)(B). This provision provides for a 10-point reduction in the total available measure achievement points for MIPS eligible clinicians that submit five measures or fewer and register for the CAHPS for MIPS survey but do not meet the minimum beneficiary sampling requirement. As the case minimum is not applicable to the CAHPS for MIPS survey, we did not intend to preclude ACOs that do not meet the minimum beneficiary sampling requirement to field a CAHPS for MIPS survey from meeting the Shared Savings Program quality performance standard or the alternative quality performance standard. We propose revisions to the following regulation text sections:

- At § 425.512(a)(2)(ii) and (iii), we propose to replace the phrase ''case minimum requirement at § 414.1380 of this subchapter'' with the phrase ''receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter.''

Additionally, we propose to replace the phrase ''CAHPS for MIPS survey'' with the phrase ''CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter).'' To read as follows: For the first performance year of an ACO's first agreement period under the Shared Savings Program, the ACO would meet the quality performance standard under the Shared Savings Program, if:

++ For performance year 2024, the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter on the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter.

++ For performance year 2025 and subsequent performance years, the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter on the three eCQMs/MIPS CQMs/Medicare CQMs and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter

- At § 425.512(a)(5)(i)(A)(2), we propose to remove the phrase ''and the case minimum requirement at § 414.1380 of this subchapter.'' As follows: For performance year 2024, under the eCQM/MIPS CQM reporting incentive, the ACO would meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses, as applicable, if the ACO: (1) meets the data completeness requirement at § 414.1340 for all three eCQMs/MIPS CQMs; (2) achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and (3) achieves a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set.

++ We are not including a requirement under § 425.512(a)(5)(i)(A)(2) for the ACO to receive a MIPS Quality performance category score under § 414.1380(b)(1). As described at § 414.1380(b)(1)(vii), the MIPS Quality performance category score is the sum of all the measure achievement points divided by the sum of total available measure achievement points for the quality performance category. Therefore, we do not believe that it would be appropriate to require an ACO to receive a MIPS Quality performance category score in determining whether the ACO met the Shared Savings Program quality performance standard based on measure-level performance (such as in the case of the eCQM/MIPS CQM reporting incentive).

- At § 425.512(c)(3), we propose to remove the phrase ''case minimum'' for performance 2024 and subsequent performance years and replace with the phrase ''receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter.'' To read as follows: Under the extreme and uncontrollable circumstances policy, for performance year 2024 and subsequent performance years, if the ACO reports quality data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, CMS would use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

We are proposing to revise § 425.512(a)(5)(iii)(A) and (B) to read as follows:

- For performance year 2024, the ACO does not report any of the ten CMS Web Interface measures, any of the three eCQMs/MIPS CQMs/Medicare CQMs and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter) under the APP.

- For performance year 2025 and subsequent years, the ACO does not report any of the three eCQMs/MIPS CQMs/Medicare CQMs and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter) under the APP.

Additionally, we propose to add clarifying language to the proposed redesignated paragraph (b)(2) of § 425.512 on calculating an ACO's health equity adjusted quality performance score as follows:

- For performance year 2024 and subsequent performance years, CMS will calculate the ACO's health equity adjusted quality performance score as the sum of: the ACO's MIPS Quality performance category score for all measures in the APP measure set, and the ACO's health equity adjustment bonus points calculated in accordance with paragraph (b)(3) of this section, to which the sum of these values may not exceed 100 percent, if the following requirements are met: (1) The ACO reports the three eCQMs/MIPS CQMs/Medicare CQMs in the APP measure set; (2) meets the data completeness requirement at § 414.1340 for the three eCQMs/MIPS CQMs/Medicare CQMs; and (3) administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)).

3. Determining Beneficiary Assignment Under the Shared Savings Program

a. Proposed Modifications to the Step-Wise Assignment Methodology and Approach To Identifying the Assignable Beneficiary Population

(1) Background

(a) Background on Assignment Methodology

Section 1899(c)(1) of the Act, as amended by the CURES Act and the Bipartisan Budget Act of 2018, provides that the Secretary shall determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of primary care services provided by physicians in the ACO and, in the case of performance years beginning on or after January 1, 2019, services provided by a FQHC or RHC. As we have explained in earlier rulemaking, the term ''assignment'' for purposes of the Shared Savings Program in no way implies any limits, restrictions, or diminishment of the rights of Medicare FFS beneficiaries to exercise freedom of choice in the physicians and other health care practitioners from whom they receive covered services. In the context of the Shared Savings Program, ''assignment'' refers to an operational process by which Medicare will determine whether a beneficiary has chosen to receive a sufficient level of certain primary care services from physicians and other health care practitioners associated with a specific ACO so that the ACO may be appropriately designated as exercising basic responsibility for that beneficiary's care.[151]

The regulations governing the assignment methodology under the Shared Savings Program are in 42 CFR part 425, subpart E. Under claims-based assignment, we determine a Medicare FFS beneficiary is assigned to an ACO if the beneficiary meets the criteria in § 425.401(a) to be eligible for assignment to an ACO, and the beneficiary's utilization of primary care services meets the criteria established under the assignment methodology specified in §§ 425.402 and 425.404. Section 425.402 specifies a step-wise assignment methodology for determining an ACO's assigned beneficiary population based on beneficiaries' use of primary care services. In accordance with § 425.402(b)(1), as a ''pre-step'' in the two-step claims-based assignment process, CMS identifies all beneficiaries who had at least one primary care service furnished by a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or has one of the primary specialty designations specified in § 425.402(c). This pre-step is designed to satisfy the statutory requirement under section 1899(c)(1) of the Act that beneficiaries be assigned to an ACO based on their use of primary care services furnished by physicians participating in the ACO. Beneficiaries who meet the pre-step requirement are then assigned to an ACO through either one of two steps specified in § 425.402(b)(3) and (b)(4).

Under the first step of the assignment process, a beneficiary who is eligible for assignment and meets the pre-step requirement is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary during the assignment window by primary care physicians, nurse practitioners, physician assistants, and clinical nurse specialists who are ACO professionals in the ACO are greater than the allowed charges for primary care services furnished during the assignment window by primary care physicians, nurse practitioners, physician assistants, or 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. The second step of the assignment methodology applies to the remainder of the beneficiaries who are eligible for assignment and meet the pre-step requirement, who have not had a primary care service rendered during the assignment window by any primary care physician, nurse practitioner, physician assistant, or clinical nurse specialist, either inside or outside the ACO. The beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary during the assignment window by physicians who are ACO professionals with specialty designations specified in § 425.402(c) are greater than the allowed charges for primary care services furnished during the assignment window by physicians with such specialty designations who are ACO professionals in any other ACO, or who are unaffiliated with an ACO and are identified by a Medicare-enrolled billing TIN.

The Shared Savings Program step-wise assignment process is offered in two similar, but distinct, claims-based assignment methodologies, prospective assignment and preliminary prospective assignment with retrospective reconciliation. Consistent with the requirements of section 1899(c)(2)(A) of the Act, we offer all Shared Savings Program ACOs the opportunity to select their assignment methodology annually, starting with agreement periods beginning on July 1, 2019. We use the same step-wise assignment methodology under § 425.402 to assign beneficiaries to ACOs under prospective assignment and ACOs under preliminary prospective assignment with retrospective reconciliation.

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 offset from the calendar year (for example, October through September preceding 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 step-wise assignment 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 step-wise assignment methodology was initially established with the November 2011 final rule and was modified through subsequent rulemaking. For instance, with the June 2015 final rule, we modified the approach to include claims for primary care services furnished by non-physician practitioners (nurse practitioners, physician assistants, and clinical nurse specialists) in step one of the assignment methodology rather than in step two, and to exclude services provided by certain physician specialties from step two of the assignment process. We refer readers to the November 2011 final rule and the June 2015 final rule for a discussion of the relevant background and related considerations (see 76 FR 67853 through 67858, and 80 FR 32748 through 32755). Generally, as we have previously explained in rulemaking, the step-wise assignment methodology maintains the statutory requirement to conduct claims-based beneficiary assignment based on beneficiaries' utilization of physician primary care services, recognizing the necessary and appropriate role of certain specialists in providing primary care services, such as

[151] See for example, 76 FR 67851, and 83 FR 67863.

in areas with primary care physician shortages (see, for example, 76 FR 67853 through 67855; see also 80 FR 32748 and 32754). Further, including services furnished by nurse practitioners, physician assistants, and clinical nurse specialists in determining where a beneficiary has received the plurality of primary care services in step one of the assignment methodology helps ensure that a beneficiary is assigned to the ACO whose ACO participants are actually providing the plurality of primary care for that beneficiary, and thus, should be responsible for managing the patient's overall care, or is not assigned to any ACO if the plurality of the beneficiary's primary care is furnished by practitioners in a non-ACO entity (see, for example, 80 FR 32748).

Various Shared Savings Program operations are based on the ACO's assigned population, or consider the size of the ACO's assigned population, which are summarized as follows:

- Within the Shared Savings Program's financial methodology:

++ CMS determines benchmark and performance year expenditures based on the ACO's assigned population as specified under subpart G of the regulations.

++ CMS determines the counties to include in the ACO's regional service area based on the ACO's assigned population (refer to definition of ACO's regional service area in § 425.20), and uses the ACO's assigned population in determining the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO (see §§ 425.601(a)(5)(v) and 425.652(a)(5)(v)) which is applied in calculating the two-way blend of national and regional growth rates used to trend forward BY1 and BY2 expenditures to BY3 according to §§ 425.601(a)(5)(iv) and 425.652(a)(5)(iv) and as part of the blended growth rates used to update the benchmark according to §§ 425.601(b) and 425.652(b)(2). CMS also uses the ACO's regional service area to determine the regional adjustment to the ACO's historical benchmark according to § 425.656.

++ CMS considers the proportion of the ACO's assigned beneficiary population that is dually eligible for Medicare and Medicaid and the difference between the ACO's weighted average prospective HCC risk score for BY3 taken across the four Medicare enrollment types and when calculating the offset factor applied to negative regional adjustments (see § 425.656(c)(4)).

++ CMS considers the size of the ACO's assigned population in calculating the proration factor when determining the ACO's eligibility for the prior savings adjustment (see § 425.658(b)(3)) as well as in determining the minimum savings rate (MSR)/minimum loss rate (MLR) for ACOs that select the option to have their MSR/MLR calculated based on the number of beneficiaries assigned to the ACO (refer to § 425.605(b)(2)(i)(C) (BASIC track) and § 425.610(b)(1)(iii) (ENHANCED track)).

++ CMS determines average prospective HCC risk scores for assigned beneficiaries for purposes of adjusting assigned beneficiary expenditures for severity and case mix (refer to §§ 425.601(a)(3), 425.601(a)(10), 425.605(a)(1), 425.610(a)(2), 425.652(a)(3), and 425.652(a)(10)), adjusting for differences in severity and case mix between the ACO's assigned beneficiary population and the assignable beneficiary population for the ACO's regional service area according to §§ 425.601(a)(8)(i)(C) and 425.656(b)(3), and adjusting the flat dollar amount ACPT for differences in severity and case mix between the ACO's BY3 assigned beneficiary population and the national assignable FFS population according to § 425.660(b)(4).

- In determinations related to an ACO's eligibility for participation for the Shared Savings Program:

++ CMS determines expenditures based on the ACO's assigned population when identifying if the ACO is a high revenue or low revenue ACO (as defined under § 425.20).

++ CMS considers whether an ACO meets the requirement to have at least 5,000 Medicare FFS assigned beneficiaries (see § 425.110).

++ CMS uses the ACO's number of assigned beneficiaries in calculating and recalculating the amount of the repayment mechanism required for ACOs participating under a two-sided model (see § 425.204(f)).

- For ACOs eligible to receive advance investment payments (see § 425.630(b)), CMS considers the size of the ACO's assigned population and the risk factors-based score of those beneficiaries in determining the quarterly payment amount (see § 425.630(f)).

- For ACOs that meet the reporting requirements for receiving a health equity adjusted quality performance score (see § 425.512(b)), CMS considers the proportion of the ACO's assigned beneficiary population that is underserved in determining the ACO's health equity adjustment bonus points (see § 425.512(b)(2)(iv)).

- For ACOs affected by an extreme and uncontrollable circumstance, CMS considers the proportion of the ACO's assigned beneficiaries residing in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance in determining the ACO's quality score (see § 425.512(c)(1)(i)). CMS considers the percentage of the ACO's performance year assigned beneficiary population affected by an extreme and uncontrollable circumstance in determining the amount of shared losses owed by ACOs under a two-sided model (refer to §§ 425.605(f)(1) and 425.610(i)(1)).

- For ACOs that have established a beneficiary incentive program, beneficiaries assigned to an ACO who receive a qualifying service are eligible to receive an incentive payment (see § 425.304(c)(3)(ii) through (iv)).

- In accordance with the Shared Savings Program regulations under subpart H, CMS provides ACOs with certain aggregate reports and beneficiary-identifiable claims data on the ACO's assigned beneficiary population.

Further, a non-claims-based process for voluntary alignment applies to all Shared Savings Program ACOs and is used to supplement claims-based assignment. Section 1899(c) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, requires the Secretary to permit a Medicare FFS beneficiary to voluntarily identify an ACO professional as their primary care provider for purposes of assignment to an ACO. In the November 2018 final rule (83 FR 59959 through 59964), we finalized changes to the beneficiary voluntary alignment policies CMS previously established to implement the requirements under section 1899(c)(2)(B) of the Act (refer to § 425.402(e), as revised). In the November 2018 final rule (83 FR 59964), we revised the requirements related to primary care services and practitioner specialties previously established for the voluntary alignment process. As a result of this change, a voluntarily aligned beneficiary is no longer required to receive a primary care service from an ACO professional to be assigned to the ACO in which the beneficiary's designated primary care clinician is participating. Additionally, the revision established that a beneficiary can be voluntarily aligned to an ACO based on their selection of any ACO professional as their primary clinician, regardless of the ACO professional's specialty and including nurse practitioners, physician assistants, and clinical nurse specialists. As specified in § 425.402(e)(1), and subject to § 425.402(e)(2), assignment under voluntary alignment supersedes

any assignment that otherwise may have occurred under claims-based assignment.

(b) Background on Identification and Uses of the Assignable Beneficiary Population Under the Shared Savings Program

To identify the assignable beneficiary population, which is used in program financial calculations, we apply a similar logic as is used to identify the Medicare beneficiaries who can be assigned to an ACO in the pre-step to the claims-based assignment methodology (see, for example, 81 FR 5843, and 81 FR 37985). In the June 2016 final rule (81 FR 37950), we finalized policies to use the assignable beneficiary population (a subset of the larger population of Medicare FFS beneficiaries) as the basis of certain calculations that had previously been based on the overall Medicare FFS population, including expenditures used to trend and update ACOs' historical benchmarks and to establish the truncation thresholds used in expenditure calculations. In the June 2016 final rule, we finalized the definition of ''assignable beneficiary'' under § 425.20 to mean a Medicare FFS beneficiary who receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c). We specified that the assignable population used to calculate national and regional benchmarking factors was to be identified using the 12-month calendar year assignment window corresponding to the benchmark or performance year for all ACOs, regardless of assignment methodology which applied to the ACO, which at that time was determined by an ACO's track (see 81 FR 37985 through 37988). We explained our belief that using assignable beneficiaries across all program calculations based on national and regional FFS expenditures would result in factors that are generally more comparable to ACO expenditures than factors based on the overall Medicare FFS population, which can include non-utilizers of health care services and other beneficiaries not eligible for assignment (see, for example, 81 FR 5843 and 5844).

In the CY 2023 PFS final rule (87 FR 69929 through 69932), we finalized a modification to this policy, applicable for agreement periods beginning on January 1, 2024, and in subsequent years, to calculate risk-adjusted regional expenditures and the share of assignable beneficiaries assigned to an ACO using county-level values based on the assignable population identified using an assignment window that is consistent with the ACO's assignment methodology selection for the applicable performance year. (Refer to §§ 425.652(a)(5)(v)(A) and (b)(2)(iv)(A), and 425.654(a)(1)(i).) Under this approach, for ACOs selecting prospective assignment, we will use an assignable population of beneficiaries that is identified based on the offset assignment window (for example, October through September preceding the calendar year) and for ACOs selecting preliminary prospective assignment with retrospective reconciliation, we will use an assignable population of beneficiaries identified based on the calendar year assignment window (87 FR 69930). We also specified in the CY 2023 PFS final rule that we would continue to compute all factors used in calculations that are based on the national assignable FFS population using an assignable population identified based on the calendar year assignment window. (Refer to 87 FR 69931.) For ACOs participating under agreement periods beginning on or after July 1, 2019, and before January 1, 2024, we will continue to identify the assignable population that is the basis for calculating national and regional factors using the 12-month period based on a calendar year, which aligns with the assignment window for preliminary prospective assignment with retrospective reconciliation, regardless of the ACO's assignment methodology. (See § 425.601. See also, 87 FR 69929, for a description of relevant background.)

The assignable beneficiary population is used in various calculations under the Shared Savings Program, including the following:

- CMS determines the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries for purposes of truncating beneficiary expenditures in order to minimize variation from catastrophically large claims (see §§ 425.601(a)(4) and (c)(3), 425.605(a)(3), 425.610(a)(4)(ii), 425.652(a)(4), and 425.654(a)(3)).
- CMS determines average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county of an ACO's regional service area (see §§ 425.601(c) and 425.654(a)) for purposes of calculating the ACO's regional fee-for-service expenditures (see §§ 425.601(d) and 425.654(b)). CMS also determines the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO (see §§ 425.601(a)(5)(v) and 425.652(a)(5)(v)). The ACO's regional fee-for-service expenditures and the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO are used in the following calculations:
  - ++ Trend forward BY1 and BY2 expenditures to BY3 according to §§ 425.601(a)(5) and 425.652(a)(5).
  - ++ Determine the blended growth rates used to update the benchmark according to §§ 425.601(b) and 425.652(b)(2).
  - ++ Determine the adjustment to the ACO's benchmark according to §§ 425.601(a)(8) and 425.652(a)(8).
- CMS determines national per capita fee-for-service expenditures for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark according to §§ 425.601(a)(8)(ii)(C) and 425.656(c)(3), capping the prior savings adjustment according to § 425.652(a)(8)(iv), and determining a flat dollar amount ACPT according to § 425.660(b)(3).
- CMS determines national growth rates for assignable beneficiaries that are used to trend forward BY1 and BY2 expenditures to BY3 according to §§ 425.601(a)(5)(ii) and 425.652(a)(5)(ii) and to determine the blended growth rates used update the benchmark according to §§ 425.601(b)(2) and 425.652(b)(2)(i).
- CMS determines average prospective HCC risk scores for assignable beneficiaries for purposes of adjusting county fee-for-service expenditures for severity and case mix of assignable beneficiaries in the county according to §§ 425.601(c)(4) and 425.654(a)(4), calculating the regional adjustment to the historical benchmark by adjusting for differences in severity and case mix between the ACO's assigned beneficiary population and the assignable beneficiary population for the ACO's regional service area according to §§ 425.601(a)(8)(i)(C) and 425.656(b)(3), and adjusting the flat dollar amount ACPT for differences in severity and case mix between the ACO's BY3 assigned beneficiary population and the national assignable FFS population according to § 425.660(b)(4).

(c) Concerns About Beneficiaries Excluded From the Current Assignment Methodology Based on the Pre-Step Requirement and Definition of an Assignable Beneficiary

CMS has established a goal that 100 percent of beneficiaries enrolled in Original Medicare be involved in a care relationship with accountability for

quality and total cost of care by 2030.[152] CMS has also established health equity as a top priority through our CMS Framework for Health Equity (2022–2032).[153] However, CMS believes that the assignment pre-step and definition of assignable beneficiary may create barriers for some beneficiaries otherwise eligible for assignment to be assigned to ACOs. Revising the pre-step and definition of assignable beneficiary thus represents an opportunity to expand the assigned and assignable populations.

ACOs and other interested parties have also raised concerns that the current pre-step and definition of assignable beneficiary create barriers for some beneficiaries to be assigned to ACOs. For example, in previous proposed rules, we have received input from commenters that the pre-step requirement, as implemented in the current assignment methodology, systematically excludes from assignment beneficiaries who only received primary care from nurse practitioners, physician assistants, and clinical nurse specialists. In response to the CY 2023 PFS proposed rule, a commenter noted that the current claims-based assignment methodology creates a barrier for nurse practitioners and their patients to participate in ACOs.[154]

Additional analysis by CMS has found that expanding the assignment methodology to allow more opportunities for beneficiaries to be assignable based on their receipt of primary care services provided by nurse practitioners, physician assistants, or clinical nurse specialists would reduce the barriers for underserved beneficiaries to be assigned to ACOs. As described in section III.G.3.a.(2)(d) of this proposed rule, we have observed from initial modeling of expanding the definition of an assignable beneficiary that such an approach could add to the national assignable population identified under current Shared Savings Program policies a population of beneficiaries that are more likely to be disabled, be enrolled in the Medicare Part D low-income subsidy (LIS), and reside in areas with higher ADI scores. The newly assignable population of beneficiaries also had a lower average prospective HCC risk score, lower total per capita-year spending, higher hospice utilization, and a higher mortality rate than the national assignable population under the current definition of an assignable beneficiary. Therefore, we believe that adjusting the assignment methodology within the flexibility available under the statute so that additional beneficiaries can be included in the population of beneficiaries assigned to ACOs participating in the Shared Savings Program, and modifying the definition of assignable beneficiary to include a broader population, would make meaningful steps toward greater health equity and align with priorities recently emphasized in our CMS Framework for Health Equity (2022–2032).[155]

(2) Proposed Revisions

(a) Overview of Proposed Revisions To Incorporate Use of an Expanded Window for Assignment

Section 1899(c)(1)(A) of the Act requires that claims-based assignment to ACOs be based on beneficiaries' utilization of primary care services furnished by ACO professionals who are physicians. We are proposing to use an expanded window for assignment in a new step three to the claims-based assignment process to identify additional beneficiaries for ACO assignment (described in section III.G.3.a.(2)(b). of this proposed rule), and we are proposing to modify the definition of ''assignable beneficiary'' to be consistent with this use of an expanded window for assignment to identify additional beneficiaries to include in the assignable population after application of the existing methodology (described in section III.G.3.a.(2)(c). of this proposed rule). We propose to add a new definition of ''Expanded window for assignment'' in § 425.20 to mean the 24-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both that includes the applicable 12-month assignment window (as defined under § 425.20) and the preceding 12 months.

To follow is a brief summary of the proposed uses of the expanded window for assignment, described in greater detail elsewhere within this section of this proposed rule. First, the proposed addition of a step three to the beneficiary assignment methodology would occur after the current steps one and two and would apply only to beneficiaries who do not meet the pre-step requirement but who received at least one primary care service during the proposed expanded window for assignment with an ACO professional who is a primary care physician or a physician who has one of the specialty designations included in § 425.402(c). Beneficiaries qualifying for step three would be assigned based on the plurality of allowed charges for primary care services during this expanded window for assignment. Second, the proposed revision to the definition of an assignable beneficiary would similarly include beneficiaries who receive at least one primary care service during the proposed expanded window for assignment from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c). In combination with using the expanded window for assignment for identifying beneficiaries who received at least one primary care service from a primary care physician or a physician whose specialty designation is used in assignment, under both the proposed step three for assignment and proposed revised definition of an assignable beneficiary, we would continue to consider whether beneficiaries received at least one primary care service during the 12-month assignment window. We propose that these changes would be effective for the performance year beginning on January 1, 2025, and subsequent performance years.

A number of factors informed our consideration of the duration of the expanded window for assignment. We believe that a 24-month expanded window for assignment, as opposed to a longer period, would prioritize primary care services that were provided more recently. Through the proposed modifications to the assignment methodology and the definition of assignable beneficiary, we seek to better account for beneficiaries who may be receiving their primary care predominantly from non-physician practitioners during the 12-month assignment window, but who received care from a physician in the preceding 12 months, in recognition of the statutory requirement in section 1899(c) of the Act that claims-based assignment be based on receipt of primary care services from physicians who are ACO professionals. We believe that primary care services furnished by nurse practitioners, physician assistants, and

[152] Seshamani M, Fowler E, Brooks-LaSure C. Building On The CMS Strategic Vision: Working Together For A Stronger Medicare. Health Affairs. January 11, 2022. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20220110.198444*.

[153] Centers for Medicare & Medicaid Services, *The CMS Framework for Health Equity 2022–2032* (April 2022), available at *https://www.cms.gov/files/document/cms-framework-health-equity.pdf*.

[154] See comment letter from American Association of Nurse Practitioners, to Chiquita Brooks-LaSure, Administrator, CMS (September 6, 2022), available at *https://www.regulations.gov/comment/CMS-2022-0113-21927*.

[155] Centers for Medicare & Medicaid Services, *The CMS Framework for Health Equity 2022–2032* (April 2022), available at *https://www.cms.gov/files/document/cms-framework-health-equity.pdf*.

clinical nurse specialists during the 12-month assignment window could reflect their work in clinical teams in collaboration with and under the supervision of physicians, and thereby represent a continuation of the beneficiary's primary care relationship with a physician from the previous year. Furthermore, use of a 24-month expanded window for assignment would build on experience we have gained and lessons learned from testing Medicare ACO initiatives by the Center for Medicare and Medicaid Innovation (Innovation Center), specifically from the use of a two-year beneficiary alignment period in the ACO Realizing Equity, Access, and Community Health (REACH) Model and the Next Generation ACO (NGACO) Model.[156]

We also believe it is timely to propose modifications to the definition of ''assignment window'' under § 425.20 for improved clarity and consistency with the programmatic applications of the assignment window. Under the existing definition, assignment window means the 12-month period used to assign beneficiaries to an ACO. However, under existing Shared Savings Program policies and under the proposed changes described in this section of this proposed rule, we use the term assignment window in referencing our identification of assignable beneficiaries. Therefore, we are proposing to modify the definition of assignment window to mean the 12-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both.

We seek comment on proposed modifications to § 425.20, to revise the definition of ''assignable beneficiary,'' ''assignment window,'' and add a new definition of ''expanded window for assignment''.

[156] See, for example, CMS, Center for Medicare & Medicaid Innovation, ACO Realizing Equity, Access, and Community Health (REACH) Model, PY2023 Financial Operating Guide: Overview, available at *https://innovation.cms.gov/media/document/aco-reach-py2023-financial-op-guide* (refer to Appendix B, Beneficiary Alignment Procedures). See also, CMS, Center for Medicare & Medicaid Innovation, Next Generation ACO Model Benchmarking Methods (December 15, 2015), available at *https://innovation.cms.gov/files/x/nextgenaco-methodology.pdf* (refer to Appendix A, Next Generation ACO Model Alignment Procedures). In summary, under the ACO REACH Model and NGACO Model the alignment period consists of two alignment years. The first alignment year is the 12-month period ending 18 months prior to the start of the relevant performance year or base year. The second alignment year is the 12-month period ending 6 months prior to the start of the relevant performance year or base year.

(b) Proposed Revisions To Add a Step Three to the Beneficiary Assignment Methodology

For the performance year beginning on January 1, 2025, and subsequent performance years, we propose to revise the step-wise beneficiary assignment methodology, as described in § 425.402, to include a step three, which would utilize the proposed expanded window for assignment to identify additional beneficiaries for assignment among Medicare FFS beneficiaries who were not identified under the existing pre-step. Specifically, step three would identify all such beneficiaries not identified by the pre-step criterion specified in § 425.402(b)(1), who also meet the following criteria:

(1) Received at least one primary care service with a non-physician ACO professional (nurse practitioner, physician assistant, or clinical nurse specialist) in the ACO during the applicable 12-month assignment window.

(2) Received at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in § 425.402(c) during the applicable 24-month expanded window for assignment.

A beneficiary meeting the aforementioned criteria would then be assigned to the ACO if the allowed charges for primary care services furnished to the beneficiary by ACO professionals in the ACO who are primary care physicians, non-physician ACO professionals, or physicians with specialty designations included in § 425.402(c) during the applicable expanded window for assignment are greater than the allowed charges for primary care services furnished by primary care physicians, physicians with specialty designations included in § 425.402(c), nurse practitioners (as defined at § 410.75(b)), physician assistants (as defined at § 410.74(a)(2)), and clinical nurse specialists (as defined at § 410.76(b)) who are ACO professionals in any other ACO or not affiliated with any ACO and identified by a Medicare-enrolled billing TIN.

Further, in order to be assigned to an ACO through the step-wise assignment methodology, a Medicare FFS beneficiary would continue to need to meet the eligibility criteria in § 425.401(a) for the 12-month assignment window, regardless of whether the beneficiary is assigned to an ACO in step one or two, or proposed step three. Under the proposed approach, beneficiaries who do not receive any primary care services during the assignment window would continue to be excluded from claims-based assignment as they are under the current assignment methodology. Beneficiaries who meet the pre-step based on a 12-month assignment window (as specified in § 425.402(b)(1)) but are not assigned to an ACO in steps one or two would also continue to not be assigned to an ACO as these beneficiaries would not be considered for assignment in step three. The proposed changes also would not change beneficiary voluntary alignment, which would continue to supersede claims-based assignment, as specified in § 425.402(e).

As specified in § 425.400(a)(3)(ii), beneficiaries who are prospectively assigned to an ACO will remain assigned to the ACO at the end of the benchmark or performance year, unless they meet any of the exclusion criteria under § 425.401(b). As a result, under claims-based assignment, a beneficiary prospectively assigned to an ACO is not eligible for assignment to a different ACO for the same benchmark or performance year.[157] We propose to continue to apply this approach for beneficiaries prospectively assigned at step one, step two, or proposed step three. In other words, a beneficiary who is assigned to an ACO based on prospective assignment through step one or two or proposed step three would remain assigned to that ACO for the benchmark or performance year (unless they meet any of the exclusion criteria under § 425.401(b)). Under this approach, a beneficiary prospectively assigned to an ACO for a benchmark or performance year would not be assigned to another ACO under prospective assignment or to an ACO under preliminary prospective assignment with retrospective reconciliation, even if the other ACO provides the plurality of the beneficiary's primary care services during the relevant benchmark or performance year.

The use of a 24-month expanded window for assignment would also require changes to the timeframe for which we recognize additional primary care service codes related to the COVID–19 Public Health Emergency (PHE), as outlined in § 425.400(c)(2). Under § 425.400(c)(2), we use certain additional primary care service codes in

[157] See, for example, Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version #11, January 2023), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2*(see section 2.3.2.2, ''Prospective Assignment'').

determining beneficiary assignment under § 425.400(c)(1) when the assignment window for a benchmark or performance year includes any month(s) during the COVID–19 PHE (as defined in § 400.200). In accordance with § 425.400(c)(2)(ii), the additional primary care service codes are applicable to all months of the assignment window, when the assignment window includes any month(s) during the COVID–19 PHE, with the exception of certain additional CPT codes (99441, 99442, and 99443) which we use in determining assignment until they are longer payable under Medicare FFS payment policies (as specified under § 425.400(c)(2)(i)(A)(2)). We refer readers to discussions in earlier rulemaking for the development of this policy, including 85 FR 84748 through 84755, 85 FR 84791 through 84793, and 86 FR 65276. We propose to modify the regulations at § 425.400(c)(2)(i) and (ii) to incorporate references to the expanded window for assignment, such that we would apply the additional primary care service codes to all months of the assignment window or applicable expanded window for assignment when the assignment window or applicable expanded window for assignment includes any month(s) during the COVID–19 PHE. These proposed changes are necessary to capture the additional codes related to the COVID–19 PHE when using the expanded window for assignment in determining assignment for a benchmark or performance year.[158]

The proposed use of an expanded window for assignment in an enhanced step-wise assignment methodology would result in a greater overall number of beneficiaries assigned to ACOs. All beneficiaries who are assigned to an ACO under the current methodology would continue to be assigned to an ACO under the proposed methodology. Under the proposed methodology, a beneficiary who does not meet the current pre-step requirement would also be eligible to be assigned to an ACO if they (a) received at least one primary care service from a nurse practitioner, physician assistant, or clinical nurse specialist who is an ACO professional in the ACO during the applicable assignment window and (b) received at least one primary care service from a primary care physician or physician with a specialty used in assignment who is an ACO professional in the ACO during the applicable expanded window for assignment.

Under proposed changes, the 12-month assignment window would continue to represent the period used to identify allowed charges for primary care services received from ACO professionals and analogous practitioners not participating in an ACO, for purposes of claims-based beneficiary assignment during steps one and two. Thus, most beneficiaries currently assigned to an ACO under the existing assignment methodology would continue to be assigned to the same ACO under the proposed changes. We anticipate that only a very small share of beneficiaries would be assigned to a different ACO under the proposed assignment methodology, and any change in ACO assignment would be due to the operational order in which assignment is run and the precedence of prospective assignment over preliminary prospective assignment with retrospective reconciliation. Specifically, there may be a small share of beneficiaries who would be prospectively assigned to an ACO under the proposed step three for prospective assignment that differs from the retrospective ACO the beneficiary is currently assigned to under steps one or two for preliminary prospective assignment with retrospective reconciliation. This precedence of prospective assignment follows the current assignment methodology, which currently assigns beneficiaries via steps one and two of prospective assignment to an ACO that may be different than the ACO to which the beneficiary would have been assigned via steps one or two if assigned to an ACO under preliminary prospective assignment with retrospective reconciliation. For the average retrospective ACO, the share of assigned beneficiaries affected by this precedence of prospective assignment has historically been very small, approximately 1.3 percent from 2018 through 2021.

The proposed addition of step three would add a population of otherwise omitted beneficiaries by using the expanded window for assignment to identify the required physician visit with an ACO professional and to determine the plurality of allowed charges for primary care services. Functionally, the beneficiaries who would be newly assigned are beneficiaries who received a primary care service from an ACO professional who is a primary care physician (as defined under § 425.20) or who has one of the specialty designations included in § 425.402(c) in the 12-month period prior to the assignment window and received a primary care service from a nurse practitioner (as defined at § 410.75(b)), a physician assistant (as defined at § 410.74(a)(2)), or a clinical nurse specialist (as defined at § 410.76(b)) during the assignment window. Notably, the proposed step 3 would continue to be consistent with section 1899(c)(1)(A) of the Act, because a beneficiary would have to have received a primary care service from a primary care physician or physician with a specialty used in assignment who is an ACO professional in the ACO during the expanded window for assignment to be eligible for assignment to the ACO.

Similar to any other change that affects beneficiary assignment, the proposed use of an expanded window for assignment in a step three could impact downstream aspects of the Shared Savings Program that rely on the assigned population, including the following potential effects:

- Larger populations of assigned beneficiaries could contribute to more ACOs meeting minimum size requirements to participate in the program.
- A larger assigned population would result in lower minimum savings rates for ACOs subject to a variable minimum savings rate (that is, ACOs in a one-sided risk model on the BASIC track's glide path or ACOs in a two-sided risk model that elected a variable minimum savings rate). Lower minimum savings rates reflect a lower threshold for ACOs to meet in order to share in savings. Similarly, a larger assigned population would result in a lower minimum loss rate for ACOs in a two-sided risk model with a variable minimum loss rate, which reflects a lower threshold for two-sided risk ACOs to meet before they must share in losses.
- A larger assigned population would enable higher performance payment limits, which are based on a percentage of an ACO's total benchmark expenditures. As an ACO's assigned beneficiary population increases, so too do the ACO's total benchmark expenditures. Because the maximum shared savings an ACO can earn is determined as a percentage of total benchmark expenditures, a larger assigned population would result in a higher performance payment limit. Similarly, a larger assigned population

[158] See, for example, HHS Secretary Xavier Becerra Statement on End of the COVID–19 Public Health Emergency (May 11, 2023), available at *https://www.hhs.gov/about/news/2023/05/11/hhs-secretary-xavier-becerra-statement-on-end-of-the-covid-19-public-health-emergency.html*. See also Letter to U.S. Governors from HHS Secretary Xavier Becerra on renewing COVID–19 Public Health Emergency (PHE), available at *https://www.hhs.gov/about/news/2023/02/09/letter-us-governors-hhs-secretary-xavier-becerra-renewing-covid-19-public-health-emergency.html* (specifying the U.S. Department of Health and Human Services is planning for the COVID–19 PHE to end on May 11, 2023).

would result in larger loss sharing limit for ACOs in two-sided risk models because loss sharing limits are also determined as a percentage of aggregate benchmarks.

- A larger assigned population could affect an ACO's revenue status as the ACO's ACO participants' total Medicare Parts A and B fee-for-service (FFS) revenue would not change but the ACO's assigned beneficiary population's total Medicare Parts A and B FFS expenditures would increase. In other words, revenue-to-expenditure ratios would decrease for ACOs that receive a larger assigned beneficiary population. Compared to the current assignment methodology, the proposed assignment methodology change could result in some ACOs being identified as low revenue instead of high revenue. As a result, other program elements tied to revenue status could then be affected by the proposed changes, specifically an ACO's eligibility for Advance Investment Payments.
- Changes in the assigned population could directly affect ACOs' average risk scores, mix of beneficiaries across enrollment types, regional service area, and total expenditures during benchmark and performance years.

Expected impacts on several other program elements would depend on differences in the changes observed for beneficiaries added to the assignable population versus beneficiaries added to the ACO's assigned beneficiaries. For example, the impact of the proposed change to the assignment methodology on ACO performance would depend in part on the difference in spending levels and trends between those beneficiaries added to the assignable population, nationally and within an ACO's regional service area, versus those beneficiaries added to the ACO's assigned beneficiary population. The data shared with ACOs on their assignable and assigned beneficiaries would change under the proposed policy as the population of assignable and assigned beneficiaries changes.

We propose modifications to subpart E of the Shared Savings Program regulations to specify the revised beneficiary assignment methodology. We propose to specify the new step three in a new provision at § 425.402(b)(5). We also propose technical and conforming changes to incorporate the revised methodology. We propose to amend § 425.402(b)(1), describing the existing pre-step of the assignment methodology that would remain applicable for step one and step two, to refer to the identification of all beneficiaries who had ''at least one primary care service *during the applicable assignment window* with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in [§ 425.402(c)]'' (emphasis added to reflect revised text). In § 425.402(c), which indicates the primary specialty designations used in assignment, we propose to specify that the listed specialties would be considered for ACO professionals in step two (as described in § 425.402(b)(4)) and the proposed step three (which would become a new provision at § 425.402(b)(5)) of the assignment methodology. In § 425.400(a)(2)(ii), which generally describes quarterly updates to preliminary prospective assignment with retrospective reconciliation, we propose to specify that assignment would be updated quarterly based on the most recent 12 or 24 months of data, as applicable, under the methodology described in §§ 425.402 and 425.404. Lastly, in § 425.400(a)(3)(i), which generally describes prospective assignment of beneficiaries to ACOs at the beginning of each benchmark or performance year, we propose to amend the reference that specifies that we base prospective assignment on the beneficiary's use of primary care services in the most recent 12 months for which data are available, to specify instead the beneficiary's use of primary care services in the most recent 12 months or 24 months, as applicable, for which data are available, using the assignment methodology described in §§ 425.402 and 425.404.

(c) Proposed Revisions to the Definition of an Assignable Beneficiary

Consistent with the previously described proposal to use an expanded window for assignment in an enhanced step-wise assignment methodology, we are proposing to revise the definition of Assignable beneficiary in § 425.20 to include additional beneficiaries who would be identified using the expanded window for assignment. Under this proposal, we would continue to utilize the criterion in the existing definition, under which assignable beneficiary means a Medicare FFS beneficiary who receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c). Further, for the performance year beginning January 1, 2025 and subsequent performance years, we propose that a Medicare fee-for-service beneficiary who does not meet this requirement but who meets both of the following criteria would also be considered an assignable beneficiary:

- Receives at least one primary care service with a date of service during a specified 24-month expanded window for assignment from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c).
- Receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled practitioner who is a nurse practitioner (as defined at § 410.75(b)), physician assistant (as defined at § 410.74(a)(2)), or a clinical nurse specialist (as defined at § 410.76(b)).

The proposed use of an expanded window for assignment would result in a greater number of beneficiaries included in the assignable population. All beneficiaries who are currently assignable would continue to be assignable under the proposed revisions to the definition of an assignable beneficiary. Under the proposed definition, beneficiaries who do not receive any primary care services during the assignment window would continue to be excluded from the population of assignable beneficiaries, just as they are excluded in the current definition of an assignable beneficiary. In other words, the 12-month assignment window would continue to represent the timeframe within which beneficiaries must receive at least one primary care service to be identified as an assignable beneficiary. Moreover, to identify a broader assignable population under this proposed approach, we believe it is important to consider the criterion for the beneficiary to have received a primary care service during the 12-month assignment window to be met through a service furnished from a non-physician practitioner (nurse practitioner, physician assistant, and clinical nurse specialist), or from a primary care physician or a physician who has one of the specialty designations included in § 425.402(c) (as is required under the current definition).

The proposed approach to expanding the assignable beneficiary population could impact downstream aspects of the Shared Savings Program that rely on the assignable population, including the following effects:

- Changes in the distribution of expenditures among the national assignable population could affect the thresholds used to truncate expenditures.

• Changes in average per capita expenditures and risk scores among assignable beneficiaries in a given benchmark year could affect the average risk-adjusted spending within ACOs' regional service areas, which could affect regional adjustments.

• Differential changes in average per capita expenditures and risk scores over time could affect trend and update factors that are based on changes in expenditures for the national assignable population and in the risk-adjusted expenditures for the population of assignable beneficiaries in an ACO's regional service area.

• Changes in average prospective HCC risk scores for the national assignable population could affect the factors used to renormalize risk scores each benchmark and performance year and to risk-adjust the flat-dollar ACPT amounts.

• Changes in the number of assignable beneficiaries across ACO regional service areas could affect ACOs' market shares, which determine the weights used for blending the national and regional benchmark trend and update factors.

• Changes in the level of national fee-for-service expenditures for the assignable population could affect the caps applied to the regional adjustment and prior savings adjustment to the historical benchmark and the calculation of the flat-dollar ACPT amount.

Under the current regulations, the time period we use to identify the assignable population that will be used to calculate different factors used in program financial calculations depends on whether it is a national or regional factor, the start date of an ACO's agreement period and, in some cases, an ACO's selected assignment methodology. Under the proposed revised definition of assignable beneficiary, for all ACOs (regardless of agreement period start date), for the performance year beginning on January 1, 2025, and subsequent performance years, for benchmark year and performance year factors based on the national assignable population, we would identify the assignable population using the 24-month expanded window for assignment comprised of the 12-month calendar year assignment window, which aligns with the assignment window for preliminary prospective assignment with retrospective reconciliation, and the preceding 12 months. We note that under this proposal we would also use the 24-month expanded window for assignment comprised of the 12-month calendar year assignment window and the preceding 12 months when identifying the assignable population for regional factors for performance year 2025 and subsequent years for use in calculations for ACOs that are continuing in agreement periods that began before January 1, 2024.

For ACOs participating in agreement periods beginning on January 1, 2024, and in subsequent years, for performance year 2025 and in subsequent years for regional factors, we would identify the assignable population using the 24-month expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii). That is, for ACOs selecting preliminary prospective assignment with retrospective reconciliation, we would use the 24-month expanded window for assignment comprised of the 12-month calendar year assignment window and the preceding 12 months. For ACOs selecting prospective assignment, the 24-month expanded window for assignment would be comprised of the 12-month, offset assignment window plus the preceding 12 months. For example, we would use October 1, 2022, to September 30, 2024, as the 24-month expanded window for assignment to identify the assignable population for performance year 2025 for ACOs under prospective assignment.

We propose technical and conforming changes to provisions in subpart G of the Shared Savings Program regulations that refer to the assignment window used to identify the assignable beneficiary population in order to incorporate references to the proposed approach to using an expanded window for assignment in identifying the assignable population for performance year 2025 and in subsequent years. The regulations establishing the benchmarking methodology for ACOs with agreement periods beginning before January 1, 2024, do not directly reference the assignment window, and thus would not require conforming changes. However, there are benchmarking methodology provisions for ACOs with agreement periods beginning on January 1, 2024, and in subsequent years that directly refer to the assignment window. Thus, we propose to amend these provisions to specify that the assignable population would be identified for the relevant benchmark year or the performance year (as applicable) using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii):

• In §§ 425.652(a)(5)(v)(A) and (b)(2)(iv)(A), provisions on calculating the county-level share of assignable beneficiaries who are assigned to the ACO for each county in the ACO's regional service area for purposes of calculating the blended national-regional growth rates used in trending and updating the benchmark (respectively).

• In the provision on redetermination of the regional adjustment for the second or each subsequent performance year during the term of the agreement period in § 425.652(a)(9)(ii).

• In the provision on the calculation of average county FFS expenditures for assignable beneficiaries in each county in the ACO's regional service area in § 425.654(a)(1)(i).

• In the provision on adjusting for differences in severity and case mix between the ACO's assigned beneficiary population for BY3 and the assignable beneficiary population for the ACO's regional service area for BY3, in calculating average per capita expenditures for the ACO's regional service area, in § 425.656(b)(3).

Similarly, we also propose to specify in the proposed new provision at § 425.655(b)(1) that the assignable population that would be used to calculate average county prospective HCC and demographic risk scores for purposes of calculating the proposed regional risk score growth cap adjustment factor (refer to section III.G.4.b. of this proposed rule) would be identified for the relevant benchmark year or the performance year (as applicable) using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

We seek comment on our proposed modifications to the definition of assignable beneficiary in § 425.20. We also seek comment on our proposed technical and conforming changes to references to the identification of assignable beneficiaries in subpart G of the Shared Savings Program regulations, as well as in the proposed new regulation at § 425.655 (on calculating the regional risk score growth cap adjustment factor), to incorporate the use of the assignment window or expanded window for assignment in identification of the assignable beneficiary population.

(d) Simulations To Understand the Potential Effect of Proposed Changes

To understand the potential impact of using an expanded window for assignment in a proposed step 3 of the claims-based assignment methodology, we simulated using the proposed definition for an assignable beneficiary and proposed step 3 using the set of ACOs and data for performance year (PY) 2021. To simplify the analysis, this simulation used CY 2021 as the assignment window. Thus, the expanded window for assignment spanned from January 1, 2020, through December 31, 2021. We used a calendar year basis because we do not expect the impact of the proposed changes to meaningfully differ between retrospective and prospective assignment windows, the latter of which uses an offset window. In this analysis, the national assignable population included a total of 26.2 million beneficiaries based on the current methodology. The simulation applying the proposed policies then added 762,156 newly assignable beneficiaries, growing the national assignable population by about 2.9 percent. For additional analysis on estimated impacts, we also refer commenters to the Regulatory Impact Analysis in section VII.E. of this proposed rule. We seek comment on the proposed approach discussed in this proposed rule and the potential effects of the proposed approach, including its effects modeled in the aforementioned simulation and its effects in other scenarios that might be considered by commenters. We anticipate continuing additional simulations on the effect of the proposed changes to the assignment methodology to further inform our understanding of the potential impacts of the proposal, and we are planning to publish results from such additional simulations in the final rule.

Simulation results suggest that an expanded window for assignment may increase access to accountable care for underserved beneficiaries. Relative to the national assignable population as determined under the current assignment methodology, the group of added beneficiaries from the expanded window for assignment simulation had a larger share of beneficiaries with disabled Medicare enrollment type, resided in areas with slightly higher average Area Deprivation Index (ADI) national percentile rank (a measure of neighborhood socioeconomic disadvantage), and had a larger share with any months of Medicare Part D LIS enrollment (refer to Table 30).

TABLE 30: Selected Characteristics of Beneficiaries Added to the National Assignable Population for PY 2021 through the Expanded Window for Assignment Simulation

	National Assignable Population Under Current Assignment Methods	Added to the National Assignable Population in the Simulation	National Assignable Population Under the Simulation
Total Beneficiaries	26,169,153	762,156	26,931,309
Total Person Years[1]	24,900,013	694,132	25,594,145
Share of Person Years by Medicare Enrollment Type			
End Stage Renal Disease (ESRD)	0.9%	1.0%	0.9%
Disabled	11.1%	15.2%	11.2%
Aged/Dual	8.5%	7.6%	8.5%
Aged/Non-Dual	79.5%	76.3%	79.4%
Mean ADI National Percentile Rank[2]	43.2	46.5	43.3
Share of beneficiaries with at least one month of Medicare Part D LIS Enrollment	20.4%	24.0%	20.5%

[1] This approach is consistent with calculation of ACO assigned beneficiary person years as described in the Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version # 11, January 2023) available *at https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2*. Note that calculations of person years exclude months associated with episodes of care for treatment of COVID-19. Refer to Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications of Policies to Address the Public Health Emergency for COVID-19 (December 2020) available at: https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf.

[2] Mean ADI National Percentile Rank was calculated as a weighted mean, weighted by person years, among beneficiaries with non-missing ADI percentile.

Simulation results also suggest that using a 24-month expanded window for assignment in proposed step 3 of the claims-based assignment methodology would increase access to accountable care among beneficiaries with Medicare coverage for part of a year (such as beneficiaries who die during the performance year). The group of added assignable beneficiaries in the simulation previously described had a lower average prospective HCC risk score, lower total per capita spending in CY 2021, higher hospice utilization, and a higher mortality rate when compared to assignable beneficiaries determined using the current definition of assignable beneficiary and assignment

methodology. These results suggest that beneficiaries who would be added to the assignable population under the proposed changes may benefit from greater care coordination through ACOs.

(e) Implementation of Proposed Revisions

We are proposing that the expanded window for assignment and revised step-wise assignment methodology would be applicable to all ACOs for the performance year beginning on January 1, 2025, and in subsequent years. For example, for a calendar year assignment window that runs from January 1, 2025, through December 31, 2025, the expanded window for assignment would run from January 1, 2024, through December 31, 2025. For an offset assignment window that runs from October 1, 2023, through September 30, 2024, the expanded window for assignment would run from October 1, 2022, through September 30, 2024. Consistent with how we have implemented previous changes to the Shared Savings Program assignment methodology, we would use the new methodology each time assignment is determined for a given benchmark or performance year and, as applicable, to determine the eligibility of ACOs applying to enter into or renew participation in the Shared Savings Program. For example, applicant eligibility for PY 2024 will be determined during CY 2023. We would not be able to review public comments and decide whether to finalize the proposed changes in sufficient time to apply the expanded window for assignment and revised methodology for PY 2024 applications. Additionally, we anticipate that the proposed revised approach, if finalized, would require significant operational changes to the Shared Savings Program assignment methodology, which would take time to prepare in advance of initial use of the approach during the application process. For these reasons, we would not be able to apply the expanded window for assignment and revised step-wise beneficiary assignment methodology for the performance year starting on January 1, 2024, and we are proposing to apply this change beginning with the performance year starting on January 1, 2025.

We would apply the proposed revised approach to determining beneficiary assignment and the revised definition of assignable beneficiary in establishing, adjusting, updating, and resetting historical benchmarks for ACOs entering new agreement periods beginning on January 1, 2025, and subsequent years. Also consistent with how we have implemented previous changes to the assignment methodology, we would adjust benchmarks for all ACOs in agreement periods for which performance year 2025 is a second or subsequent performance year at the start of performance year 2025, so that the ACO benchmarks reflect the use of the same assignment rules and definition of assignable beneficiary as would apply in the performance year (refer to §§ 425.601(a)(9) and 425.652(a)(9)). We believe that the expanded window for assignment and proposed step three represent a valuable change that would fill an important gap in the current assignment methodology. CMS has outlined a renewed vision and strategy for driving health system transformation to achieve equitable outcomes through high-quality, affordable, person-centered care for all beneficiaries.[159] In a January 2022 article, CMS stated our goal that 100 percent of people with Original Medicare will be in a care relationship with accountability for quality and total cost of care by 2030.[160] Many Medicare FFS beneficiaries are currently excluded from the assignable and Shared Savings Program assigned populations despite receiving primary care from ACO professional nurse practitioners, physician assistants, and clinical nurse specialists during the existing 12-month assignment window, and these excluded beneficiaries tend to come from populations characterized by greater social risk factors. Specifically, beneficiaries likely to be added to the assignable population are more likely to be disabled, be enrolled in the Medicare Part D LIS, and reside in areas with higher ADI scores (as described in section III.G.3.a.(2)(d) of this proposed rule). The proposed change to the assignment methodology represents an opportunity to not only grow the share of Medicare beneficiaries involved in accountable care relationships but to also support efforts to improve health equity in the Medicare program.

In summary, we seek comment on the proposed changes to establish a new defined term in § 425.20, expanded window for assignment, for use in a proposed additional step three in the beneficiary assignment methodology and in identifying the assignable beneficiary population, revisions to the definition of assignable beneficiary, as well as proposed technical and conforming changes to provisions of the Shared Savings Program regulations, including the definition of assignment window under § 425.20, and provisions within subpart E and subpart G. If finalized, the proposed changes would be applicable for the performance year beginning on January 1, 2025, and subsequent performance years. We welcome comments on any aspects of the proposed changes, including the length of the expanded window for assignment. We also seek comment on additional policies that CMS should consider for potential future rulemaking on our assignment methodology, with the goal of increasing the number of Original Medicare fee-for-service beneficiaries assigned to an ACO, particularly in underserved communities.

b. Proposed Revisions to the Definition of Primary Care Services Used in Shared Savings Program Beneficiary Assignment

(1) Background

Section 1899(c)(1) of the Act, as amended by the 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 a list of services considered to be 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 Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (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 (refer to 80 FR 32746 through 32748; 80 FR 71270 through 71273; 82 FR 53212 and 53213; 83 FR 59964 through 59968; 85 FR 27582 through 27586; 85 FR 84747 through 84756; 85 FR 84785 through 84793; 86 FR 65273 through 65279; 87

[159] See, for example, CMS Innovation Center ''Strategic Direction'' web page, at *https://innovation.cms.gov/strategic-direction.* See also, CMS, Innovation Center Strategy Refresh, available at *https://innovation.cms.gov/strategic-direction-whitepaper.*

[160] Seshamani M, Fowler E, Brooks-LaSure C. Building On The CMS Strategic Vision: Working Together For A Stronger Medicare. Health Affairs. January 11, 2022. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20220110.198444.*

FR 69821 through 69825) to reflect additions or modifications to the codes that have been recognized for payment under the PFS and to incorporate other changes to the definition of primary care services for purposes of the Shared Savings Program.

For the performance year beginning on January 1, 2023, and subsequent performance years, we defined primary care services in § 425.400(c)(1)(vii) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the following HCPCS/CPT codes:

- *CPT codes:*

++ 96160 and 96161 (codes for administration of health risk assessment).

++ 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; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

++ 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).

++ 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)(vi)).

++ 99421, 99422, and 99423 (codes for online digital evaluation and management).

++ 99424, 99425, 99426, and 99427 (codes for principal care management services).

++ 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

++ 99439 (code for non-complex chronic care management).

++ 99483 (code for assessment of and care planning for patients with cognitive impairment).

++ 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

++ 99495 and 99496 (codes for transitional care management services).

++ 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

- *HCPCS codes:*

++ G0402 (code for the Welcome to Medicare visit).

++ G0438 and G0439 (codes for the annual wellness visits).

++ G0442 (code for alcohol misuse screening service).

++ G0443 (code for alcohol misuse counseling service).

++ G0444 (code for annual depression screening service).

++ G0463 (code for services furnished in ETA hospitals).

++ G0506 (code for chronic care management).

++ G2010 (code for the remote evaluation of patient video/images).

++ G2012 and G2252 (codes for virtual check-in).

++ G2058 (code for non-complex chronic care management).

++ G2064 and G2065 (codes for principal care management services).

++ G0317, G0318, and G2212 (code for prolonged office or other outpatient visit for the evaluation and management of a patient).

++ G2214 (code for psychiatric collaborative care model).

++ G3002 and G3003 (codes for chronic pain management).

- Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(vi)(A) of § 425.400 or a HCPCS code specified in paragraph (c)(1)(vi)(B) of § 425.400, when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

(2) Proposed Revisions

Based on feedback from ACOs and our further review of the HCPCS and CPT codes that are currently recognized for payment under the PFS or that we are proposing to recognize for payment starting in CY 2024, we believe 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 to 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, 2024, and subsequent performance years, in order to remain consistent with billing and coding under the PFS.

We propose to revise the definition of primary care services used for assignment in the Shared Savings Program regulations to include the following additions: (1) Smoking and Tobacco-use Cessation Counseling Services CPT codes 99406 and 99407; (2) Remote Physiologic Monitoring CPT codes 99457 and 99458; (3) Cervical or Vaginal Cancer Screening HCPCS code G0101; (4) Office-Based Opioid Use Disorder Services HCPCS codes G2086, G2087, and G2088; (5) Complex Evaluation and Management Services Add-on HCPCS code G2211, if finalized under Medicare FFS payment policy; (6) Community Health Integration services HCPCS codes GXXX1 and GXXX2, if finalized under Medicare FFS payment policy; (7) Principal Illness Navigation (PIN) services HCPCS codes GXXX3 and GXXX4, if finalized under Medicare FFS payment policy; (8) SDOH Risk Assessment HCPCS code GXXX5, if finalized under Medicare FFS payment policy; (9) Caregiver Behavior Management Training CPT Codes 96202 and 96203, if finalized under Medicare FFS payment policy; and (10) Caregiver Training Services CPT codes 9X015, 9X016, and 9X017, if finalized under Medicare FFS payment policy. The following provides additional information about the HCPCS codes that we are proposing to add to the definition of primary care services used for purposes of beneficiary assignment:

- *Smoking and tobacco-use cessation counseling services CPT codes 99406 and 99407:* Effective January 1, 2008, CPT codes 99406 (*Smoking and tobacco-use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes*) and 99407 (*Smoking and tobacco-use cessation counseling visit; intensive, greater than 10 minutes*) were implemented for billing for smoking and tobacco-use cessation counseling services. As described in Medicare National Coverage Determinations (NCD) Manual, Publication 100–3, chapter 1, section 210.4.1, tobacco use remains the leading cause of preventable morbidity and mortality in the U.S. and is a major contributor to the nation's increasing medical costs. Despite the growing list of adverse health effects associated with smoking, more than 45 million U.S. adults continue to smoke and approximately 1,200 die prematurely each day from tobacco-related diseases. Since these are recognized as preventive services,[161] similar to other preventive services such as alcohol misuse screening and counseling (HCPCS codes G0442 and G0443) which are currently included in the definition of primary care services for purposes of beneficiary assignment, we believe it appropriate to include CPT codes that identify counseling to prevent tobacco use in the definition of

[161] Medicare Learning Network (MLN006559, May 2023) Medicare Preventive Services Quick Reference Chart, available at: *https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html#TOBACCO.*

primary care services for purposes of beneficiary assignment.

• *Remote Physiologic Monitoring CPT codes 99457 and 99458:* Chronic care remote physiologic monitoring (RPM) services involve the collection, analysis, and interpretation of digitally collected physiologic data, followed by the development of a treatment plan, and the managing of a patient under the treatment plan. In the CY 2020 PFS final rule (84 FR 62697) we finalized a revised 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; initial 20 minutes*) and added 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; additional 20 minutes*) to adopt the CPT Editorial Panel revised structure for CPT code 99457. The new code structure retained CPT code 99457 as a base code that describes the first 20 minutes of the treatment management services, and uses a new add-on code to describe subsequent 20-minute intervals of the service. We further designated CPT codes 99457 and 99458 as care management services because care management services include establishing, implementing, revising, or monitoring treatment plans, as well as providing support services, and because RPM services include establishing, implementing, revising, and monitoring a specific treatment plan for a patient related to one or more chronic conditions that are monitored remotely. Because these remote therapeutic monitoring services are designated as care *management* services [162] and because we broadly include care management services (for example, CPT codes 99437, 99487, 99489, 99490 and 99491) in the Shared Savings Program definition of primary care services for purposes of beneficiary assignment, we believe CPT codes 99457 and 99458 should also be included in the definition of primary care services for purposes of beneficiary assignment.

• *Cervical or Vaginal Cancer Screening Code HCPCS code G0101:* Section 4102 of the Balanced Budget Act of 1997 provides for coverage of screening pelvic examinations (including a clinical breast examination) for all female beneficiaries, subject to certain frequency and other limitations.[163] Cervical and vaginal cancer screening and clinical breast examination are important preventive health care services intended to detect early cancer, precancers and sexually transmitted infections. HCPCS code G0101 (*Cervical or vaginal cancer screening; pelvic and clinical breast examination*) can be reimbursed by Medicare Part B every 2 years. For patients who are considered high risk, it is allowed on an annual basis. Obstetrics/gynecology and gynecology/oncology are identified as physician specialty designations for purposes of identifying primary care services furnished to beneficiaries used in assignment operations according to § 425.402(c), so we believe it appropriate to use wellness and preventive care visits provided by these specialists in our definition of primary care services used in assignment. CMS considers these to be a preventive health service that can be provided in a primary care setting [164] similar to the annual wellness visit HCPCS codes G0438 and G0439, which are already included in the Shared Savings Program definition of primary care services used in assignment, so we believe that they should be included in the definition of primary care services for purposes of beneficiary assignment.

• *Office-Based Opioid Use Disorder Services HCPCS Codes G2086, G2087, and G2088:* In the CY 2020 PFS final rule (84 FR 62568) we finalized our proposal to establish bundled payments for the overall treatment of Opioid Use Disorder (OUD), including management, care coordination, psychotherapy, and counseling activities HCPCS codes 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*), 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*), and 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)*). Refer to the CY 2020 PFS final rule (84 FR 62673) for detailed, technical discussion regarding the description, payment and utilization of these HCPCS codes.

The bundled payment under the PFS for office-based treatment for OUD was intended to create an avenue for physicians and other health professionals to bill for a bundle of services that is similar to the bundled OUD treatment services benefit, but not furnished by an Opioid Treatment Program (OTP). By creating a separate bundled payment for these services under the PFS, we hoped to incentivize increased provision of counseling and care coordination for patients with OUD in the office setting, thereby expanding access to OUD care. We note that use of these codes is limited to only beneficiaries diagnosed with OUD and these codes should not be billed for beneficiaries who are receiving treatment at an OTP, as we believe that would be duplicative since the bundled payments made to OTPs cover similar services for the treatment of OUD.

Because the separately reportable initiating visit requirement for the OUD bundle HCPCS codes G2086, G2087 and G2088 is similar to the separately reportable initiating visit requirements for chronic care management (CCM) services, and behavioral health integration services (BHI), as they include overall management and care coordination activities, we believe these services should be considered primary care services for purposes of beneficiary assignment.[165] Additionally, we anticipate that the billing clinician, likely an addiction medicine specialist, would manage the patient's overall OUD care, as well as supervise any other individuals participating in the treatment, such as those billing incident to services of the billing physician or other practitioner, which is similar to the requirements related to the furnishing of psychiatric collaborative care model (CoCM) services. CCM, BHI,

[162] Medicare Physician Fee Schedule Care Management Services Information, available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.*

[163] Medicare National Coverage Determination for Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancers (Pub. No. 100–3, Manual Section 210.2), available at: *https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=185#:~:text=Section%204102%20of%20the%20Balanced%20Budget%20Act%20of,beneficiaries%2C%20subject%20to%20certain%20frequency%20and%20other%20limitations.*

[164] Medicare Learning Network (MLN006559, May 2023) Medicare Preventive Services Quick Reference Chart, available at: *https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html#PELVIC.*

[165] Medicare Physician Fee Schedule Office-Based Opioid Use Disorder (OUD) Treatment Billing Information, available at: *https://www.cms.gov/medicare/physician-fee-schedule/office-based-opioid-use-disorder-oud-treatment-billing.*

CoCM, and alcohol misuse screening and counseling services are included in our definition of primary care services, so we believe that HCPCS codes G2086, G2087 and G2088 are appropriate to be included in the definition of primary care services for purposes of beneficiary assignment. For additional clarity, incident to services are services rendered to a patient by a provider other than the physician treating the patient more broadly, that are an integral, although incidental, part of the patient's normal course of diagnosis or treatment of an injury or illness. These services are billed as Medicare Part B services, as if the original physician personally provided the care using that physician's NPI number. We anticipate that these services would often be billed by addiction specialty practitioners but note that these codes are not limited to use by any particular physician or non-physician practitioner specialty. Further, since addiction medicine is identified as one of the physician specialty designations for purposes of identifying primary care services used in assignment operations according to § 425.402(c)(13), we believe it would be appropriate to include care coordination services provided by these specialists in our definition of primary care services used for purposes of beneficiary assignment.

We further recognize that OUD bundle HCPCS codes G2086, G2087 and G2088 are identified as codes for alcohol and substance abuse-related diagnoses that are excluded from Shared Savings Program Claim and Claim Line Feeds. Given this, we want to make transparent that ACOs will not be able to see the claims that may have been used in assignment for beneficiaries receiving OUD services, and possibly not be able to identify why certain beneficiaries were assigned to their ACO related to these codes.

• *Complex Evaluation and Management Services Add-on HCPCS Code G2211, if finalized under Medicare FFS payment policy:* As discussed in section II.F. of this proposed rule, HCPCS add-on code 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)*) can be reported in conjunction with office/outpatient (O/O) evaluation and management (E/M) visits to better account for additional resources associated with primary care, or similarly ongoing medical care related to a patient's single, serious condition, or complex condition (84 FR 62854 through 62856, 85 FR 84571). Section 113 of Division CC of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260, December 27, 2020) imposed a moratorium on Medicare payment for this service by prohibiting CMS from making payment under the PFS for inherently complex E/M visits described by HCPCS code G2211 (or any successor or substantially similar code) before January 1, 2024. The moratorium on Medicare payment under the PFS for HCPCS code G2211 will end on December 31, 2023, therefore we are proposing to make HCPCS code G2211 separately payable effective January 1, 2024. Refer to section II.F. of this proposed rule for detailed, technical discussion regarding the description, payment, and utilization of these HCPCS codes.

Since G2211 is an add on code used in conjunction with O/O E/M services and such services are included in our definition of primary care services, we believe that the proposed inclusion of HCPCS code G2211 is consistent with our intent to encompass primary care and wellness services in the definition of primary care services used for purposes of beneficiary assignment.

• *Community Health Integration Services HCPCS Codes GXXX1 and GXXX2, if finalized under Medicare FFS payment policies:* In section II.E. of this proposed rule, separate coding, payment, service elements and documentation requirements for the following Community Health Integration (CHI) services are being proposed:

GXXX1—Community health integration (CHI) services performed by certified or trained auxiliary personnel including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit:

• *Person-centered assessment, performed to better understand the individualized context of* the *intersection between* the *SDOH need(s) and problem(s) addressed in the initiating E/M visit.*

++ *Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors.*

++ *Facilitating patient-driven goal-setting and establishing an action plan.*

++ *Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.*

• *Practitioner, Home, and Community-Based Care Coordination:*

++ *Coordination with practitioner; home, and community-based service providers; and caregiver (if applicable).*

++ *Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and* needs, *functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.*

++ *Coordination of care transitions between and among health care practitioners and settings, including transitions involving referrals to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.*

++ *Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) to address SDOH need(s).*

• *Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the SDOH need(s), and educating the patient on how to best participate in medical decision-making.*

• *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the SDOH need(s), in ways that are more likely to promote personalized and effective diagnosis and treatment.*

• *Health care access/health system navigation:*

++ *Helping the patient access care, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.*

• *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*

• *Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the SDOH need(s), and adjust daily routines*

to better meet diagnosis and treatment goals.

GXXX2—Community health integration services, each additional 30 minutes per calendar month (List separately in addition to GXXX1).

As proposed in section II.E. of this proposed rule, all auxiliary personnel who provide CHI services must be certified or trained to perform all included service elements and authorized to perform them under applicable State laws and regulations. Under § 410.26(a)(1) of our regulations, auxiliary personnel must meet any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished.[166] A billing practitioner may arrange to have CHI services provided by auxiliary personnel external to, and under contract with, the practitioner or their practice, such as through a community-based organization (CBO) that employs CHWs, if all of the ''incident to'' and other requirements and conditions for payment of CHI services are met. The payment policy proposal explains that we would expect the auxiliary personnel performing the CHI services to communicate regularly with the billing practitioner to ensure that CHI services are appropriately documented in the medical record, and to continue to involve the billing practitioner in evaluating the continuing need for CHI services to address the SDOH need(s) that limit the practitioner's ability to diagnose and treat the problem(s) addressed in the initiating visit. Refer to section II.E. of this proposed rule for detailed, technical discussion regarding the proposed description, payment and utilization of these HCPCS codes.

Since the proposal described in section II.E. of this proposed rule proposes to designate CHI services as care management services that may be furnished under general supervision under § 410.26(b)(5) and because we broadly include care management services in the definition of primary care services used for purposes of beneficiary assignment, we believe it would be similarly appropriate to include CHI services in the list of primary care services used for purposes of beneficiary assignment. Additionally, since CHI services require an initiating E/M visit and these services can be billed as incident to by the billing practitioner who bills for the CHI initiating E/M visit, and E/M services are currently included in the list of primary care services used for purposes of beneficiary assignment, we believe it would be similarly appropriate to include CHI services in the list of primary care services used for purposes of beneficiary assignment.

• *Principal Illness Navigation (PIN) Services HCPCS codes GXXX3 and GXXX4, if finalized under Medicare FFS payment policies:* In section II.E. of this proposed rule, new coding for Principal Illness Navigation (PIN) services is being proposed. In considering the appropriate patient population to receive these services, we considered the patient population eligible for principal care management service codes (CPT codes 99424 through 99427), as well as clinical definitions of ''serious illness.'' For example, one peer-review study defined ''serious illness'' as a health condition that carries a high risk of mortality and either negatively impacts a person's daily function or quality of life, or excessively strains their caregivers.[167] Another study describes a serious illness as a health condition that carries a high risk of mortality and commonly affects a patient for several years, while some measure serious illness by the amount of urgent health care use (911 calls, emergency department visits, repeated hospitalizations) and polypharmacy.[168] The navigation services such patients need are similar to CHI services, but Social Determinants of Health (SDOH) need(s) may be fewer or not present. Accordingly, a parallel set of services focused on patients with a serious, high-risk illness who may not necessarily have SDOH-related needs is being proposed. PIN services could be furnished following an initiating E/M visit addressing a single high-risk disease.

The following codes would be reported for PIN services:

GXXX3—Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities:

• *Person-centered assessment, performed to better understand the individualized context of the serious, high-risk condition.*

++ *Conducting a person-centered assessment to understand the patient's life story, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors.*

++ *Facilitating patient-driven goal setting and creating an action plan.*

++ *Providing tailored support as needed to accomplish the practitioner's treatment plan.*

• *Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.*

• Practitioner, Home, and Community-Based Care Coordination

++ *Coordinating receipt of needed services from healthcare practitioners, providers and facilities; home-, and community-based service providers; and caregiver (if applicable).*

++ *Communication with practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, and preferences, including cultural and linguistic factors.*

++ *Coordination of care transitions between and among health care practitioners and settings, including transitions involving referrals to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.*

++ *Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s).*

• *Health education—Helping the patients contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver, if applicable) on how to best participate in medical decision-making.*

• *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition.*

• *Health care access/health system navigation.*

++ *Helping the patient access healthcare, identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.*

• *Facilitating behavioral change necessary for meeting diagnosis and*

[166] CHW Roles As Outlined In The C3 Project available at: *https://chwtraining.org/c3-project-chw-skills/.*

[167] Kelley AS, Bollens-Lund E. Identifying the Population with Serious Illness: The ''Denominator'' Challenge. J Palliat Med. 2018 Mar;21(S2):S7–S16. doi: 10.1089/jpm.2017.0548. Epub 2017 Nov 10. PMID: 29125784; PMCID: PMC5756466. available at *https://pubmed.ncbi.nlm.nih.gov/29125784/.*

[168] Silver, Alison. Serious Illness: A High Priority for Accountable Care. The American Journal of Accountable Care. 2020;8(2):32–33. available at *https://www.ajmc.com/view/serious-illness-a-high-priority-for-accountable-care.*

treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.

- *Facilitating and providing social and emotional support for the patient to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis or treatment goals.*
- *Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

GXXX4—Principal Illness Navigation services, additional 30 minutes per calendar month (List separately in addition to GXXX3).

As discussed in section II.E. of this proposed rule, a billing practitioner may arrange to have PIN services provided by auxiliary personnel who are external to, and under contract with, the practitioner or their practice, such as through a community-based organization (CBO) that employs CHWs, if all of the ''incident to'' and other requirements and conditions for payment of PIN services are met. We would expect the auxiliary personnel performing the PIN services to communicate regularly with the billing practitioner to ensure that PIN services are appropriately documented in the medical record, and to continue to involve the billing practitioner in evaluating the continuing need for PIN services to address the serious, high-risk condition. Refer to section II.E. of this proposed rule for detailed, technical discussion regarding the description, payment and utilization of these HCPCS codes.

Since the proposal described in section II.E. of this proposed rule proposes to designate PIN services as care management services that may be furnished under general supervision under § 410.26(b)(5) and because we broadly include care management services in the list of primary care services used for purposes of beneficiary assignment, we believe it would be similarly appropriate to include PIN services in the list of primary care services used for purposes of beneficiary assignment. Additionally, since these services are meant to provide assistance to the beneficiary through communication and coordination with practitioners, providers, including referrals to other clinicians and follow-up after emergency or inpatient care, we believe that these services can further the ACO's goal of care coordination and the provision of value-based care and should, therefore, be included in the definition of primary care services for purposes of beneficiary assignment. Further, since PIN services require an initiating E/M visit and these services can be billed as incident to by the billing practitioner who bills for the PIN initiating E/M visit, and E/M services are currently included in the list of primary care services used for purposes of beneficiary assignment, we believe it would be similarly appropriate to include PIN services in the list of primary care services used for purposes of beneficiary assignment.

- *SDOH Risk Assessment HCPCS code GXXX5, if finalized under Medicare FFS payment policies:* In section II.E. of this proposed rule, a new stand-alone G code, GXXX5 (*administration of a standardized, evidence-based Social Determinants of Health Risk Assessment tool, 5–15 minutes, at most every 6 months.*) is being proposed to identify and value the work involved in the utilization of SDOH risk assessment as part of a comprehensive social history when medically reasonable and necessary in relation to an E/M visit. SDOH risk assessment through a standardized, evidence-based tool can more effectively and consistently identify unmet SDOH needs and enables comparisons across populations. The SDOH risk assessment must be furnished by the practitioner on the same date they furnish an E/M visit, as the SDOH assessment would be reasonable and necessary when used to inform the patient's treatment plan that is established during the visit. Required elements are described in detail in the payment policy proposal described in section II.E.

Under the proposal described in section II.E. of this proposed rule, the practitioner billing or furnishing the SDOH risk assessment would be required to have the ability to furnish CHI or other care management services. Given the multifaceted nature of SDOH needs, ensuring adequate referral to appropriate services and supports is critical for addressing both the SDOH need and the impact of that need on the patient's health. Refer to section II.E. of this proposed rule for detailed, technical discussion regarding the description, payment and utilization of these HCPCS codes.

Additionally, the proposal detailed in section III.T of this proposed rule proposes to add elements to the Annual Wellness Visit (AWV) by adding a new SDOH Risk Assessment as an optional, additional element with an additional payment. Under this proposal, the SDOH Risk Assessment would be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV, and would inform the care the patient is receiving during the visit, including taking a medical and social history, applying health assessments, and conducting prevention services education and planning.

Since the proposals described in sections II.E. and III.T. of this proposed rule propose that these services would be provided in conjunction with professional services, such as E/M visits, which can be provided in a primary care setting, we believe it would be appropriate to include these services in the definition of primary care services for purposes of beneficiary assignment. Additionally, since these are separately payable services when provided with an AWV and the AWV is included in the Shared Savings Program definition of primary care services for purposes of beneficiary assignment, we believe it would be appropriate to include SDOH risk assessment in the definition of primary care services for purposes of beneficiary assignment. Further, since these services precede the utilization of CHI, PIN, and Care Management services, which are either currently included or proposed to be included in the definition of primary care services for purposes of assignment, we believe the inclusion of the new SDOH risk assessment HCPCS code would be appropriate as well.

- *Caregiver Behavior Management Training CPT Codes 96202 and 96203, if finalized under Medicare FFS payment policy:* CPT code 96202 (*Multiple-family group behavior management/modification training for guardians/caregivers of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers; initial 60 minutes*) and its add-on code, CPT code 96203 (*Multiple-family group behavior management/modification training for guardians/caregivers of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers; each additional 15 minutes (List separately in addition to code for primary service)*) are two new codes created by the CPT Editorial Panel during its February 2021 meeting used to report the total duration of face-to-face time spent by the physician or other qualified health professional providing group training to guardians or caregivers of patients. Although the patient does not attend the group trainings, the goals and outcomes of the

sessions focus on interventions aimed at improving the patient's daily life.

In section II.E. of this proposed rule, an active payment status for CPT codes 96202 and 96203 (caregiver behavior management/modification training services) is being proposed for CY 2024. These codes allow treating practitioners to report training furnished to a caregiver, in tandem with the diagnostic and treatment services furnished directly to the patient, in strategies and specific activities to assist the patient to carry out the treatment plan. Caregiver behavior management/modification training services may be reasonable and necessary when they are integral to a patient's overall treatment and furnished after the treatment plan (or therapy plan of care) is established. The caregiver behavior management/modification training services themselves need to be congruent with the treatment plan in order to effectuate the desired patient outcomes.

For purposes of caregiver behavior management/modification training services, the proposal requires that a caregiver receiving behavior management/modification training services is a family member, friend, or neighbor who provides unpaid assistance to the patient, assisting or acting as a proxy for a patient with an illness or condition of short or long-term duration (not necessarily chronic or disabling). In this context, caregivers would be trained by the treating practitioner in strategies and specific activities that improve symptoms, functioning, adherence to treatment, and/or general welfare related to the patient's primary clinical diagnoses. Under this proposal, caregiver behavior management/modification training services may be furnished directly by the treating practitioner or provided by auxiliary personnel incident to the treating practitioner's professional services as specified in 42 CFR 410.26, as applicable for the types of practitioners whose covered services include ''incident to'' services. Refer to section II.E. of this proposed rule for detailed, technical discussion regarding the description, payment and utilization of these HCPCS codes.

Since the proposal described in section II.E. of this proposed rule proposes that these services can be billed as incident to by the billing practitioner who could be a primary care physician who also bills for an E/M visit, and these services cannot duplicate services provided in conjunction with transitional care management, chronic care management, behavioral health integration services, and virtual check-in services which are currently included in the list of primary care services used for purposes of beneficiary assignment, we believe that these services should be included in the definition of primary care services for purposes of beneficiary assignment in support of the Shared Savings mission to give coordinated, high quality care to an ACO's Medicare beneficiaries.

• *Caregiver Training Services CPT codes 9X015, 9X016, and 9X017, if finalized under Medicare FFS payment policy:* CPT codes 9X015 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face; initial 30 minutes*), add-on code, CPT code 9X016 (*each additional 15 minutes (List separately in addition to code for primary service) (Use 9X016 in conjunction with 9X015)*), and 9X017 (*Group caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face with multiple sets of caregivers*) are new codes created by the CPT Editorial Panel during its October 2022 meeting. The three codes are to be used to report the total duration of face-to-face time spent by the physician or other qualified health professional providing individual or group training to caregivers of patients. Although the patient does not attend the trainings, the goals and outcomes of the sessions focus on interventions aimed at improving the patient's ability to successfully perform activities of daily living (ADLs). Activities of daily living generally include ambulating, feeding, dressing, personal hygiene, continence, and toileting.

These codes allow treating practitioners to report the training furnished to a caregiver, in tandem with the diagnostic and treatment services furnished directly to the patient, in strategies and specific activities to assist the patient to carry out the treatment plan. As discussed above, we believe training furnished to a caregiver may be reasonable and necessary when it is integral to a patient's overall treatment and furnished after the treatment plan (or therapy plan of care) is established. The Caregiver Training Services (CTS) themselves need to be congruent with the treatment plan in order to effectuate the desired patient outcomes, especially in medical treatment scenarios where the caregiver receiving CTS is necessary to ensure a successful treatment outcome for the patient.

In section II.E., an active payment status for CPT codes 9X015, 9X016, and 9X017 for CY 2024 under the PFS is proposed. CTS may be furnished directly by the treating practitioner or provided by auxiliary personnel incident to the treating practitioner's professional services as specified in 42 CFR 410.26, as applicable for the types of practitioners whose covered services include ''incident to'' services. Under this proposal, 9X015, 9X016, and 9X017 are designated as ''sometimes therapy''. This means that the services represented by these codes are always furnished under a therapy plan of care when provided by PTs, OTs, and SLPs; but, in cases where they are appropriately furnished by physicians and NPPs outside a therapy plan of care (that is, where the services are not integral to a therapy plan of care), they can be furnished under a treatment plan by physicians and NPPs. Refer to section II.E. of this proposed rule for detailed, technical discussion regarding the description, payment and utilization of these HCPCS codes.

Since the proposal described in section II.E. of this proposed rule proposes that these services can be billed as incident to by the billing practitioner who could be a primary care physician who also bills for an E/M visit, and these services cannot duplicate services provided in conjunction with transitional care management, chronic care management, behavioral health integration services, and virtual check-in services which are currently included in the list of primary care services used for purposes of beneficiary assignment, and we believe that these services are reported to Medicare only when furnished in conjunction with treatment for particular conditions and reflected in a plan of care, we believe they should be included in the definition of primary care services for purposes of beneficiary assignment in support of the Shared Savings Program mission to give coordinated, high quality care to an ACO's Medicare beneficiaries.

We propose to specify a revised definition of primary care services in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(viii) to include the list of HCPCS and CPT codes specified in § 425.400(c)(1)(vii) along with the proposed additional CPT codes 99406 and 99407, and 99457 and 99458, 96202 and 96203, if finalized under Medicare FFS payment policy; and 9X015, 9X016,

and 9X017, if finalized under Medicare FFS payment policy and HCPCS codes G0101; G2086, G2087, and G2088; G2211, if finalized under Medicare FFS payment policy; GXXX1 and GXXX2, if finalized under Medicare FFS payment policy; GXXX3 and GXXX4, if finalized under Medicare FFS payment policy; and GXXX5, if finalized under Medicare FFS payment policy; as discussed in the preceding paragraphs. We propose that the new provision at § 425.400(c)(1)(viii) would be applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2024, and subsequent performance years.

We seek comment on these 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, 2024, and subsequent performance years. We also welcome comments on any other existing HCPCS or CPT codes and new HCPCS or CPT codes proposed elsewhere in this proposed rule that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking.

4. Benchmarking Methodology

a. Overview

In this section of the proposed rule, we are proposing modifications to the benchmarking methodology under the Shared Savings Program. We propose a combination of modifications to the Shared Savings Program's benchmarking methodology to encourage sustained participation by ACOs in the program. Specifically, we are proposing to revise the benchmarking methodology by modifying the existing calculation of the regional update factor used to update the historical benchmark between benchmark year (BY) 3 and the performance year (section III.G.4.b. of this proposed rule). We are additionally proposing to further mitigate the impact of the negative regional adjustment to the historical benchmark (section III.G.4.c. of this proposed rule). We are also proposing refinements to the prior savings adjustment calculation methodology (section III.G.4.d. of this proposed rule), that would apply in the establishment of benchmarks for renewing ACOs and re-entering ACOs entering an agreement period beginning on January 1, 2024, and in subsequent years, to account for the following: a change in savings earned by the ACO in a benchmark year due to compliance action taken to address avoidance of at-risk beneficiaries or a change in the amount of savings or losses for a benchmark year as a result of issuance of revised initial determination under § 425.315. Finally, we propose to specify in the regulations an approach to calculating prospective HCC risk scores used in Shared Savings Program benchmark calculations, applicable for agreement periods beginning on January 1, 2024, and in subsequent years, in which we would use the CMS–HCC risk adjustment model(s) applicable to the calendar year corresponding to the performance year to calculate a Medicare FFS beneficiary's prospective HCC risk score for the performance year, and for each benchmark year of the ACO's agreement period (section III.G.4.e. of this proposed rule). Our specific proposals are discussed in detail in the following sections.

b. Proposal To Cap Regional Service Area Risk Score Growth for Symmetry With ACO Risk Score Cap

(1) Background

In the June 2016 final rule (81 FR 37977 through 37981), we established a policy of utilizing a regional growth rate to update the benchmark annually. In that rule, we finalized a policy that, for ACOs in their second or subsequent agreement period whose rebased historical benchmark incorporates an adjustment to reflect regional expenditures, the annual update to the benchmark would be calculated as a growth rate that reflects growth in risk adjusted regional per beneficiary FFS spending for the ACO's regional service area, for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible, aged/non-dual eligible (refer to § 425.603(d)).

In proposing and finalizing the regional growth rate policy, we explained that incorporating regional expenditures in the benchmark would make the ACO's cost target more independent of its historical expenditures and more reflective of FFS spending in its region. We also explained that the use of regional trend factors to trend forward BY1 and BY2 to BY3 in resetting ACO benchmarks and regional growth rates used to update the historical benchmark to the performance year annually would likely result in relatively higher benchmarks for ACOs that are low growth relative to their region compared to benchmarks for ACOs that are high growth relative to their region (refer to 81 FR 37955).

In the December 2018 final rule (83 FR 68013 through 68031), we finalized a proposal to use a blend of national and regional trend factors to trend forward BY1 and BY2 to BY3 when determining the historical benchmark and a blend of national and regional update factors to update the historical benchmark to the performance year for all agreement periods beginning on or after July 1, 2019 (refer to § 425.601(a) and (b)). Under this policy, the national component of the blended trend and update factors receives a weight equal to the share of assignable beneficiaries in the regional service area that are assigned to the ACO, computed by taking a weighted average of county-level shares. The regional component of the blended trend and update factors receives a weight equal to 1 minus the national weight. Calculations are made separately for each Medicare enrollment type. In the December 2018 final rule (83 FR 68024), we acknowledged that, for an ACO that serves a high proportion of beneficiaries in select counties making up its regional service area (referred to herein as having ''high market share''), a purely regional trend would be more influenced by the ACO's own expenditure patterns, making it more difficult for the ACO to outperform its benchmark and conflicting with our goal to move ACOs away from benchmarks based solely on their own historical costs. Incorporating national trends that are more independent of an ACO's own performance was therefore intended to reduce the influence of the ACO's assigned beneficiaries on the ultimate blended trend and update factors applied.

In the CY 2023 PFS final rule (87 FR 69881 through 69899), we finalized a policy for agreement periods starting on or after January 1, 2024, under which we will update the historical benchmark between BY3 and the performance year for each year of the agreement period using a three-way blend calculated as a weighted average of a two-way blend of national and regional growth rates determined after the end of each performance year and a fixed projected growth rate determined at the beginning of the ACO's agreement period called the Accountable Care Prospective Trend (ACPT) (refer to § 425.652(b)). Under this policy, we will make separate calculations for expenditure categories for each Medicare enrollment type. We explained that incorporating this prospective trend in the update to the benchmark would insulate a portion of the annual update from any savings occurring as a result of the actions of ACOs participating in the Shared Savings Program and address the impact of increasing market penetration by ACOs in a regional service area on the existing blended national-regional growth factor.

For ACOs in agreement periods beginning on July 1, 2019, and in subsequent years, we account for changes in severity and case mix of the ACO's assigned beneficiary population when establishing the benchmark for an agreement period and also in adjusting the benchmark for each performance year during the agreement period. In accordance with § 425.601(a)(3) and § 425.652(a)(3), in establishing the benchmark, we adjust expenditures for changes in severity and case mix using CMS Hierarchical Condition Category (CMS–HCC) prospective risk scores (herein referred to as prospective HCC risk scores). Pursuant to § 425.601(a)(10) and § 425.652(a)(10), we further adjust the ACO's historical benchmark at the time of reconciliation for a performance year to account for changes in severity and case mix for the ACO's assigned beneficiary population between BY3 and the performance year (refer to § 425.605(a)(1), (a)(2); § 425.610(a)(2), (a)(3)). In performing this risk adjustment, we make separate adjustments for the population of assigned beneficiaries in each Medicare enrollment type used in the Shared Savings Program (ESRD, disabled, aged/dual eligible, aged/non-dual eligible).

As finalized in the CY 2023 PFS final rule (87 FR 69932 through 69946), for agreement periods beginning on or after January 1, 2024, we will use prospective HCC risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries between BY3 and the performance year, with positive adjustments subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year plus 3 percentage points (herein referred to as the ''aggregate demographics plus 3 percent cap'') (refer to § 425.605(a)(1)(ii); § 425.610(a)(2)(ii)). This cap applies only if the ACO's aggregate growth in prospective HCC risk scores between BY3 and the performance year across all of the Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) exceeds this cap. If the cap is determined to apply, the value of the cap is the maximum increase in prospective HCC risk scores (expressed as a ratio of the ACO's performance year risk score to the ACO's BY3 risk score) for the applicable performance year, such that any positive adjustment between BY3 and the performance year cannot be larger than the value of the aggregate demographics plus 3 percent cap for any of the Medicare enrollment types. This cap is applied separately for the population of beneficiaries in each Medicare enrollment type.

In the CY 2023 PFS final rule, we further explained that we were finalizing the aggregate demographics plus 3 percent cap to address concerns with the prior approach to risk adjustment, which used prospective HCC risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries between BY3 and the performance year, subject to a cap of positive 3 percent for the agreement period that was applied separately by Medicare enrollment type (referred to herein as the ''3 percent cap'') (refer to § 425.605(a)(1)(i); § 425.610(a)(2)(i)). The 3 percent cap was finalized through the December 2018 final rule (83 FR 68013) and is applicable to ACOs in agreement periods beginning on or after July 1, 2019, and prior to January 1, 2024.

We believe that the aggregate demographics plus 3 percent cap addresses several concerns raised by interested parties [169] about the 3 percent cap by: accounting for higher volatility in prospective HCC risk scores for certain Medicare enrollment types due to smaller sample sizes; allowing for higher benchmarks than the prior risk adjustment methodology for ACOs that care for larger proportions of beneficiaries in aged/dual eligible, disabled and ESRD enrollment types (which are frequently subject to the 3 percent cap); and continuing to safeguard the Trust Funds by limiting returns from coding initiatives. However, the demographics plus 3 percent cap does not address concerns from certain interested parties that the current policy places a cap on an ACO's risk score growth between BY3 and the performance year but does not place a cap on the regional prospective HCC risk score growth between BY3 and the performance year, which is reflected in the regional growth rate used to calculate the update factor (pursuant to § 425.652(b)(2)(ii)).[170]

Under the methodology finalized in CY 2023 PFS final rule, as described in § 425.652(b), we express the regional update factor, used to update the historical benchmark to the performance year, as the ratio of an ACO's performance year regional service area risk adjusted expenditures to its BY3 regional service area risk adjusted expenditures for each Medicare enrollment type. Table 31 provides a numeric example of the current methodology for calculating the regional update factor for the ESRD Medicare enrollment type for a hypothetical ACO with a regional service area that includes counties A, B, C, and D.

Pursuant to § 425.654, an ACO's regional expenditures are calculated using risk adjusted county FFS expenditures. The counties included in the ACO's regional service area are based on the ACO's assigned beneficiary population for the applicable benchmark or performance year. We determine average county FFS expenditures based on expenditures for the assignable population [171] of beneficiaries in each county in the ACO's regional service area. We make separate calculations for each Medicare enrollment type. We adjust these county-level FFS expenditures (refer to Table 31, rows [A] and [F]) for severity and case mix of assignable beneficiaries in the county using county-level prospective HCC risk scores (refer to Table 31, rows [B] and [G]). The adjustment is made by dividing the county-level FFS expenditures for the Medicare enrollment type by county-level prospective HCC risk scores for the Medicare enrollment type, resulting in risk adjusted county-level FFS expenditures shown in Table 31 rows [C] and [H].

We then calculate an ACO's regional expenditures for each Medicare enrollment type by weighting these risk adjusted county-level FFS expenditures according to the ACO's proportion of assigned beneficiaries [172] in the county for that Medicare enrollment type (refer to Table 31, rows [D] and [I]), determined by the number of the ACO's

[169] For summaries of these concerns of interested parties, refer to the CY 2022 PFS final rule (86 FR 65302 through 65306), CY 2023 PFS final rule (87 FR 69932 *through* 69934).

[170] For summaries of these concerns of interested parties, refer to the CY 2021 PFS final rule (85 FR 84783 through 84785), the CY 2022 PFS final rule (86 FR 65302 through 65306), and the CY 2023 PFS final rule (87 FR 66942 and 69943).

[171] Assignable beneficiary expenditures are calculated using the payment amounts included in Parts A and B FFS claims with dates of service in the 12-month calendar year that corresponds to the relevant benchmark or performance year, using a 3-month claims run out with a completion factor. These expenditure calculations exclude IME and DSH payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals; and consider individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program. Refer to § 425.654(a)(2). The assignable population of beneficiaries is identified for the assignment window corresponding to the relevant benchmark or performance year that is consistent with the assignment window that applies under the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii). Refer to § 425.654(a)(1)(i). We refer readers to the discussion of the proposed changes to the methodology for identifying the assignable beneficiary population in section III.G.3.a of this proposed rule.

[172] Proportions are calculated using beneficiary person years.

assigned beneficiaries in the applicable population (according to Medicare enrollment type) residing in the county in relation to the ACO's total number of assigned beneficiaries in the applicable population (according to Medicare enrollment type) for the relevant benchmark or performance year. We then aggregate those values for each population of beneficiaries (according to Medicare enrollment type) across all counties within the ACO's regional service area [173] (refer to Table 31, rows [E] and [J]).

We then calculate the regional update factor as the ratio of an ACO's performance year expenditures to BY3 regional expenditures. This calculation is performed separately for each Medicare enrollment type. Refer to Table 31, row [K] for an example of how the regional update factor would be calculated for the ESRD Medicare enrollment type. This calculation would then be repeated for each of the other Medicare enrollment types.

TABLE 31: Example Calculation of the Regional Update Factor for the ESRD Medicare Enrollment Type for a Hypothetical ACO

	County A	County B	County C	County D	Regional
BY3 ESRD Calculations					
[A] County FFS Expenditures	72,000	108,000	86,400	79,200	
[B] County Prospective HCC Risk Scores	0.980	1.100	1.050	1.100	
[C] Risk Adjusted County FFS Expenditures, [A]/[B]	73,469	98,182	82,286	72,000	
[D] Proportion of Assigned Beneficiaries	0.55	0.30	0.15	0.00	
[E] Regional Risk Adjusted Expenditures, weighted average of [C] using weights [D]					**82,206**
PY ESRD Calculations					
[F] County FFS Expenditures	74,880	112,320	89,856	82,368	
[G] County Prospective HCC Risk Scores	1.000	1.210	1.124	1.166	
[H] Risk Adjusted County FFS Expenditures, [F]/[G]	74,880	92,826	79,943	70,642	
[I] Proportion of Assigned Beneficiaries	0.58	0.26	0.15	0.01	
[J] Regional Risk Adjusted Expenditures, weighted average of [H] using weights [I]					**80,263**
ESRD Regional Update Factor Calculation					
[K] ESRD Regional Update Factor, [J]/[E]					**0.976**

While the regional expenditures for BY3 and the performance year are risk adjusted, as described previously in this section, there is currently no cap on prospective HCC risk score growth in an ACO's regional service area between BY3 and the performance year. As discussed previously in this section, ACOs and other interested parties have expressed concerns that the program's current cap on ACO risk score growth between BY3 and the performance year does not account for risk score growth in the ACO's regional service area and that there is not an equivalent cap on regional risk score growth. High prospective HCC risk score growth in an ACO's regional service area between BY3 and the performance year has the effect of decreasing the regional update factor, resulting in a lower updated benchmark for the ACO than if the regional risk score growth were capped (assuming that the risk score growth was high enough to be capped). In past rulemaking, some commenters have encouraged CMS to adopt a policy of applying a cap on ACO risk score growth after accounting for regional increase in risk scores.[174] Others have suggested more generally that CMS align the use of a risk adjustment cap for the ACO and its region by applying a consistent capping policy to both.[175]

In the CY 2022 PFS proposed rule (86 FR 39294 through 39295), we sought comment on an alternate approach to capping ACO prospective HCC risk score growth between BY3 and the performance year in relation to the prospective HCC risk score growth in the ACO's regional service area. The option we presented was to allow an ACO's risk score growth cap to increase above 3 percent by a percentage of the difference between the 3 percent cap and risk score growth in the AC''s regional service area for a given Medicare enrollment type. In this alternate approach (herein referred to as the ''3 percent cap plus regional difference''), the percentage applied would be equal to 1 minus the ACO's regional market share for the Medicare enrollment type. For example, if regional risk score growth for a particular Medicare enrollment type was 5 percent and the ACO's regional market share was 20 percent, we would increase the cap on the ACO's risk score growth for that Medicare enrollment type by an amount equal to the difference between the regional risk

[173] Refer to the Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version #11, January 2023), sections 4.1.1 ''Determining Regional FFS Expenditures'' and 4.1.4 ''Risk Adjusting and Updating the Historical Benchmark'', available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2.*

[174] Refer to CY 2021 PFS final rule (85 FR 84784).

[175] Refer to CY 2021 PFS final rule (85 FR 84784) and CY 2023 PFS final rule (87 FR 69943).

score growth and the 3 percent cap (2 percent) multiplied by one minus the ACO's regional market share (80 percent). Thus, the ACO would face a cap for this Medicare enrollment type equal to 4.6 percent instead of 3 percent (3 percent + (2 percent × 80 percent)). This approach would raise the 3 percent cap while limiting the ability for ACOs with high market share to increase their cap by engaging in coding intensity initiatives that raise the regional prospective HCC risk score. As discussed in the CY 2022 PFS final rule, a few commenters noted their support for this 3 percent cap plus regional difference methodology.[176] MedPAC, however, expressed concern that increasing the cap beyond 3 percent could effectively reward ACOs for greater coding intensity in their region, particularly for those with higher market share.[177] [178]

In the CY 2023 PFS final rule (87 FR 69932 through 69946), we indicated that we had considered the 3 percent cap plus regional difference methodology described in the CY 2022 PFS proposed rule. However, we opted not to propose this policy and instead proposed, and ultimately finalized, the aggregate demographics plus 3 percent cap. One reason we did not propose the 3 percent cap plus regional difference was that a relatively small share of ACOs affected by the 3 percent cap operated in regional service areas where regional risk score growth was greater than 3 percent, indicating that this was not a widespread issue impacting ACO performance. Additionally, we explained that we still had concerns that allowing the cap on an ACO's risk score growth to increase with regional risk score growth could incentivize ACOs, particularly those with high market share, to engage in coding behavior that would increase their cap, even if this incentive would be mitigated to some degree by limiting the allowable increase in the cap based on the ACO's market share. Under the 3 percent cap, ACOs with high market share have a disincentive to engage in coding initiatives, as it could increase risk score growth in their regional service area and potentially decrease the value of the regional component of their update factor. We noted that raising the 3 percent cap based on risk score growth in an ACO's regional service area could change these incentives and encourage ACOs to engage in coding initiatives. In addition to finalizing the aggregate demographics plus 3 percent cap, in the CY 2023 PFS final rule, we noted that we declined to consider an approach that would impose a direct cap on risk score growth in an ACO's regional service area (87 FR 69932 through 69947). As with the 3 percent cap plus regional difference, we were concerned that such an approach would create adverse incentives for coding behavior, especially for ACOs with high market share.

In response to the discussion of the cap on prospective HCC risk score growth in the CY 2023 PFS proposed rule, commenters took the opportunity to reiterate their concerns that the program's current cap on ACO risk score growth between BY3 and the performance year does not account for risk score growth in the ACO's regional service area and suggested ways to incorporate a cap on regional risk score growth. A couple of commenters requested that the risk score cap be allowed to further increase for ACOs in regions where risk score growth exceeds the cap, with one stating that a flat percentage cap will always disadvantage ACOs in regions where risk score growth exceeds the cap and another stating that this additional flexibility would ensure ACOs are not disadvantaged by operating in underserved communities. Additionally, many commenters supported capping regional risk score growth in addition to capping ACO risk score growth. Several of those commenters stated that it was critical that, whatever policy CMS adopted for capping ACOs' risk score growth, the same policy must also apply to regional risk score growth. Several commenters noted that CMS should not apply adjustments to only one side of the equation, that is, capping ACO risk ratios without capping regional risk ratios, with many commenters saying this would lead to unintended consequences and another commenter saying it would have inequitable results. Several commenters stated that not capping increases in regional risk scores would stifle growth in exactly the areas CMS wants growth the most. A few commenters explained that lack of regional risk score growth caps incentivizes ACOs not to grow in places with certain types of populations, such as those with increasing health burdens, higher needs, or higher numbers of aged/dual and disabled enrollees.[179] In response to these comments, we indicated that we would continue to monitor the impacts of regional risk score growth and may propose further refinements to our risk adjustment policies in future rulemaking.[180]

(2) Proposed Revisions

Since the publication of the CY 2023 PFS final rule, we have performed further analysis on prospective HCC risk score growth in ACOs' regional service area between BY3 and the performance year and considered ways in which we could reduce impacts to ACOs in regions with high risk score growth, particularly when such growth is not due to the ACO's own complete and accurate coding, while also limiting the impact from coding initiatives, particularly among ACOs with high market share. Based on this additional analysis, which is detailed later in this section, we are proposing to modify the calculation of the regional update factor used to update the historical benchmark between BY3 and the performance year. The proposed approach would cap prospective HCC risk score growth in an ACO's regional service area between BY3 and the performance year by applying an adjustment factor to the regional update factor. This cap on regional risk score growth would be applied independently of the cap on an ACO's own prospective HCC risk score growth between BY3 and the performance year, meaning that this proposed cap on prospective HCC risk score growth in an ACO's regional service area would be applied whether or not the ACO's prospective risk score growth was capped when updating the benchmark between BY3 and the performance year. Applying these caps independently would be more equitable to ACOs serving high risk patients in regions with high risk score growth, and avoid creating incentives for ACOs to avoid high risk and more medically complex patients. Adjusting the regional service area risk score growth cap based on the percentage of original Medicare fee-for-service beneficiaries the ACO serves in the region would help to mitigate the impact an ACO's own coding initiatives have on risk score growth in the ACO's regional service area, particularly when the ACO has a greater influence on its regional service area risk score growth rate.

To determine the cap on prospective HCC risk score growth in an ACO's regional service area we propose to follow a similar methodology as the one adopted in the CY 2023 PFS final

[176] Refer to 86 FR 65304.

[177] Refer to 86 FR 65303 through 65305.

[178] Refer to Letter from MedPAC to Chiquita Brooks-LaSure, Administrator, CMS (September 9, 2021), regarding File code CMS–1751–P (pages 16–18 ''Risk adjustment methodology''), available at *https://www.medpac.gov/wp-content/uploads/2021/10/09092021_PartB_CMS1751_MedPAC_Comment_V2_SEC.pdf*.

[179] Refer to 87 FR 69942 through 69943.

[180] Refer to 87 FR 69943.

rule [181] for capping ACO risk score growth, codified at § 425.605(a)(1)(ii) and § 425.610(a)(2)(ii), while additionally accounting for an ACO's aggregate market share. The effect of the regional risk score growth cap would be to increase the regional component of the update factor for ACOs in regions with aggregate regional prospective HCC risk score growth above the cap, with ACOs with higher aggregate market shares seeing smaller increases, all else being equal. ACOs in regions with aggregate regional prospective HCC risk score growth below the cap would not be affected by the proposed policy.

By symmetrically limiting risk score growth within both an ACO's assigned beneficiary population and its region, this proposed approach is expected to improve the accuracy of the regional update factors for ACOs operating in regional service areas with high risk score growth, particularly in later years of the 5-year agreement period where the difference between an ACO's BY3 and performance year regional risk scores is expected to be the greatest. We believe capping regional risk score growth will strengthen incentives for ACOs to form or continue to operate in regions with high risk score growth and thereby incentivize ACOs to care for higher risk beneficiaries. This approach would also offer an incentive for potential applicant ACOs that may be examining recent risk score growth in their region and making the decision whether to participate in the Shared Savings Program. Additionally, by adjusting the regional risk score growth cap based on ACO market share, this proposal would also maintain a disincentive against coding intensity for ACOs with high market share.

To implement the new cap on regional risk score growth, we would multiply the original regional update factor used to update the historical benchmark between BY3 and the performance year (determined in accordance with § 425.652(b)(2)(ii)) by a regional risk score growth cap adjustment factor. The regional risk score growth cap adjustment factor would be calculated as follows:

- *Step 1:* Calculate county-level risk scores. We would calculate county-level prospective HCC and demographic risk scores by Medicare enrollment type for both BY3 and the performance year. To do this for a given benchmark or performance year, we would first determine the renormalized, prospective HCC and demographic risk score for each assignable beneficiary [182] in each county in the ACO's regional service area. For both HCC and demographic risk scores, we would then compute the weighted average risk score for each county for each Medicare enrollment type by multiplying each assignable beneficiary's risk score for that Medicare enrollment type by the beneficiary's person years enrolled in that Medicare enrollment type, summing these weighted risk scores across all assignable beneficiaries for that Medicare enrollment type in the county, and then dividing by total person years for that Medicare enrollment type among assignable beneficiaries in the county. Note that this approach would be similar to the approach that is currently used to determine county-level prospective HCC risk scores as an intermediate step in calculating risk adjusted regional expenditures under the current methodology.[183]
- *Step 2:* Calculate regional risk scores. We would calculate regional-level BY3 and performance year prospective HCC and demographic risk scores as a weighted average of county-level HCC and demographic risk scores for the Medicare enrollment type (calculated in step 1), with weights reflecting the proportion of the ACO's assigned beneficiaries [184] in the county. This proportion is determined by the number of the ACO's assigned beneficiaries (by Medicare enrollment type) residing in each county in relation to the ACO's total number of assigned beneficiaries for that Medicare enrollment type for the relevant benchmark or performance year. These would be the same weights as used to calculate regional expenditures under § 425.654(b).
- *Step 3:* Determine aggregate growth in regional risk scores. To calculate aggregate growth in regional risk scores, we would first calculate growth in prospective HCC and demographic risk scores between BY3 and the performance year for each Medicare enrollment type, expressed as the ratio of the performance year regional risk score for a Medicare enrollment type (calculated in step 2) to the BY3 regional risk score for that enrollment type (calculated in step 2). We would next take a weighted average of the regional prospective HCC or demographic risk ratios, as applicable, across the four Medicare enrollment types, where the weight applied to the growth in risk scores for each Medicare enrollment type would be the ACO's performance year assigned beneficiary person years for the Medicare enrollment type multiplied by the ACO's regionally adjusted historical benchmark expenditures for the Medicare enrollment type.[185]
- *Step 4:* Determine the cap on regional risk score growth. We would first calculate the non-market share adjusted cap on the ACO's regional risk score growth as the sum of the aggregate growth in regional demographic risk scores (calculated in step 3) and 3 percentage points.[186]

We would next adjust the cap to reflect the ACO's aggregate market share. We would calculate an ACO's aggregate market share as a weighted average of the ACO's market share across the four Medicare enrollment types. An ACO's market share for each Medicare enrollment type would be equal to the weight that is applied to the national component of the blended update factor in the two-way blend that is calculated as the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO for the applicable performance year (refer to § 425.652(b)(2)(iv)). The weights for each Medicare enrollment type used to compute the weighted average would be the ACO's performance year assigned person years for the Medicare enrollment type.

We would adjust the cap on regional risk score growth to reflect the ACO's aggregate market share by adding to the non-market share adjusted cap the product of:

++ The ACO's aggregate market share, and

++ The difference (subject to a floor of zero) between:

[181] 87 FR 69932 through 69946.

[182] Consistent with our proposal to revise the definition of an assignable beneficiary (refer to section III.G.3.a of this proposed rule), we propose that the assignable population of beneficiaries for a benchmark or performance year would be identified using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the applicable performance year according to § 425.400(a)(4)(ii).

[183] Refer to the Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version #11, January 2023), section 4.1.1 ''Determining Regional FFS Expenditures'', available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2*.

[184] Proportions are calculated using beneficiary person years.

[185] These are the same weights that are to be used when calculating weighted average ACO prospective HCC and demographic risk ratios under the risk adjustment methodology adopted in the CY 2023 PFS final rule (87 FR 69932 through 69946) and codified in §§ 425.605(a)(1)(ii)(C) and 425.610(a)(2)(ii)(C).

[186] This is similar to the calculation of the cap on ACO prospective HCC risk score growth finalized in the CY 2023 PFS (87 FR 69932 through 69946) and codified in §§ 425.605(a)(1)(ii)(A) and 425.610(a)(2)(ii)(A).

-- The aggregate regional prospective HCC risk score growth (calculated in step 3), and

-- The non-market share adjusted cap (calculated first in this step).

This adjustment of the cap on regional risk score growth using the ACO's aggregate market share creates a sliding scale. Assuming that an ACO has aggregate regional prospective HCC risk score growth above the non-market share adjusted cap, an ACO with close to 0 percent aggregate market share would receive a market share adjusted cap on regional risk score growth close to the aggregate growth in regional demographic risk scores plus 3 percentage points and an ACO with 100 percent aggregate market share would receive a market share adjusted cap on regional risk score growth equal to the aggregate regional prospective HCC risk score growth calculated in step 3 (which is effectively no cap at all). Under this approach, as an ACO's aggregate market share increases, so does the cap on the ACO's regional risk score growth, ultimately limiting the potential increase to the regional update factor for ACOs with high market share.

• *Step 5:* Determine the regional risk score growth cap adjustment factor. First, we would determine if the ACO's regional risk score growth is subject to a cap by comparing the ACO's aggregate regional prospective HCC risk score growth (calculated in step 3) to the market share adjusted cap on regional risk score growth (calculated in step 4).

++ If the aggregate regional prospective HCC risk score growth does not exceed the cap on regional risk score growth, the ACO's regional risk score growth would not be subject to the cap. For these ACOs we would set the risk score growth cap adjustment factor equal to 1 for each Medicare enrollment type (which is effectively no adjustment).

++ If the aggregate regional prospective HCC risk score growth exceeds the market share adjusted cap, the ACO's regional risk score growth is subject to the cap. For these ACOs we would next determine whether the cap on regional risk score growth applies for each Medicare enrollment type. To do this, we would compare regional prospective HCC risk score growth for each Medicare enrollment type (calculated in step 3) with the market share adjusted cap (calculated in step 4). If the regional risk score growth for a Medicare enrollment type does not exceed the cap, the enrollment type is not subject to the cap and the regional risk score growth cap adjustment factor for that Medicare enrollment type is set equal to 1 (effectively no adjustment). Otherwise, the Medicare enrollment type is subject to the cap and we would set the adjustment factor for the Medicare enrollment type equal to the regional prospective HCC risk score growth for the Medicare enrollment type (calculated in step 3) divided by the market share adjusted cap calculated in step 4. In this case, the adjustment factor for the Medicare enrollment type would represent a measure of how far above the cap the regional prospective HCC risk score growth is.

Table 32 provides a numeric example of the calculation of the regional risk score growth cap adjustment factor for a hypothetical ACO that is determined to be subject to the market share adjusted cap. Table 32 begins at the end of step 2 of the calculation, and therefore only reflects regional-level calculations and does not include the county-level calculations:

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TABLE 32: Example of Calculation of the Regional Risk Score Growth Cap Adjustment Factor for a Hypothetical ACO

Regional Level Measure	ESRD	Disabled	Aged/dual	Aged/non-dual	Weighted Average
Results of Step 2 (Regional Risk Scores (Calculation not shown))					
[A] BY3 Prospective HCC Risk Scores	1.027	1.016	1.037	1.006	
[B] PY Prospective HCC Risk Scores	1.075	1.049	1.043	1.053	
[C] BY3 Demographic Risk Scores	1.016	0.996	1.047	1.007	
[D] PY Demographic Risk Scores	0.962	1.012	1.054	0.983	
Step 3 (Determine growth in aggregate risk scores)					
[E] Prospective HCC Risk Ratio, [B] / [A]	1.047	1.032	1.006	1.047	
[F] Demographic Risk Ratio, [D] / [C]	0.947	1.016	1.006	0.977	
[G] Risk Score Weights (ACO performance year assigned person years multiplied by regionally adjusted historical benchmark expenditures, as a proportion)	0.010	0.090	0.150	0.750	
[H] Weighted Average HCC Risk Ratio, weighted average of [E] using weights [G]					1.039
[I] Weighted Average Demographic Risk Ratio, weighted average of [F] using weights [G]					0.984
Step 4 (Determine the cap on regional risk score growth)					
[J] Non-market Share Adjusted Cap, [I] + 0.030					1.014
[K] Market Share Weights (ACO performance year assigned person years, as a proportion)	0.007	0.085	0.120	0.788	
[L] ACO Market Share	0.150	0.200	0.180	0.300	
[M] Weighted Average Market Share, weighted average of [L] using weights [K]					0.276
[N] Market Share Adjusted Cap, [J]+([M]*([H]-[J])), Note that [H]-[J] is subject to a floor of 0					1.021
Step 5 (Determine the regional risk score growth cap adjustment factor)					
[O] Is the ACO Subject to Cap? [H] > [N]?					Yes
[P] Is the Enrollment Type Subject to Cap, If [O] = Yes, is [E]>[N]? If [O] = No, then No	Yes	Yes	No	Yes	
[Q] Regional Risk Score Growth Cap Adjustment Factor, If [P] =Yes, then [E]/[N], else 1	1.025	1.011	1.000	1.025	

Table Note: This numeric example shows only three decimal places and so attempting to replicate the calculations may result in slight differences due to rounding. In actual calculations all decimal places would be used.

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In this example, the hypothetical ACO was in a regional service area with aggregate prospective HCC risk score growth (a weighted average risk ratio of 1.039, refer to row [H]) above the market share adjusted cap of 1.021 (refer to row [N]). The ACO's regional prospective HCC risk score growth (shown in row [E]) was above this cap for three of the four Medicate enrollment types (all but the aged/dual eligible Medicare enrollment type). Therefore, the regional risk score growth cap adjustment factor (refer to row [Q]) calculated for those three capped Medicare enrollment types was above one, and the regional risk score growth cap adjustment factor calculated for the one uncapped Medicare enrollment type was equal to one. Once the regional risk score growth cap adjustment factors are multiplied by the original regional update factors used to update the historical benchmark between BY3 and the performance year, the regional update factor would increase for the three capped Medicare

enrollment types. For example, if the original regional update factor for the ESRD Medicare enrollment type was 0.976, then the final regional ESRD update factor after the application of the regional risk score growth cap adjustment factor would be 1.000 (the product of 0.976 and the regional risk score growth cap adjustment factor of 1.025). There would be no change to the original regional update factor for the uncapped aged/dual eligible Medicare enrollment type as it would be multiplied by one. Because of the increase in original regional update factor for the three capped Medicare enrollment types, this hypothetical ACO would have a higher updated benchmark under this proposed policy than under current policy.

However, if an ACO was in a regional service area with aggregate prospective HCC risk score growth that was not above the regional risk score growth cap, the regional risk score growth cap adjustment factor for all Medicare enrollment types would be equal to one, thus resulting in no change to the original regional update factor for any Medicare enrollment type and therefore no change to the ACO's updated benchmark compared to current policy.

We believe this proposed policy would help increase the accuracy of the regional update factor for ACOs operating in regional service areas with high risk score growth, including those serving more medically complex beneficiaries, therefore increasing incentives for ACOs to form or continue participation in such areas. At the same time, we believe that incorporating the market share adjustment helps to mitigate concerns related to coding intensity for ACOs with high market share and thus a relatively high level of influence over risk scores in the ACOs regional service area as discussed in section III.G.4.b.(1) of this proposed rule and would therefore protect the Trust Funds by continuing to limit incentives for this behavior.

We simulated the impact of the proposed policy using PY 2021 financial reconciliation data for ACOs in agreement periods beginning on or after July 1, 2019. This simulation found that 38 of the 332 ACOs (11 percent) would have been subject to the cap on regional risk score growth determined in step 4 of the proposed methodology and therefore would have had a higher regional update factor than under current policy for at least one Medicare enrollment type. Thirty-six of those 38 ACOs were subject to the 3 percent cap on their own risk score growth for at least one enrollment type in actual PY 2021 results. Table 33 shows the percentage of ACOs determined to be subject to the cap on regional risk score growth for each Medicare enrollment type and the average increase in the regional update factor for that enrollment type among those ACOs.

TABLE 33: Share of ACOs Subject to Regional Risk Score Growth Cap and Average Increase in Regional Update Factor among those ACOs by Medicare Enrollment Type

	ESRD	Disabled	Aged/Dual	Aged/Non-Dual
Share of ACOs Capped in Simulation	2%	5%	10%	11%
Average Change in Regional Update Factor	0.011	0.015	0.035	0.016

While this modeling shows that only a small proportion of ACOs would have benefitted from this policy in PY 2021, our analyses have also shown that this proportion is predicted to increase as more ACOs advance farther into their 5-year agreement period. This is supported by the finding that ACOs in the simulation were significantly more likely to be impacted if their agreement period started in 2019 with a BY3 of 2018 (16 percent) than if their agreement period started in 2020 with a BY3 of 2019 (6 percent).[187] Because the analysis of PY 2021 data demonstrates that circumstances like the PHE for COVID–19 and progression along a 5-year agreement period can interact to increase the share of ACOs in regional service areas with aggregate regional risk score growth above the cap, we have determined that our initial concerns about creating adverse incentives for coding behavior by capping regional risk score growth, as discussed in section III.G.4.b.(1) of this proposed rule, are outweighed by the potential harm to ACOs in regions with high risk score growth, particularly when such growth is not due to the ACO's own coding activities. Additionally, we believe the market share adjustment to the cap on regional risk score growth will limit overly advantaging ACOs with high market share if they participate in coding initiatives.

Table 34 displays information on the impact of the market share adjustment on the cap on regional risk score growth within our simulation of the proposed policy in PY 2021 for the ACOs with the minimum, median, and maximum aggregate market share that were found to be subject to the cap on regional risk score growth.

[187] While analysis of average FFS risk score changes at the hospital referral region (HRR) level further supports the assumption that more ACOs would be impacted toward the end of their 5-year agreement period, such analysis also indicates that variation from the PHE for COVID–19 likely accentuated this phenomenon in the simulation on PY2021 data. For this reason, the finding in the PY2021 simulation that 16 percent of 2019 starters were impacted is likely indicative of an upper bound for the share of ACOs potentially impacted by PY5 in agreement periods that start in 2024 or later (that is, where the impact of the PHE for COVID–19 is minimal in BY3 relative to the BY3s in this simulation).

TABLE 34: Aggregate Market Share and Impact of Market Share Adjustment on Cap on Regional Risk Score Growth among ACOs Subject to Regional Risk Score Growth Cap (N=38)

	Aggregate Market Share (proportion)	Non-Market Share Adjusted Cap	Market Share Adjusted Cap	Difference between Market Share Adjusted and Non-Market Share Adjusted Cap
Minimum	0.009	1.036	1.036	<0.001
Median	0.127	1.034	1.034	0.001
Maximum	0.536	1.008	1.028	0.020

Note: The minimum, median, and maximum refer to the minimum, median and maximum aggregate market share. The non-market share adjusted cap, market share adjusted cap, and difference between market share adjusted and non-market share adjusted cap represent data from the ACOs with the minimum, median, and maximum market shares. Because there are an even number of impacted ACOs, there are two ACOs comprising the median of 0.127. These two ACOs have the same non-market share adjusted and market share adjusted caps and have been combined into a single row for simplicity.

Based on this data in Table 34, the majority of ACOs found to be impacted in this simulation had a relatively small aggregate market share, with a median of about 13 percent. Because of this, the median increase to the cap on regional risk score growth from the market share adjustment was small (0.001). (This is both the median increase among all 38 impacted ACOs and the increase for the impacted ACO with the median market share). Further analysis showed that results were similar among both rural and urban ACOs. Of the 38 impacted ACOs, 34 were classified as urban and had a median aggregate market share of about 12 percent. The remaining four impacted ACOs were rural ACOs with a median aggregate market share of about 24 percent. While the market share was higher on average among rural ACOs, average market share for both types of ACOs was under 25 percent and both groups had only a small median increase to the cap on regional risk score growth from the market share adjustment of 0.001.[188]

ACOs with a larger aggregate market share received a larger increase in the cap on regional risk score growth due to the market share adjustment. For example, in Table 34, the ACO with the highest market share of 53.6 percent (an ACO that has a regional service area in an urban area), had a 20 percent increase in its cap from the market share adjustment, going from a non-market share adjusted cap of 1.008 to an adjusted cap of 1.028. We believe that, while the impact of the market share adjustment on the cap on regional risk score growth will be small for the majority of ACOs, this market share adjustment is important to address both our own concerns related to incentives for coding intensity and the similar concerns raised by MedPAC in the CY 2023 PFS final rule, as discussed in section III.G.4.b.(1) of this proposed rule. The market share adjustment to the cap limits the adverse coding incentives that can arise when allowing larger benchmark increases when an ACO increases its coding, especially for ACOs with high market share. Specifically, ACOs with high market share will still have a disincentive to engage in coding initiatives, as these initiatives could increase risk score growth in their regional service area and potentially decrease the value of the regional component of their update factor.

Apart from the market share adjustment, the calculation of the proposed cap on regional risk score growth between BY3 and the performance year is calculated in the same way as the aggregate demographics plus 3 percent cap on ACO risk score growth under §§ 425.605(a)(1)(ii)(A) and 425.610(a)(2)(ii)(A). Specifically, the cap is calculated as the aggregate growth in regional demographic risk scores between BY3 and the performance year plus 3 percentage points, prior to application of the market share adjustment. Additionally, as a result of incorporating the risk adjustment into the regional update factor at the county level, the current methodology does not directly calculate a regional risk ratio that can be directly modified. The proposed approach of modifying the regional update factor by multiplying by an adjustment factor achieves the goal of reducing the impact of regional risk score growth while leaving the existing methodology for calculating risk-adjusted regional expenditures intact.

As we have explained in earlier rulemaking (see 87 FR 69887 and 69888), we have used our authority under section 1899(i)(3) of the Act to adopt a three-way blended benchmark update factor (weighted one-third ACPT, and two-thirds national-regional blend) for agreement periods beginning on January 1, 2024, and in subsequent years, in place of an update factor based on the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original FFS program as called for in section 1899(d)(1)(B)(ii) of the Act. Therefore, the proposed changes to the regional component of the three-way blended update factor described in this section of this proposed rule would similarly require continued use of our statutory authority under section 1899(i)(3) of the Act. Section 1899(i)(3) of the Act grants the Secretary the authority to use other payment models, including payment models that use alternative benchmarking methodologies, if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under the Medicare program and program expenditures under the alternative methodology would be equal to or lower than those that would result under the statutory payment model. We believe the changes to the methodology for updating the benchmark that we are proposing pursuant to section 1899(i)(3) of the Act would improve the quality and efficiency of items and services furnished under the Medicare Program. More specifically, we believe that the proposed changes to the regional component of the update factor would—

[188] For this analysis, ACOs were classified as rural if the plurality of their assigned beneficiaries resided in either micropolitan or noncore counties and urban if the plurality of their assigned beneficiaries resided in either large central metro, large fringe metro, medium metro, or small metro counties as defined by The United States Census Bureau and the Office of Management and Budget (OMB).

in the context of the downward effects on the benchmark resulting from elevated variation in regional average prospective HCC risk score growth as shown in the PY 2021 analysis—reinforce the incentive for ACOs to enter and remain in the Shared Savings Program, particularly in regions with changing populations. Moreover, we believe that the proposed approach, by encouraging ACOs to enter and continue participation in the Shared Savings Program, would lead to improvement in the quality of care furnished to Medicare FFS beneficiaries because participating ACOs have an incentive to perform well on quality measures in order to maximize the shared savings they may receive. In addition, as discussed in the Regulatory Impact Analysis (section VII.E.10. of this proposed rule), we believe the proposed changes to the regional component of the three-way blended update factor, in combination with the other proposals for which we must use our authority under section 1899(i)(3) of the Act, would result in a marginal impact that is estimated to result in $330 million in lower net spending over the 10-year projection window, which supports our finding that the relatively minor changes to program spending resulting from these proposed changes would not violate the requirements of section 1899(i)(3)(B) of the Act. We will continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

We propose to revise the Shared Savings Program regulations governing the calculation of the regional growth rate when updating the historical benchmark between BY3 and the performance year at § 425.652(c) to incorporate a regional risk score growth cap adjustment factor. We also propose to add a new section to the regulations at § 425.655 to describe the calculation of the adjustment factor.

We seek comment on the proposed changes to calculation of the regional component of the update factor for agreement periods beginning on or after January 1, 2024.

c. Mitigating the Impact of the Negative Regional Adjustment on the Benchmark To Encourage Participation by ACOs Caring for Medically Complex, High-Cost Beneficiaries

(1) Background

In earlier rulemaking we have discussed our use of the Secretary's discretion under section 1899(d)(1)(B)(ii) of the Act to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate'' in order to adjust ACO historical benchmarks to reflect FFS expenditures in the ACO's regional service area (81 FR 37962). We initially established a regional adjustment in a benchmark rebasing methodology that applied to ACOs entering a second agreement period beginning on January 1, 2017, January 1, 2018, or January 1, 2019 (§ 425.603(c) through (g)), before modifying our policy to apply this adjustment program wide beginning with agreement periods starting on July 1, 2019, and in subsequent years (§ 425.601(a)(8)). In the CY 2023 PFS final rule (87 FR 69915 through 69923) we modified the way we would calculate the regional adjustment for ACOs in agreement periods starting on January 1, 2024, and in subsequent years (§ 425.656). We also finalized a policy that would modify the way we would apply the regional adjustment to the benchmark that would also take into account a new adjustment for prior savings that would be available to eligible ACOs (§ 425.652(a)(8)).

In accordance with § 425.601(a)(8), for ACOs in agreement periods beginning on or after July 1, 2019 and before January 1, 2024, we adjust historical benchmark expenditures by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) by a percentage of the difference between the average per capita expenditure amount for the ACO's regional service area and the average per capita amount of the ACO's historical benchmark (referred to herein as the ''regional adjustment''). The percentage applied in calculating the regional adjustment depends on whether the ACO has lower or higher spending compared to the ACO's regional service area and the agreement period for which the ACO is subject to the regional adjustment, according to the phase-in schedule of applicable weights. We cap the per capita dollar amount of the regional adjustment for each Medicare enrollment type at a dollar amount equal to positive or negative 5 percent of national per capita FFS expenditures for Parts A and B services under the original Medicare FFS program in benchmark year (BY) 3 for assignable beneficiaries (as defined in § 425.20) in that Medicare enrollment type identified for the 12-month calendar year corresponding to BY3 (§ 425.601(a)(8)(ii)(C)) (referred to herein as positive or negative 5 percent of national per capita FFS expenditures for assignable beneficiaries, and as the ''symmetrical cap,'' terms which we consider to be synonymous). We then apply the capped regional adjustment for each Medicare enrollment type by adding it to the historical benchmark expenditure for that enrollment type. A positive regional adjustment for a given Medicare enrollment type increases the benchmark for that enrollment type, whereas a negative regional adjustment decreases the benchmark for that enrollment type.

With the policies finalized in the CY 2023 PFS final rule (87 FR 69915 through 69923), we sought to reduce the impact of negative regional adjustments in several ways for agreement periods beginning on January 1, 2024, and subsequent years. First, we finalized a policy that replaced the negative 5 percent cap on the negative regional adjustment with a negative 1.5 percent cap. Under this policy, we would continue to cap positive adjustments for each Medicare enrollment type at a dollar amount equal to 5 percent of national per capita FFS expenditures for assignable beneficiaries for that enrollment type but would cap negative adjustments for each enrollment type at a dollar amount equal to negative 1.5 percent of national per capita FFS expenditures for assignable beneficiaries for that enrollment type. Additionally, after applying the negative 1.5 percent cap, we would apply an offset factor that would gradually decrease the negative regional adjustment amount for a given Medicare enrollment type as an ACO's proportion of dually eligible Medicare and Medicaid beneficiaries increases or its weighted average prospective HCC risk score increases. Finally, for an ACO eligible for the prior savings adjustment for which the regional adjustment expressed as a single value (based on taking a person year weighted average across the four Medicare enrollment types) is negative, we would further offset the regional adjustment by the prior savings adjustment. In the CY 2023 PFS final rule (87 FR 69919) we expressed our belief that by reducing the impact of negative regional adjustments, these policies would incentivize ACOs that serve high-cost beneficiaries to join or

continue to participate in the Shared Savings Program.

These policies to reduce the impact of negative regional adjustments are reflected in several new sections of the regulations. Section 425.652 is the main provision that describes the methodology for establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years, including the interaction of the regional adjustment and the prior savings adjustment. Sections 425.656 and 425.658 provide additional detail on the calculations of the regional adjustment and the prior savings adjustment, respectively.

Table 35 illustrates how the caps to the regional adjustment would be calculated and applied to positive and negative regional adjustments at the Medicare enrollment type level under the policy finalized in the CY 2023 PFS final rule. Note that the uncapped regional adjustment values would be calculated using the applicable percentage phase-in weight based on whether the ACO has lower or higher spending as compared to its regional service area and the ACO's agreement period subject to a regional adjustment as described in § 425.656(d). For example, if an ACO is considered to have lower spending compared to the ACO's regional service area, and it is the ACO's first agreement period subject to the regional adjustment, we would use a weight of 35 percent when applying the regional adjustment. If an ACO is considered to have higher spending compared to the ACO's regional service area, and it is the ACO's first agreement period subject to the regional adjustment, we would use a weight of 15 percent when applying the regional adjustment.

TABLE 35: Hypothetical Example of Cap on Regional Adjustment

Medicare Enrollment Type	Medicare Enrollment Type Proportion	Uncapped Regional Adjustment ($)	Positive Regional Adjustment Cap: - 5% of National Assignable Per Capita Expenditures ($)	Negative Regional Adjustment Cap: -1.5% of National Assignable Per Capita Expenditures ($)	Capped Regional Adjustment ($)
ESRD	0.015	932	4,437	-1,331	932
Disabled	0.190	-185	639	-192	-185
Aged/dual	0.100	258	974	-292	258
Aged/non-dual	0.695	-307	553	-166	-166
Weighted Average		-209			-111

The hypothetical ACO in this example has a mix of positive and negative regional adjustments across the four enrollment types. The ACO's uncapped aged/non-dual eligible adjustment is outside the negative 1.5 percent cap and thus changes from −$307 to −$166 when the cap is applied. The ACO's adjustments for the other three enrollment types are all within the applicable positive or negative caps and are thus unaffected. The ACO's overall weighted average regional adjustment (calculated by multiplying the adjustment for each enrollment type by the corresponding enrollment type proportion and then summing across the four enrollment types) changes from −$209 to −$111 when the negative regional adjustment cap is applied, reducing the per capita impact of the negative regional adjustment by $98.

Under the methodology adopted in the CY 2023 PFS final rule (87 FR 69917 and 69920), after we apply the caps, we next apply an offset factor to any negative regional adjustments at the enrollment type level. The offset factor is based on the following: [A] the ACO's overall proportion of BY3 assigned beneficiaries that are dually eligible for Medicare and Medicaid (including dually eligible ESRD, disabled, and aged beneficiaries) [189] and [B] the ACO's weighted average prospective HCC risk score for BY3 taken across the four Medicare enrollment types.[190] Before taking this weighted average, the risk score for each enrollment type is first renormalized by dividing by the national mean risk score for the assignable FFS population for that enrollment type identified for the calendar year corresponding to BY3. Specifically, the offset factor is calculated as:

Offset factor = [A] + ([B] − 1)

We apply the offset factor, which is subject to a minimum of zero and a maximum of one, by subtracting its value from 1 and multiplying this difference by the negative regional adjustment for each Medicare enrollment type, calculated as:

Final regional adjustment = Negative regional adjustment × (1 − Offset factor)

The higher an ACO's proportion of dually eligible beneficiaries or the higher its risk score, the larger the offset factor would be and the larger the reduction to the overall negative regional adjustment. If the offset factor is equal to the maximum value of one, the ACO would not receive a negative regional adjustment for any enrollment type, because each negative adjustment would be multiplied by a value of 1 minus the offset factor, or 0. For these ACOs, the overall weighted average regional adjustment would either be 0 (if the ACO had negative adjustments for all four enrollment types prior to the application of the offset factor) or positive (if the ACO had a mix of positive and negative adjustments at the

[189] In computing this proportion, we use for each beneficiary the fraction of the year (referred to as person years) in which they were eligible for the aged/dual eligible enrollment type or for which they were eligible for the ESRD or disabled enrollment type and dually eligible for Medicare and Medicaid.

[190] In computing this weighted average, we apply a weight to the risk score for BY3 for an enrollment type that is equal to the product of the ACO's BY3 per capita expenditures for that enrollment type and the ACO's BY3 person years for that enrollment type.

enrollment type level prior to the application of the offset factor). If the offset factor is equal to the minimum value of zero, the ACO would receive no benefit from the offset factor.

To illustrate how the offset factor would be calculated and applied, assume that the hypothetical ACO from Table 35 had a proportion of dually eligible beneficiaries of 0.130 and a weighted average prospective HCC risk score for BY3 of 1.240. The offset factor for this ACO would be calculated as:

Offset factor = 0.130 + (1.240 − 1) = 0.370

This factor would be applied as illustrated in Table 36 by multiplying the negative regional adjustment for each applicable Medicare enrollment type by 1 minus the offset factor or 0.630.

TABLE 36: Hypothetical Example of Offset Factor Applied to Negative Regional Adjustments

Medicare Enrollment Type	Enrollment Proportion	Capped Regional Adjustment (Before Offset) ($)	Offset Factor	1 – Offset Factor	Final Regional Adjustment ($)
ESRD	0.015	932	N/A	N/A	932
Disabled	0.190	-185	0.370	0.630	-117
Aged/dual	0.100	258	N/A	N/A	258
Aged/non-dual	0.695	-166	0.370	0.630	-105
Weighted Average		-111			-55

Here, the offset factor is applied to the regional adjustments for the disabled and aged/non-dual eligible populations, as both are negative, but not to the regional adjustments for the ESRD and aged/dual eligible populations, which are both positive. Taking the weighted average across the enrollment types following application of the offset factor shows that the ACO's overall weighted regional adjustment changes from −$111 before the offset to −$55 after the offset, further reducing the per capita impact of the negative regional adjustment by $56. The overall per capita impact of both the cap and offset factor for this ACO would be $154.

In the CY 2023 PFS final rule (87 FR 69918 and 69921) we presented simulations of the combined impact of the cap and offset factor relative to the symmetrical positive and negative 5 percent cap then in place for ACOs in agreement periods beginning on July 1, 2019, and in subsequent years. The results of these simulations, which used data from PY 2020 historical benchmarks for ACOs in agreement periods starting on or after July 1, 2019, and from PY 2022 historical benchmarks for ACOs starting an agreement period on January 1, 2022, found the negative regional adjustment for almost every ACO that had an overall negative regional adjustment in the PY 2020 and PY 2022 data under the symmetrical cap would have been reduced (or eliminated), with an average per capita impact of approximately $114 for PY 2020 and $48 for PY 2022. ACOs with higher weighted average BY3 prospective HCC risk scores and higher proportions of dually eligible Medicare and Medicaid beneficiaries had overall greater reductions in their negative regional adjustments. Four ACOs in the PY 2020 simulation and one in the PY 2022 simulation had an offset factor of 1, meaning they would have received a full offset to their negative regional adjustments.

Under a separate policy also finalized in the CY 2023 PFS final rule, an ACO beginning an agreement period on January 1, 2024, and in subsequent years that is a renewing or re-entering ACO may be eligible to receive an adjustment to its benchmark to account for savings generated in performance years that correspond to the benchmark years of its new agreement period. A full discussion of this policy can be found in that earlier rulemaking (87 FR 69899 through 69915). The policy was designed such that an eligible ACO would receive the higher of its overall positive regional adjustment or its prior savings adjustment, or a combination of the two if its overall regional adjustment is negative and it had prior savings. ACOs ineligible for the prior savings adjustment would receive the regional adjustment (computed as described earlier in this section applying a 5 percent cap on positive regional adjustments and a −1.5 percent cap and offset factor on negative regional adjustments). Specifically, if the regional adjustment, expressed as a single value, is positive, the ACO would receive a final adjustment equal to the higher of the regional adjustment or an adjustment based on the ACO's prior savings (see § 425.652(a)(8)(iii)(B)). If the regional adjustment, expressed as a single value, is negative, we would calculate the final adjustment as described in § 425.652(a)(8)(iii)(A), with the ACO receiving either a smaller negative regional adjustment or a positive adjustment for prior savings depending on the relative size of the negative regional adjustment and the ACO's pro-rated prior savings.

Based on further consideration, we believe it is important and timely to revisit the policy that allows for negative adjustments to be applied in establishing the benchmark for ACOs. While we did not consider eliminating negative regional adjustments program-wide in CY 2023 PFS rulemaking, one commenter noted that there is an argument for doing so. We believe further mitigating the impact of the negative regional adjustment for ACOs with high-cost populations, thereby resulting in higher benchmarks for ACOs compared to the recently finalized methodology, could further bolster the business case for Shared Savings Program participation by such ACOs.

As we discussed in the CY 2023 PFS proposed rule (87 FR 46161), there is evidence that certain aspects of the program's benchmarking methodology, notably the regional adjustment to the benchmark, may deter participation among ACOs with spending above their regional service area including those serving medically complex, high-cost populations. High-cost ACOs are underrepresented in the Shared Savings Program, with around 86 percent of all participating ACOs receiving an overall

positive regional adjustment in PY 2022 indicating that a majority of ACOs are lower spending than their regional service area. We also observed that ACOs that received an overall negative regional adjustment for PY 2022 were less likely to continue participation in the program in PY 2023 than were ACOs that received an overall positive regional adjustment, with 22 percent of ACOs with a negative overall adjustment leaving the program compared to 12 percent of ACOs with a positive overall adjustment. Since PY 2017 the overall annual average share of ACOs that leave the program has been 12 percent. A recent academic study also found evidence suggesting selective participation among ACOs in response to the original adoption of a regional adjustment in 2017, with the composition of ACOs between 2017 to 2019 increasingly shifting to providers with lower preexisting levels of spending.[191] The authors attributed these changes to a combination of the entry of new ACOs with lower baseline spending, the exit of higher-spending ACOs, and the reconfiguration of ACO participant lists to favor lower-spending practices among ACOs continuing participation in the program.

Relatedly, we have observed that negative regional adjustments may make it more difficult for ACOs to succeed in the program financially. Between PY 2017, when regional adjustments were first introduced in the Shared Savings Program, and PY 2021, ACOs that received negative regional adjustments have been consistently less likely to share in savings than ACOs that received positive regional adjustments. For example, in PY 2021 we observed that 37 percent of ACOs that received a negative regional adjustment shared in savings compared to 63 percent among those with a positive adjustment.

We believe that eliminating the possibility that an ACO will receive an overall negative regional adjustment to its benchmark in combination with the other elements of the benchmarking methodology finalized in the CY 2023 PFS final rule, would work together to further our efforts to ensure sustainability of the benchmarking methodology. More specifically, we believe this policy change would further encourage continued participation among high-cost ACOs that serve medically complex beneficiaries by eliminating the potential of a lower benchmark due to an overall negative regional adjustment. It may also encourage ACOs serving such populations that may have otherwise been discouraged from participating in the Shared Savings Program by the idea of a lower benchmark to join. The implementation of this policy would allow ACOs to serve the most vulnerable populations while lessening the concern of how this may affect their performance in the program. We believe that program participation by ACOs serving these populations has the potential, over time, to produce cost savings for the Medicare Trust funds by improving care coordination and quality of care for such beneficiaries.

Additionally, we believe that eliminating overall negative regional adjustments could further incentivize greater participation among ACOs whose ACO participants have historically been less efficient than other providers and suppliers in their regions. Such ACOs may have the greatest potential to generate cost savings for the Medicare Trust Funds by adopting more efficient practices, therefore we believe that their participation in the program should not be discouraged.

(2) Proposed Revisions

In light of these considerations, we are proposing to modify the policies we adopted in the CY 2023 PFS final rule so as to prevent any ACO from receiving an adjustment that would cause its benchmark to be lower than it would have been in the absence of a regional adjustment. Specifically, we are proposing the following approach to calculate and apply the regional adjustment, or the regional adjustment in combination with the prior savings adjustment, if applicable, for ACOs in agreement periods starting on January 1, 2024, and in subsequent years:

- We would continue to calculate the original uncapped regional adjustment by Medicare enrollment type using the applicable percentage phase-in weight based on whether the ACO has lower or higher spending compared to its regional service area and the ACO's agreement period subject to a regional adjustment as described in § 425.656(d).
- We would continue to apply the 5 percent cap on positive regional adjustments and the −1.5 percent cap and offset factor on negative regional adjustments at the enrollment type level, as finalized in the CY 2023 PFS final rule and described in § 425.656(c). For the performance year beginning on January 1, 2025, and subsequent performance years, the national assignable fee-for-service population used to calculate the caps would reflect the revised definition of assignable beneficiary that incorporates the expanded window for assignment as proposed in section III.G.3.a of this proposed rule, if finalized.
- After applying the cap and offset factor (if applicable), we would express the regional adjustment as a single per capita value by calculating a person year weighted average of the Medicare enrollment type-specific regional adjustment values.
- If the ACO's regional adjustment amount (expressed as a single per capita value) is positive, the ACO would receive a regional adjustment, according to the approach we finalized in the CY 2023 PFS final rule. That is, we would apply the enrollment type-specific regional adjustment amounts separately to the historical benchmark expenditures for each Medicare enrollment type. If the ACO is also eligible for a prior savings adjustment, the ACO would receive the higher of the two adjustments. If the regional adjustment amount (expressed as a single per capita value) is higher, we would apply the enrollment type-specific regional adjustment amounts separately to the historical benchmark expenditures for each Medicare enrollment type. If the prior savings adjustment is higher, we would apply the adjustment in the manner finalized in the CY 2023 PFS final rule as a flat dollar amount applied separately to the historical benchmark expenditures for each Medicare enrollment type.
- If the ACO's regional adjustment amount (expressed as a single per capita value) is negative, the ACO would receive no regional adjustment to its benchmark for any enrollment type. If the ACO is eligible for a prior savings adjustment, it would receive the prior savings adjustment as its final adjustment, without any offsetting reduction for the negative regional adjustment.

Under the proposed approach, ACOs that would face a negative overall adjustment to their benchmark based on the methodology adopted in the CY 2023 PFS final rule would benefit, as they would now receive no downward adjustment. Additionally, ACOs that have a negative regional adjustment amount (expressed as a single value) and are eligible for prior savings adjustment under the policy adopted in the CY 2023 PFS final rule (§ 425.658) would also be expected to benefit from the proposed policy. Specifically, these ACOs could receive a larger positive adjustment to their benchmark or a positive adjustment instead of a negative adjustment, as we would no

[191] Lyu P, Chernew M, McWilliams J. Benchmarking Changes And Selective Participation In The Medicare Shared Savings Program. *Health Affairs*. May 1, 2023. Available at *https://www.healthaffairs.org/doi/10.1377/hlthaff.2022.01061*.

longer offset the prior savings amount by the negative regional adjustment amount when determining the final adjustment that would apply to the ACO's benchmark as described in the current regulations in § 425.652(a)(8)(iii)(A).[192] We believe that by increasing the potential benefit of the prior savings adjustment in this manner, our proposed policy would be responsive to the comments discussed in the CY 2023 PFS final rule recommending that CMS make the prior savings adjustment more favorable, particularly for ACOs serving high-risk populations (see 87 FR 69910 through 69914).

[192] For examples of the calculation of the final adjustment when an ACO is eligible for a prior savings adjustment and the overall regional adjustment is negative under the policy adopted in the CY 2023 PFS final rule, please refer to Tables 65 and 66 of the CY 2023 PFS final rule (87 FR 69904 and 69905). In Table 65 the hypothetical ACO receives a positive final adjustment and in Table 66 a negative final adjustment.

Importantly, no ACO would be made worse off under the proposed policy. ACOs that have an overall positive regional adjustment amount would continue to receive the same adjustment to their benchmark as they would under the methodology finalized in the CY 2023 PFS final rule calculated and applied as described in the current regulations at §§ 425.656 and 425.652(a)(8), respectively. For these ACOs, the regional adjustment would continue to reflect the percentage phase-in weight based on whether the ACO has lower or higher spending compared to its regional service area and the ACO's agreement period subject to a regional adjustment as described in § 425.656(d) and we would continue to allow negative adjustments to be applied at the enrollment type level for those ACOs that receive a positive overall regional adjustment. We believe this is appropriate because these ACOs would continue to receive a positive overall adjustment to their benchmark and thus should already have greater incentive to join or continue participation in the program than ACOs that might otherwise face an adjustment that reduces their benchmark.

Tables 37 and 38 present hypothetical examples to demonstrate how we would determine the final adjustment to an ACO's benchmark under the proposed policy. Both tables include two hypothetical ACOs. The first ACO, ACO A, is the same hypothetical ACO as illustrated in Tables 35 and 36 within this section and has an overall negative regional adjustment. The second ACO, ACO B, has an overall positive regional adjustment. Table 37 assumes that both ACOs are ineligible for a prior savings adjustment, whereas Table 38 shows how the calculation would change if both ACOs were eligible for such an adjustment.

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TABLE 37: Hypothetical Examples of the Determination of the Final Adjustment to the Benchmark Assuming ACOs are Not Eligible for a Prior Savings Adjustment

Calculation Step	ACO A: Negative Regional Adjustment	ACO B: Positive Regional Adjustment
Historical benchmark expenditures by enrollment type, before adjustment ($) [A]:		
ESRD	90,000	101,000
Disabled	16,000	12,000
Aged/dual	18,000	19,000
Aged/non-dual	10,000	9,000
Enrollment proportion [B]		
ESRD	0.015	0.005
Disabled	0.190	0.100
Aged/dual	0.100	0.050
Aged/non-dual	0.695	0.845
Regional adjustment by enrollment type, reflecting the applicable phase-in weight and after cap and offset (if applicable) ($) [C]:		
ESRD	932	-1,331
Disabled	-117	158
Aged/dual	258	-210
Aged/non-dual	-105	179
Regional adjustment (expressed as single value) ($) [D] = Sum of [B] x [C]	-55	150
Final adjustment ($) [E]= N/A if [D] is negative, otherwise [D]	N/A	150
Historical benchmark expenditures by enrollment type, after adjustment ($) [F] = [A] if [E] is N/A, otherwise [A] + [C]		
ESRD	90,000	99,669
Disabled	16,000	12,158
Aged/dual	18,000	18,790
Aged/non-dual	10,000	9,179

In Table 37, because ACO A had an overall negative regional adjustment and was not eligible for a prior savings adjustment, the ACO ultimately receives no adjustment, upward or downward, to its benchmark. For ACO B, whose overall regional adjustment is positive, the final adjustment is the regional adjustment, which is applied by adding the regional adjustment specific to each enrollment type (reflecting the percentage weight determined for the ACO and after the application of the cap and offset factor, if applicable) to the ACO's pre-adjustment historical benchmark expenditures for that enrollment type.

TABLE 38: Hypothetical Examples of the Determination of the Final Adjustment to the Benchmark Assuming ACOs are Eligible for a Prior Savings Adjustment

	ACO A: Negative Regional Adjustment	ACO B: Positive Regional Adjustment
Historical benchmark expenditures by enrollment type, before adjustment ($) [A]:		
ESRD	90,000	101,000
Disabled	16,000	12,000
Aged/dual	18,000	19,000
Aged/non-dual	10,000	9,000
Enrollment type proportions [B]		
ESRD	0.015	0.005
Disabled	0.190	0.100
Aged/dual	0.100	0.050
Aged/non-dual	0.695	0.845
Regional adjustment by enrollment type, reflecting the applicable phase-in weight and after cap and offset (if applicable) ($) [C]:		
ESRD	932	-1,331
Disabled	-117	158
Aged/dual	258	-210
Aged/non-dual	-105	179
Regional adjustment (expressed as single value) [D] = Sum of [B] x [C]	-55	150
Prior savings adjustment* ($) [E]	58	239
Final adjustment ($) [F]= [E] if [D] is negative, otherwise higher of [D] or [E]	58	239
Historical benchmark expenditures by enrollment type, after adjustment [G] = [A] + [C] if [E] = [D], otherwise [A] + [E] for each enrollment type		
ESRD	90,058	101,239
Disabled	16,058	12,239
Aged/dual	18,058	19,239
Aged/non-dual	10,058	9,239

*As provided in the proposed new provision at § 425.658(c)(1) of the regulations, the prior savings adjustment would be calculated as the lesser of 50 percent of the pro-rated positive average per capita savings amount, calculated as described in § 425.658(b)(3)(ii), and a cap equal to 5 percent of the national per capita expenditures for assignable beneficiaries in BY3 expressed as a single value by taking a person-year weighted average of the Medicare enrollment-type specific values.

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In Table 38, both ACO A and ACO B are eligible for a prior savings adjustment. Because ACO A has a negative overall regional adjustment, its final adjustment is automatically set equal to the prior savings adjustment of $58. The adjustment is applied as flat dollar amount by adding the $58 to the ACO's historical benchmark expenditures (row [A]) for each enrollment type. For ACO B, by contrast, the final adjustment is determined by comparing the regional adjustment amount (expressed as a single value) to the prior savings adjustment amount and using the higher of the two. In this case the ACO would receive a final adjustment equal to the prior savings adjustment of $239. Like with ACO A, this would be applied to the ACO's historical benchmark expenditures for each enrollment type as a flat dollar amount.

In revisiting simulations done with PY 2020 data described earlier in this section, there were 36 ACOs (of the 43 ACOs with a negative regional adjustment under the policy with the symmetrical cap) simulated to have a negative overall regional adjustment after the application of the cap and offset factor. Among these, 31 would not have been eligible for a prior savings adjustment and would have had this negative regional adjustment applied to their benchmark under the policy adopted in the CY 2023 PFS final rule. Under the new proposed policy, these ACOs would receive no adjustment to their benchmark. The average per capita benefit of eliminating the downward adjustment would be $30.

The remaining five ACOs would have been eligible for the prior savings adjustment. These ACOs would have received a positive final adjustment to their benchmark under the methodology adopted in the CY 2023 PFS final rule but would receive a larger positive adjustment under the new proposed

policy, with an average per capita increase of $26. This is because we would no longer be offsetting the prior savings amount by the negative regional adjustment as part of determining the final adjustment to the ACO's benchmark as would happen under the methodology finalized in the CY 2023 PFS final rule and codified at § 425.652(a)(8)(iii)(A).

In the PY 2022 simulation described earlier in this section, there were 26 ACOs (of the 27 ACOs with a negative regional adjustment under the policy with the symmetrical cap) that would have had a negative regional adjustment, expressed as a single per capita value, after the application of the policy adopted in the CY 2023 PFS final rule. Among these, 14 ACOs would not have been eligible for a prior savings adjustment and would have their full negative regional adjustment eliminated under the new proposed policy, with an average impact of $66. The remaining 12 ACOs that would have been eligible for a prior savings adjustment would see a larger positive adjustment under the proposed policy, with an average increase of $14.

Overall, we believe that the proposed changes to the calculation and application of the regional adjustment, including its interaction with the prior savings adjustment, would strengthen incentives for participation among ACOs that might otherwise be subject to a downward adjustment to their benchmark due to the negative regional adjustment. The proposed policy, if finalized, would not adversely impact any ACO's benchmark relative to the policy that was finalized in CY 2023 PFS final rule, all else being equal, but would tend to increase benchmarks for ACOs that have historically had higher spending than their regional service area. Based on our simulations using data from PY 2020 and PY 2022, the estimated average increase to the overall benchmark would be between 0.2 and 0.4 percent but could be larger in future years when more ACOs would be subject to higher phase-in weights for calculating the negative regional adjustment that would apply (alone or in combination with the prior savings adjustment) under the policy adopted in the CY 2023 PFS final rule. ACOs that would benefit from the proposed policy are likely to include those that serve high-cost, medically complex patients or those whose ACO participants have historically been less efficient than their regional counterparts but may have the potential to generate the greatest savings to Medicare through their participation in the Shared Savings Program.

We propose to implement the changes described in this section through revisions to §§ 425.652, 425.656, and 425.658. Specifically, within § 425.652, which is the section that sets forth the methodology for establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years, we propose revisions to § 425.652(a)(8). As revised, this provision would describe how we would determine and apply the adjustment to an ACO's benchmark depending on whether the ACO is eligible for a prior savings adjustment and whether the ACO's regional adjustment, expressed as a single value, is positive or negative. This provision would also establish that if an ACO is not eligible to receive a prior savings adjustment and has a regional adjustment, expressed as a single value that is negative or zero, the ACO will not receive an adjustment to its benchmark.

We propose to revise § 425.656 (which describes the calculation of the regional adjustment) and § 425.658 (which describes the calculation of the prior savings adjustment) to include certain elements of each calculation that were previously described in § 425.652(a)(8). Specifically, we propose to revise § 425.656 to redesignate paragraphs (d) and (e) as paragraphs (e) and (f) (respectively) and to specify in a new paragraph (d) that we would express the regional adjustment as a single value, and use this value in determining whether a regional adjustment or a prior savings adjustment would be applied to the ACO's benchmark in accordance with § 425.652(a)(8) (as revised under this proposed rule). We also propose modifications to update certain cross-references within § 425.656 for accuracy and consistency with the proposed revisions to the section.

We propose to revise § 425.658 to redesignate paragraph (c) as paragraph (d). We propose to add a new paragraph (c) under § 425.658 specifying that we would calculate the per capita savings adjustment as the lesser of 50 percent of the pro-rated average per capita savings amount (computed as described in § 425.658(b)(3)(ii)) and the cap equal to 5 percent of national per capita FFS expenditures for assignable beneficiaries for BY3 expressed as a single value by taking a person-year weighted average of the Medicare enrollment-type specific values. We propose to revise newly redesignated paragraph (d) of § 425.658 to specify CMS would compare the per capita prior savings adjustment with the regional adjustment, expressed as a single value as described in § 425.656(d), to determine the adjustment, if any, that would be applied to the ACO's benchmark in accordance with § 425.652(a)(8).

Additionally, we propose to make the following conforming changes:

- In § 425.600(f)(4)(ii), we propose to remove the reference ''425.656(d)'' and add in its place the reference ''425.656(e)''.
- In § 425.611(c)(2)(iii), we propose to remove the reference ''§ 425.652(a)(8)(iv)'' and add in its place the reference ''§ 425.658(c)(1)(ii)''.
- In § 425.652(a)(9)(v), we propose to remove the wording that references CMS redetermining the adjustment to the benchmark based on ''a combination of'' the redetermined regional adjustment and the prior savings adjustment.
- In § 425.658(b)(3)(i), which specifies that the ACO is not eligible to receive an adjustment for prior savings if the average per capita amount computed in § 425.658(b)(2) is less than or equal to zero, we propose to remove the sentence: ''The ACO will receive the regional adjustment to its benchmark as described in § 425.656.''

We seek comment on these proposed changes.

d. Proposal To Modify the Prior Savings Adjustment

(1) Background

Under section 1899(d)(1)(B)(ii) of the Act, an ACO's benchmark must be reset at the start of each agreement period using the most recent available 3 years of expenditures for Parts A and B services for beneficiaries assigned to the ACO. Section 1899(d)(1)(B)(ii) of the Act provides the Secretary with discretion to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate.'' Pursuant to this authority, as described in the CY 2023 PFS final rule (87 FR 69898 through 69915), we established a prior savings adjustment that will apply when establishing the benchmark for ACOs entering a second agreement period beginning on January 1, 2024, or in subsequent years, to account for the average per capita amount of savings generated during the ACO's prior agreement period.

The prior savings adjustment adopted in the CY 2023 PFS final rule is designed to adjust an ACO's benchmark to account for the average per capita amount of savings generated by the ACO across the 3 performance years prior to the start of its current agreement period for new and renewing ACOs. In the final rule, we explained that reinstituting a prior savings adjustment would be

broadly in line with our interest in addressing dynamics to ensure sustainability of the benchmarking methodology. Specifically, such an adjustment would help to mitigate the rebasing ratchet effect on an ACO's benchmark by returning to an ACO's benchmark an amount that reflects its success in lowering growth in expenditures while meeting the program's quality performance standard in the performance years corresponding to the benchmark years for the ACO's new agreement period. We also explained our belief that a prior savings adjustment could help address an ACO's effects on expenditures in its regional service area that result in reducing the regional adjustment added to the historical benchmark.

In the CY 2023 PFS final rule, we explained that, in order to mitigate the potential for rebased benchmarks for ACOs that are lower-spending compared with their regional service area and that achieved savings in the benchmark period to become overinflated, we believed that adjusting an ACO's benchmark based on the higher of either the prior savings adjustment or the ACO's positive regional adjustment would be appropriate. Additionally, we believed it would be appropriate to use a prior savings adjustment to offset negative regional adjustments for ACOs that are higher spending compared to their regional service area. We noted that this would permit ACOs that are subject to a negative regional adjustment, but that have generated savings in prior years, to receive a relatively higher benchmark.

Under the methodology finalized in the CY 2023 PFS final rule and codified at § 425.658 of the regulations, the prior savings adjustment that will apply in the establishment of benchmarks for renewing ACOs and re-entering ACOs entering an agreement period beginning on January 1, 2024, and in subsequent years, is calculated as follows:

- *Step 1:* Calculate total per capita savings or losses in each performance year that constitutes a benchmark year for the current agreement period. For each performance year we will determine an average per capita amount reflecting the quotient of the ACO's total updated benchmark expenditures minus total performance year expenditures divided by performance year assigned beneficiary person years. CMS will apply the following requirements in determining the amount of per capita savings or losses for each performance year:

++ The per capita savings or losses will be set to zero for a performance year if the ACO was not reconciled for the performance year.

++ If an ACO generated savings for a performance year but was not eligible to receive a shared savings payment for that year due to noncompliance with Shared Savings Program requirements, the per capita savings for that year will be set to zero.

++ For a new ACO that is identified as a re-entering ACO, per capita savings or losses will be determined based on the per capita savings or losses of the ACO in which the majority of the ACO participants in the re-entering ACO were participating.

- *Step 2:* Calculate average per capita savings. Calculate an average per capita amount of savings by taking a simple average of the values for each of the 3 performance years as determined in Step 1, including values of zero, if applicable. CMS will use the average per capita amount of savings to determine the ACO's eligibility for the prior savings adjustment as follows:

++ If the average per capita value is less than or equal to zero, the ACO will not be eligible for a prior savings adjustment. The ACO will receive the regional adjustment to its benchmark.

++ If the average per capita value is positive, the ACO will be eligible for a prior savings adjustment.

- *Step 3:* Apply a proration factor to the per capita savings calculated in Step 2 equal to the ratio of the average person years for the 3 performance years that immediately precede the start of the ACO's current agreement period (regardless of whether these 3 performance years fall in one or more prior agreement periods), and the average person years in benchmark years for the ACO's current agreement period, capped at 1. If the ACO was not reconciled for one or more of the 3 years preceding the start of the ACO's current agreement period, the person years from that year (or years) will be excluded from the averages in the numerator and the denominator of this ratio. For a new ACO that is identified as a re-entering ACO, the person years of the ACO in which the majority of the ACO participants of the re-entering ACO were participating will be used in the numerator of the calculation. This ratio will be redetermined for each performance year during the agreement period in the event of any changes to the number of average person years in the benchmark years as a result of changes to the ACO's certified ACO participant list, a change to the ACO's beneficiary assignment methodology selection, or changes to the beneficiary assignment methodology.

- *Step 4:* Determine final adjustment to benchmark. Compare the pro-rated positive average per capita savings from Step 3 with the ACO's regional adjustment, determined as specified in the regulation at § 425.656, expressed as a single per capita value by taking a person-year weighted average of the Medicare enrollment type-specific regional adjustment values.

++ If the regional adjustment, expressed as a single value, is negative or zero, calculate the sum of the regional adjustment value and the pro-rated positive average per capita savings value and determine the final adjustment as follows:

-- If the sum is positive, the ACO will receive a prior savings adjustment in place of the negative regional adjustment equal to the lesser of 50 percent of the sum of the pro-rated average per capita savings and the regional adjustment and 5 percent of national per capita FFS expenditures for Parts A and B services under the original Medicare FFS program in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3. The adjustment will be applied as a flat dollar amount to the historical benchmark expenditures for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

--If this sum is negative, this will constitute the amount of the negative regional adjustment applied to the ACO's historical benchmark. The adjustment will be applied as a flat dollar amount to the historical benchmark expenditures for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

++ If the regional adjustment, expressed as a single value, is positive, the ACO will receive an adjustment to the benchmark equal to the higher of the following:

-- The positive regional adjustment amount. The adjustment will be applied separately to the historical benchmark expenditures for each of the following populations of beneficiaries in accordance with § 425.656(c): ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

-- A prior savings adjustment equal to the lesser of 50 percent of the pro-rated positive average per capita savings value and 5 percent of national per capita FFS

expenditures for Parts A and B services in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3. The adjustment will be applied as a flat dollar amount to the historical benchmark expenditures for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

As we explained in the CY 2023 PFS final rule (87 FR 69900) in calculating an ACO's average per capita prior savings over the 3 performance years immediately preceding the start of its agreement period, we believe that a safeguard is needed to ensure that ACOs that achieved savings for a performance year that serves as a benchmark year for the current agreement period, but were ineligible to receive a shared savings payment due to noncompliance with Shared Savings Program requirements, are not subsequently eligible to have a portion of those savings included in their historical benchmark. Without such a safeguard, we would be rewarding an ACO, despite its noncompliance, through a higher benchmark in its subsequent agreement period. This would conflict with the sanction imposed on the ACO for its noncompliance during the performance year(s) of its prior agreement period. Accordingly, under the prior savings adjustment policy we finalized in the CY 2023 PFS final rule, if an ACO was ineligible to share in savings for any performance year in the 3 performance years immediately preceding the start of its agreement period due to noncompliance with Shared Savings Program requirements, we will set at zero the per capita amount of savings for the affected performance year(s) when calculating the prior savings adjustment.

There are a variety of reasons that could result in an ACO's ineligibility to receive a shared savings payment due to noncompliance. In accordance with §§ 425.605(c)(2), and 425.610(c)(2), an ACO does not qualify to receive shared savings for a performance year if it failed to meet the quality performance standard as specified under § 425.512 or otherwise did not maintain its eligibility to participate in the Shared Savings Program. Furthermore, an ACO will not receive any shared savings payments during the time it is under a corrective action plan (CAP) for avoidance of at-risk beneficiaries and is not eligible to receive shared savings for the performance year attributable to the time that necessitated the CAP (the time period during which the ACO avoided at-risk beneficiaries) (refer to § 425.316(b)(2)(ii)(B) and (C)).

In the CY 2023 PFS rulemaking to establish the current prior savings adjustment, we did not describe how we would account for certain circumstances where there could be changes to the values used in calculating the prior savings adjustment. Such changes could occur as a result of changes in savings earned by ACOs in accordance with § 425.316(b)(2)(ii)(B) or (C) as a result of a compliance action to address avoidance of at-risk beneficiaries or issuance of a revised initial determination of financial performance under § 425.315. If CMS determines that an ACO, its ACO participants, any ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities avoids at-risk beneficiaries and requires the ACO to submit a CAP, the ACO will not receive any shared savings payments during the time it is under the CAP (§ 425.316(b)(2)(ii)(B)), and it will not at any time be eligible to receive shared savings for the performance year attributable to the time that necessitated the CAP (§ 425.316(b)(2)(ii)(C)). Upon completion of an ACO's CAP for avoidance of at-risk beneficiaries, CMS may release shared savings payments withheld from an ACO during the time it was under a CAP under § 425.316(b)(2)(ii)(B), so long as the shared savings are not attributable to the time that necessitated the CAP (that is, the time period during which the ACO avoided at-risk beneficiaries). Thus, depending on the timing of compliance actions undertaken by CMS, the amount of savings eligible for inclusion in the prior savings adjustment under § 425.658(b)(1), may change as a result of the compliance action. For instance, the total savings eligible for inclusion in the prior savings adjustment may increase after the completion of a CAP and release of shared savings payment withheld under § 425.316(b)(2)(ii)(B). Further, if an initial determination of financial performance was already made and shared savings payments distributed and then the ACO was found to have avoided at-risk beneficiaries and therefore ineligible to receive a shared savings payment for the performance year, CMS would recoup the shared savings for the time period during which the ACO avoided at-risk beneficiaries. This latter scenario would result in a decrease in the total amount of savings eligible for inclusion in the prior savings adjustment calculation.

Further, if CMS determines that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO has been calculated in error, under § 425.315 CMS may reopen its prior determination and issue a revised initial determination: (1) at any time in the case of fraud or similar fault as defined in § 405.902; or (2) not later than 4 years after the date of the notification to the ACO of the initial determination of savings or losses for the relevant performance year, for good cause. If these situations—changes in the amount of shared savings for a prior performance year under § 425.316(b)(2)(ii)(B) or (C) as a result of a compliance action due to the avoidance of at-risk beneficiaries, or the issuance of a revised initial determination based on a reopening of ACO shared savings or shared losses under § 425.315—impact one of the 3 years prior to the start of the ACO's current agreement period, it is possible that the prior savings adjustment would no longer reflect the savings or losses achieved by the ACO during the applicable years. In the CY 2023 PFS rulemaking we did not adopt a mechanism to account for these changes in the prior savings adjustment, but rather focused on changes to the prior savings adjustment related to changes in an ACO's participant list, changes to the ACO's assignment methodology selection, or changes to beneficiary assignment methodology under the Shared Savings Program as a whole.

(2) Proposed Revisions

We are proposing refinements to the prior savings adjustment calculation methodology, specified in 42 CFR part 425, subpart G, that would apply in the establishment of benchmarks for renewing ACOs and re-entering ACOs entering an agreement period beginning on January 1, 2024, and in subsequent years, to account for circumstances where the amount of savings or losses for a performance year used in the prior savings adjustment calculation changes retroactively. Specifically, we are proposing to modify the list of circumstances for adjusting the historical benchmark in § 425.652(a)(9) to include two additional scenarios: a change in savings earned by an ACO in a benchmark year in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries, or a change in the amount of savings or losses for a benchmark year as a result of a reopening of a prior determination of ACO shared savings or shared losses and the issuance of a revised initial determination under § 425.315. In these situations, the amount of savings or losses that an ACO may have generated in the 3 performance years prior to the

start of the current agreement period and that would have been eligible for inclusion in the calculation of the prior savings adjustment may change. The refinements we are proposing would allow for the prior savings adjustment to be recalculated and the historical benchmark to be adjusted to reflect the any change in the amount of savings earned or losses incurred by the ACO in the 3 performance years prior to its current agreement period that are eligible for inclusion in the calculation of the prior savings adjustment.

We are proposing to modify the process currently described in § 425.652(a)(9) for adjusting the historical benchmark. Currently, an ACO may receive an adjusted historical benchmark because of changes in the ACO's assigned beneficiary population in the benchmark years of the ACO's current agreement period due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1),[193] or changes to the beneficiary assignment methodology specified in 42 CFR part 425, subpart E. We are proposing to modify § 425.652(a)(9) to indicate that an ACO would receive an adjusted historical benchmark for changes in values used in benchmark calculations in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315. More specifically, an ACO would receive an adjusted benchmark for the following reasons: (1) a change in the amount of savings calculated for any of an ACO's three benchmark years eligible for inclusion in the prior savings adjustment in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action taken to address avoidance of at-risk beneficiaries, or (2) CMS issues a revised initial determination under § 425.315 that impacts the amount of savings or losses calculated for one of the ACO's benchmark years. We note that a compliance action taken to address avoidance of at-risk beneficiaries may lead to a change in the amount of savings earned by an ACO for a previous performance year when CMS releases savings previously withheld under § 425.316(b)(2)(ii)(B) for a time period other than the time period during which the ACO avoided at-risk beneficiaries following completion of a CAP or CMS recoups shared savings previously disbursed to an ACO under § 425.316(b)(2)(ii)(C) for a time period during which the ACO is later determined to have avoided at-risk beneficiaries.

Only ACOs whose current benchmark includes a prior savings adjustment or whose benchmark would include an adjustment for prior savings following a change in the amount of savings earned for a previous performance year that is a benchmark year for the ACO's current agreement period would receive an adjusted benchmark under these proposed changes. Furthermore, we propose to modify the process currently described in § 425.652(a)(9) to indicate that if either of these two conditions occur after the ACO has already received its historical benchmark for the first performance year of its agreement period, an ACO could receive an adjusted historical benchmark for the first year of its agreement period.

We are also proposing to add a new paragraph (e) to § 425.658 to indicate that, when either of the two aforementioned scenarios occurs, the prior savings adjustment itself would be recalculated. Without this addition there is currently no mechanism for recalculating the prior savings adjustment to address changes in ACO's savings or losses for a performance year within an agreement period. Further, we are proposing that, absent any other triggers for receiving an adjusted benchmark, an ACO would only receive an adjusted historical benchmark due to a change in the ACO's savings or losses for a performance year under §§ 425.315 or 425.316(b)(2)(ii)(B) or (C) if the change would result in a change to the prior savings adjustment as determined under § 425.652(a)(8). In other words, the ACO would not receive an adjusted historical benchmark following recalculation of the prior savings adjustment if the recalculation of the prior savings adjustment would not result in a change to the historical benchmark.

We believe that, in order to issue adjusted benchmarks and complete financial reconciliation in a timely fashion, a need exists to establish a timing cutoff for when the determination to issue an adjusted historical benchmark for these two additional reasons would be made. Each of the two scenarios for which we are proposing to recalculate the prior savings adjustment may occur at any point during any performance year of the ACO's agreement period as well as after the end of that agreement period. We are proposing that for an adjusted benchmark due to the two conditions being considered to be used in financial reconciliation for a performance year, any determination that changes the amount of the ACO's savings or losses in any of the benchmark years under §§ 425.315 or 425.316(b)(2)(ii)(B) or (C) must be issued no later than the date of the initial determination of shared savings or shared losses through financial reconciliation for the relevant performance year under § 425.605(e) or § 425.610(h). Note that if we are aware of a potential change under § 425.316(b)(2)(ii)(B) or (C) in the savings earned in a benchmark year by an ACO eligible for the prior savings adjustment or an upcoming revised initial determination under § 425.315 that could impact the determination of the ACO's savings or losses for a benchmark year, we may delay the initial determination of shared savings or shared losses for the ACO for the relevant performance year beyond when initial determinations would otherwise be issued in order to assess whether the ACO should receive an adjusted historical benchmark. Under this framework, changes to savings or losses for a benchmark year that are finalized after notification to the ACO of the initial determination of shared savings or shared losses for a given performance year would be reflected in the adjusted benchmark applied to the subsequent performance year during the relevant agreement period but would not be retroactively applied to completed performance years in the agreement period.

We considered several alternatives to the timing of when we could incorporate new information about a change in savings earned by an ACO in accordance with § 425.316(b)(2)(ii)(B) or (C) or a revised initial determination under § 425.315 into the prior savings adjustment. The two primary alternatives we considered were: (1) requiring information about a change to the amount of savings calculated for a previous year in accordance with § 425.316(b)(2)(ii)(B) or (C) or a revised initial determination under § 425.315 to become available by December 31st of the year prior to the performance year; and (2) considering this information at any time it becomes available. An advantage of the former option of requiring information by December 31st is that it would allow us to issue the adjusted benchmark in March of the performance year, consistent with when adjusted benchmarks are otherwise issued to ACOs. A disadvantage of this approach is that it would provide less

[193] Refer to section III.G.7.a of this proposed rule for the proposal to revise the current reference to § 425.400(a)(4)(ii) in § 425.652(a)(9)(iv) to a reference to § 425.226(a)(1).

flexibility for when new information impacting savings or losses in the benchmark years could be applied to the benchmark used in financial reconciliation for a given performance year. An advantage of the latter approach of considering such information at any time that it becomes available is that an ACO could receive an adjusted benchmark and a revised initial determination of shared savings or shared losses even after receiving its initial determination for a performance year. However, a disadvantage of this approach is that it would generate significant operational complexities. If, for instance, information becomes available during performance year four of an ACO's agreement period that would potentially impact financial reconciliation results in the first 3 performance years of the agreement period, we would need to simultaneously issue adjusted benchmarks and revised initial determinations for several performance years. On balance, we believe it would be appropriate to consider new information that could impact the prior savings adjustment up to the point at which an ACO receives its initial determination for a particular performance year. We note that we are continuing to consider the complexities surrounding reopening initial determinations for multiple prior performance years throughout the program's benchmarking and financial reconciliation methodologies and may address this issue in future rulemaking.

We recognize that under § 425.658(b)(1)(iii), for a new ACO identified as re-entering ACO, the prior savings adjustment is based on the prior savings or losses of the ACO in which the majority of the ACO's ACO participants were participating. Accordingly, in the case of a re-entering ACO, we propose to consider whether this prior ACO is impacted by the following when determining whether to issue an adjusted benchmark: (1) a change in the amount of savings calculated for any of the ACO's benchmark years eligible for inclusion in the prior savings adjustment in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries; or (2) a revised initial determination issued under § 425.315 that impacts the determination of the ACO's savings or losses for one of the benchmark years. In this case, other aspects of this proposal would apply similarly, including the timing cutoff for issuing an adjusted benchmark and issuing an adjusted benchmark only if the change in savings or losses determined for the applicable benchmark year would result in a change to the prior savings adjustment as determined under § 425.652(a)(8).

Below are two examples that illustrate how an ACO could receive an adjusted historical benchmark that incorporates additional savings as a result of the changes we are proposing.

- *Example 1:* An ACO renews to begin a new agreement period on January 1, 2025 but is under a corrective action plan under § 425.316(b) for avoidance of at-risk beneficiaries during performance year 2023. In accordance with § 425.316(b)(2)(ii)(B) the ACO did not receive a shared savings payment for performance year 2024, which represents the third benchmark year of its new agreement period. Therefore, the ACO's prior savings adjustment for its new agreement period would be calculated by setting the gross savings and losses for the third benchmark year equal to 0 as described in § 425.658(b)(1)(ii). However, in November of 2026 the corrective action plan for avoidance of at-risk beneficiaries is closed and CMS determines that the ACO is eligible to receive payment for shared savings for performance year 2024. In this example, the ACO would have previously received notification of the initial determination of shared savings or shared losses for performance year 2025. Because the change in the status of the corrective action plan occurred after the ACO received its initial determination of shared savings and shared losses for performance year 2025, savings from the ACO's third benchmark year would be included in the calculation of the prior savings adjustment beginning with the benchmark used to determine financial performance for performance year 2026. That is, the ACO would receive an adjusted historical benchmark for performance year 2026 reflecting the recalculated prior savings adjustment, and financial reconciliation for performance year 2026 and subsequent performance years of the ACO's current agreement period would reflect that adjusted historical benchmark. However, financial reconciliation for performance year 2025 would not be reopened to reflect savings from the third benchmark year in the calculation of the prior savings adjustment because the corrective action plan was not lifted until after the ACO received its initial determination of shared savings or shared losses for that performance year.
- *Example 2:* An ACO begins a new agreement period on January 1, 2026, and receives its historical benchmark, which includes a prior savings adjustment. In February of 2027, information is identified that leads to a revised initial determination of shared savings and shared losses for benchmark year 2 of the ACO's new agreement period. Because the issue was identified in February of the second performance year of the new agreement period, which is prior to the ACO receiving an initial determination of its shared savings and shared losses for performance year 2026, the ACO would receive an adjusted historical benchmark for performance year 2026. Shared savings and shared losses calculations for performance year 2026 would reflect the recalculated prior savings adjustment included in this adjusted benchmark. All subsequent performance years in the agreement period would also reflect the recalculated prior savings adjustment.

In summary, we are proposing revisions to § 425.652(a)(9) to indicate that we would adjust the benchmark for changes in values used in benchmark calculations in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of the issuance of a revised initial determination under § 425.315. We are also proposing to add new paragraph (e) to § 425.658 to specify that the ACO's prior savings adjustment is recalculated for changes to the ACO's savings or losses for a performance year used in the prior savings adjustment calculation in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315. Further, the new provision § 425.658(e) would also establish that for new re-entering ACOs, the prior savings adjustment will be recalculated for changes in savings or losses for a performance year used in the prior savings adjustment for the ACO in which a majority of the new ACO's ACO participants were previously participating.

We seek comment on this proposal to adjust the historical benchmark to reflect changes in savings or losses for a performance year that constitutes a benchmark year for an ACO's current agreement period. These changes would be applicable for agreement periods beginning on or after January 1, 2024.

e. Proposal To Update How Benchmarks Are Risk Adjusted

(1) Overview of Risk Adjustment Within Shared Savings Program Benchmark Calculations

When establishing, adjusting, and updating an ACO's historical benchmark, CMS makes certain adjustments to account for the severity and case mix of, and certain demographic factors for, the ACO's assigned beneficiary population and the assignable beneficiary population. We use prospective HCC risk scores and (as applicable) demographic risk scores to perform this risk adjustment.

To follow is a summary of the calculations in which we will account for the severity and case mix of the ACO's assigned beneficiary population or the assignable beneficiary population when establishing, adjusting, and updating the historical benchmark, for agreement periods beginning on January 1, 2024, and in subsequent years, including as proposed elsewhere in this proposed rule.

- We risk adjust benchmark year expenditures used to establish the historical benchmark for changes in severity and case mix using prospective HCC risk scores, in accordance with § 425.652(a)(3). In making this adjustment, we account for changes in severity and case mix in the ACO's assigned beneficiary population between the first and third benchmark years and between the second and third benchmark years.[194]
- We calculate the ACO's regional FFS expenditures using risk adjusted county-level FFS expenditures, which are determined in accordance with § 425.654(a)(4) by adjusting FFS expenditures for severity and case mix of assignable beneficiaries in the county using prospective HCC risk scores and by making separate expenditure calculations for populations of beneficiaries by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries). The ACO's risk adjusted regional FFS expenditures are utilized in determining the regional adjustment to the historical benchmark (in accordance with § 425.656), the regional component of the national-regional blended trend factor (in accordance with § 425.652(a)(5)), and the regional component of the three-way blended benchmark update factor (in accordance with § 425.652(b)(2)).
- We calculate the regional adjustment to the historical benchmark in accordance with § 425.656, including the following calculations to account for severity and case mix:

++ We adjust for differences in severity and case mix between the ACO's assigned beneficiary population for BY3 and the assignable population of beneficiaries for the ACO's regional service area for BY3 in accordance with § 425.656(b)(3).

++ In calculating the negative regional adjustment, we apply an offset factor based on the ACO's overall proportion of BY3 assigned beneficiaries who are dually eligible for Medicare and Medicaid (including dually eligible ESRD, disabled, and aged beneficiaries) and the ACO's weighted average prospective HCC risk score for BY3 taken across the four Medicare enrollment types, in accordance with § 425.656(c)(4).

- We adjust the ACO's historical benchmark to account for changes in severity and case mix in the ACO's assigned beneficiary population between BY3 and the performance year in accordance with §§ 425.652(a)(10), 425.605(a)(1) and (2) (BASIC track), and 425.610(a)(2) and (3) (ENHANCED track), at the time of financial reconciliation for a performance year. We use prospective HCC risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries between BY3 and the performance year, with positive adjustments subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year plus 3 percentage points (refer to §§ 425.605(a)(1)(ii) and 425.610(a)(2)(ii), and section III.G.4.b.(1) of this proposed rule).
- In calculating the regional component of the three-way blended update factor, we are proposing to cap prospective HCC risk score growth in an ACO's regional service area between BY3 and the performance year by applying an adjustment factor, as discussed in section III.G.4.b.(2) of this proposed rule and the proposed new provision at § 425.655.
- We adjust the flat dollar amounts of the ACPT component of the three-way blended update factor for each performance year, for differences in severity and case mix between the ACO's BY3 assigned beneficiary population and the national assignable FFS population for each Medicare enrollment type identified for the 12-month calendar year corresponding to BY3, in accordance with § 425.660(b)(4).

(2) Background on Calculation of Prospective HCC Risk Scores Used To Risk Adjust Shared Savings Program Benchmark Calculations

(a) Historical Practices

We have detailed how CMS performs Shared Savings Program risk adjustment calculations in programmatic material, including publicly available specifications documents. See, for example, Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version #11, January 2023), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2* (see section 3.6, ''Risk Adjustment Policies''). While we have specified the details of these practices in guidance, we have not previously codified these practices in regulation.

More generally, CMS maintains the CMS–HCC risk adjustment models for the Medicare Advantage (MA) program. CMS maintains CMS–HCC risk adjustment models for populations of beneficiaries based on age, disability status, gender, institutional status, eligibility for Medicaid, and health status (see section 1853(a)(1)(C)(i) of the Act), including a separate MA risk adjustment model for the ESRD population, and a Part D risk adjustment model (known as the RxHCC model). Over time, CMS has implemented revised versions of the CMS–HCC risk adjustment models (also referred to generally as the ''CMS–HCC model''). Historically, transitions to a revised version of the CMS–HCC model have been gradually phased-in over time by blending the old risk adjustment model and the revised risk adjustment model. CMS specifies the CMS–HCC risk adjustment models applicable for a calendar year in the annual MA Rate Announcement (see sections 1853(a)(1)(C) and (b)(1) of the Act). Prior to doing so, CMS solicits comment on the CMS–HCC risk adjustment methodology (see section 1853(b)(2) of the Act). Using the specified model, or blend of models (if applicable), CMS calculates prospective HCC risk scores for all Medicare beneficiaries, including FFS beneficiaries. These prospective HCC risk scores are then used to set MA capitation rates and Part C and D payment policies for the applicable calendar year.

[194] See, for example, Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version #11, January 2023), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2* (see section 3.6, ''Risk Adjustment Policies'').

To perform risk adjustment calculations for the Shared Savings Program, we calculate prospective HCC risk scores for Medicare FFS beneficiaries for the relevant benchmark year or performance year. In doing so, we use the CMS–HCC risk adjustment model(s) that are applicable for the particular calendar year corresponding to the benchmark or performance year to identify a Medicare FFS beneficiary's prospective HCC risk score for that benchmark or performance year. Prospective HCC risk scores used in financial calculations for the Shared Savings Program have the MA coding pattern adjustment of 5.90 percent removed, if applicable.[195] Additionally, all prospective HCC risk scores are renormalized by Medicare enrollment type based on a national assignable FFS population to ensure that the mean risk score among assignable beneficiaries is equal to one. Renormalization helps to ensure consistency in risk scores from year to year, given changes made to the underlying risk score models. All risk adjustment calculations for the Shared Savings Program, including risk score renormalization, are performed separately for each Medicare enrollment type for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible for Medicare and Medicaid, aged/non-dual eligible for Medicare and Medicaid.[196]

Under the Shared Savings Program, we calculate demographic only risk scores using a separate model than those used to calculate prospective HCC risk scores. For agreement periods beginning on January 1, 2024 and subsequent years, CMS will use demographic risk scores to determine the cap on risk score growth between BY3 and the performance year. Demographic risk scores consider only certain specified patient demographic factors, such as age, sex, Medicaid status, and the basis for Medicare entitlement (that is, age, disability, or ESRD), without incorporating diagnostic information. As such, demographic risk scores are not subject to changes in coding intensity or coding accuracy in the same way that prospective HCC risk scores are. We note that while the Shared Savings Program uses the same demographic factors as those used in MA, Shared Savings Program demographic factor coefficients are calibrated based on the entire Medicare FFS population instead of new Medicare enrollees as is used by MA.

Currently, when establishing, adjusting, and updating the benchmark, we account for changes in severity and case mix between benchmark years or between BY3 and the performance year by multiplying the expenditures for the applicable year by a quotient of two ACO-level renormalized risk scores, known as the risk ratio. For example, to risk adjust the expenditures for an ACO's assigned beneficiary population to account for changes in case mix and severity from the first benchmark year to the third, we multiply BY1 expenditures by a risk ratio equal to the mean renormalized risk score among the ACO's assigned beneficiaries in BY3 divided by the mean renormalized risk score among the ACO's assigned beneficiaries in BY1 for each Medicare enrollment type. For instance, a one percent rate of growth in renormalized risk scores between these benchmark years would be expressed by a risk ratio of 1.010. This ratio reflects growth in risk for the ACO's assigned beneficiary population relative to that of the national assignable population. Because the risk ratios used in benchmarking calculations may be determined using risk scores calculated from different underlying CMS–HCC risk adjustment models, depending on the CMS–HCC risk adjustment model(s) applicable to the corresponding benchmark or performance year, this approach allows for the possibility that differences in risk models between the benchmark years and the performance year could impact an ACO's financial performance.

Since the inception of the Shared Savings Program in 2012, there have been several CMS–HCC model changes. Several factors reduce the impact of using different risk adjustment models to calculate prospective HCC risk scores for benchmark and performance years when performing Shared Savings Program risk adjustment calculations. One factor is that the Shared Savings Program renormalizes prospective HCC risk scores by Medicare enrollment type, which ensures that the mean risk score for the national assignable FFS population for each enrollment type is equal to one. If a new CMS–HCC model leads to a shift in the mean of the distribution of prospective HCC risk scores for the national assignable FFS population for a particular Medicare enrollment type, then renormalizing the risk scores would counterbalance this effect. Because renormalization factors are calculated across the assignable beneficiary population for each enrollment type, any adverse or beneficial impact for an ACO from a change in CMS–HCC model would derive from the mean risk score for the ACO's assigned beneficiaries within a given enrollment type being impacted in a systematically different way than the mean for the national assignable population for that enrollment type.

A second factor is that risk scores are used in multiple ways that balance their effects when establishing, adjusting or updating a benchmark. Risk scores are used to adjust ACO expenditures and also to adjust regional expenditures used in calculating the regional adjustment to the benchmark and regional growth rates in benchmark calculations. Any impact of a new CMS–HCC model that could increase or decrease an ACO's risk scores used to establish, adjust or update a benchmark may differ directionally from the impact that risk scores for the assignable FFS population in an ACO's regional service area might have on risk-adjusted regional expenditure calculations. For example, if a new CMS–HCC model lowers the risk ratio between BY3 and the PY and therefore lowers the benchmark for an ACO, all else equal, then the new risk adjustment model may also lower the risk scores for the ACO's regional service area assignable beneficiary population, which would increase risk-adjusted regional expenditures.[197] This would put upward pressure on the benchmark by increasing the regional update factor. Any changes to the ACO's risk ratio may be thus reduced by changes to the ACO's regional update factor. This would reduce the impact of CMS–HCC model changes on ACO financial performance.

A third factor is that CMS–HCC model transitions have been gradually phased-in over time by blending the old risk adjustment model and the new risk adjustment model, thereby constraining the magnitude of any change in risk ratios resulting from differences in the risk adjustment models used to calculate prospective HCC risk scores.

[195] The MA risk adjustment models used for beneficiaries classified as ESRD for the Shared Savings Program (that is, beneficiaries in long-term dialysis or transplant status, no more than three months post-graft) do not currently employ a coding intensity adjustment, therefore no adjustment is currently removed from risk scores for beneficiaries in the ESRD enrollment type.

[196] A beneficiary's final risk score for each month is the risk score determined for that beneficiary based on the beneficiary's risk adjustment model status for that month. There are risk adjustment models for MA subpopulations (for example, community model versus institutional model versus new enrollee model for aged/non-dual eligible beneficiaries), and the risk scores used by the Shared Savings Program for beneficiaries in a Medicare enrollment type may be derived from more than one risk adjustment model.

[197] For each county and Medicare enrollment type (ESRD, disabled, aged/dual eligible, and aged/non-dual eligible) in the ACO's regional service area, CMS divides average per capita county-level FFS expenditures by the county average renormalized CMS–HCC risk score to obtain risk-adjusted county expenditures.

That is, as a result of this blending, the risk ratios used to adjust expenditures between BY3 and the PY may have some degree of overlap in underlying risk adjustment models used to calculate both the numerator and denominator of the risk ratios.

(b) Introduction of the 2024 CMS–HCC Risk Adjustment Model, Version 28

On March 31, 2023, CMS released the Announcement of CY 2024 MA Capitation Rates and Part C and Part D Payment Policies,[198] which finalized the transition to a revised CMS–HCC risk adjustment model. The revised 2024 CMS–HCC risk adjustment model, Version 28 (V28), has the same structure as the 2020 CMS–HCC risk adjustment model currently used for payment in that it has eight model segments as first implemented for payment for CY 2017 and condition count variables as first implemented for payment for CY 2020. It incorporates the following technical updates: (1) updated data years used for model calibration, (2) updated denominator year used in determining the average per capita predicted expenditures to create relative factors in the model, and (3) a clinical reclassification of the hierarchical condition categories (HCCs) using the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM) codes. In addition, as part of the clinical reclassification, CMS conducted an assessment on conditions that are coded more frequently in MA relative to FFS. This assessment is consistent with Principle 10 of CMS's longstanding model principles, described in more detail initially in the December 2000 report titled, ''Diagnostic Cost Group Hierarchical Condition Category Models for Medicare Risk Adjustment (Final Report)'' (available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/pope_2000_2.pdf*). As a result of this assessment, in addition to the technical updates, the revised model includes additional constraints and the removal of several HCCs in order to reduce the impact on risk score variation in coding between MA and FFS.[199]

For CY 2024, MA risk scores will be calculated as a blend of 67 percent of the risk scores calculated under the 2020 CMS–HCC risk adjustment model, Version 24 (V24), and 33 percent of the risk scores calculated with the 2024 CMS–HCC risk adjustment model (V28). CMS expects that for CY 2025, MA risk scores will be calculated using a blend of 33 percent of the risk scores calculated with V24 and 67 percent of the risk scores calculated with V28, and for CY 2026, 100 percent of risk scores will be calculated with V28.[200]

With the transition to the use of the V28 CMS–HCC model beginning in CY 2024 in MA, it is timely to revisit how we apply the CMS–HCC risk adjustment model(s) to calculate risk scores used in Shared Savings Program calculations. As summarized in the CY 2024 Rate Announcement, some commenters questioned if the updated MA risk adjustment model will affect lines of business outside of Medicare Advantage such as the ACO REACH Model and Medicare Shared Savings Program. In response to these comments, we explained that we were considering the implications of these changes to the CMS–HCC risk adjustment model for these initiatives.[201]

In section III.G.4.e.(3) of this proposed rule, we discuss our initial analysis of the impact of the V28 CMS–HCC model on Shared Savings Program calculations, including modeling of an alternative approach to calculating benchmark year risk scores. We propose a modified approach to making such calculations for agreement periods beginning on January 1, 2024, and in subsequent years, in section III.G.4.e.(4) of this proposed rule.

(3) Initial Analysis of the Impact of Risk Adjustment Model Changes on Shared Savings Program Calculations and Modeling of an Alternative Approach to Calculating Benchmark Year Risk Scores

To further evaluate the potential impact of the V28 CMS–HCC model transition on Shared Savings Program ACOs, we analyzed the following:

- Our current approach in which we apply the CMS–HCC risk adjustment model(s) applicable for a particular calendar year to calculate a Medicare FFS beneficiary's prospective HCC risk score for the corresponding benchmark or performance year. This approach could lead to different CMS–HCC risk adjustment models being used to calculate prospective HCC risk scores for the benchmark years as compared to a particular performance year of the ACO's agreement period when there is a transition to a new CMS–HCC risk adjustment model between one or more benchmark years and the performance year.
- An alternative approach in which we would use the CMS–HCC risk adjustment model(s) applicable to the calendar year corresponding to the performance year to calculate a Medicare FFS beneficiary's prospective HCC risk score for the performance year, and for each benchmark year of the ACO's agreement period.[202] This approach ensures consistency between the CMS–HCC risk adjustment methodology used to calculate the prospective HCC risk scores for the benchmark years relative to a particular performance year.

To conduct this analysis, we calculated prospective HCC risk scores and risk ratios for CY 2018 (treated as BY3) and CY 2021 (treated as the PY) for all 275 ACOs that participated in both PY 2018 and PY 2021. Risk ratios between BY3 and the PY were calculated under the current approach, in which we used the V24 CMS–HCC model to calculate BY3 prospective HCC risk scores and the V28 CMS–HCC model to calculate PY prospective HCC risk scores, and under the alternative approach of calculating both BY and PY prospective HCC risk scores using V28.[203]

CMS performed this analysis to roughly estimate how V28 would have impacted payment to ACOs in PY 2021 using weighted average risk scores calculated across the three non-ESRD Medicare enrollment types (disabled, aged/dual eligible, aged/non-dual eligible). The analysis provides insight into the impact of a fully phased-in V28, which is expected to occur in PY 2026 (particularly for ACOs that would at that point have a BY3 prior to 2024). For the 275 ACOs in the sample, combined PY 2021 shared savings payments would have been about 11 percent lower than actual payments if V28 had been fully phased-in for the performance year,

[198] For more details, refer to Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (March 31, 2023) (herein CY 2024 Rate Announcement), available at *https://www.cms.gov/files/document/2024-announcement-pdf.pdf.*

[199] See Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (February 1, 2023), available at *https://www.cms.gov/files/document/2024-advance-notice-pdf.pdf.*

[200] See CY 2024 Rate Announcement, available at *https://www.cms.gov/files/document/2024-announcement-pdf.pdf* at 3.

[201] *See id.* at 97.

[202] A similar approach was suggested by commenters in earlier rulemaking for the Shared Savings Program. See, for example, the December 2018 final rule (83 FR 68013), in which we summarize commenters' recommendation that CMS modify the current methodology to use the same CMS–HCC risk score model to calculate risk scores for both the benchmark years and the performance year.

[203] The V24 CMS–HCC model was not applicable to CY 2018 but was used in this analysis to calculate BY3 prospective HCC risk scores under the current approach in order to measure the impact of the transition from V24 to V28 on Shared Savings Program ACOs.

when using V24 to calculate BY3 prospective HCC risk scores (reflecting the current approach to applying CMS–HCC risk adjustment models). Alternatively, combined shared savings payments would have been about 2 percent higher than actual if V28 were used for BY3 calculations as well as for PY 2021 calculations (reflecting the alternative approach to applying CMS–HCC risk adjustment models).

Table 39 compares the estimated impact on PY 2021 shared savings of the current approach, and the alternative approach to calculating BY3 and PY prospective HCC risk scores.

TABLE 39: Estimated Impacts on PY 2021 Shared Savings of the V28 CMS-HCC Model under Current and Alternative Approaches to BY3 and PY Risk Score Calculation (Expressed as Percent of Benchmark)

	Current Approach BY3 V24, PY V28	Alternative Approach BY3 V28, PY V28	Current minus Alternative
Minimum	-6.6%	-1.6%	-6.7%
10th percentile	-1.4%	-0.4%	-1.1%
25th percentile	-0.4%	0.0%	-0.5%
Median	0.0%	0.0%	0.0%
Mean	-0.2%	0.1%	-0.2%
75th percentile	0.1%	0.2%	0.0%
90th percentile	0.9%	0.6%	0.5%
Maximum	2.3%	2.2%	2.2%

Estimated decreases in PY 2021 shared savings payments are more extreme at the tail of the distribution when using the current approach. Over 10 percent of ACOs showed more than 1.4 percent in reduced shared savings payments relative to benchmark under the modeling of the current approach, in which we used V24 to calculate BY3 prospective HCC risk scores and V28 to calculate PY prospective HCC risk scores. In contrast, about 3 percent of ACOs showed declines of such magnitude in shared savings payments relative to the benchmark using the alternative approach to calculating prospective HCC risk scores for BY3 and PY 2021 with the V28 CMS–HCC model. Compared to the alternative approach, the current approach is estimated to result in a reduction in shared savings of about 0.2 percent per ACO on average, relative to benchmark. These impacts would be smaller, potentially one-third of the magnitude, if the use of V24 in BY3 was compared to the blend of 33 percent V28 and 67 percent V24 for the PY (reflecting the blend applicable for CY 2024).

Table 40 compares the estimated impact on PY 2021 shared savings of the current approach, and the alternative approach to calculating BY3 and PY risk scores (expressed as percentage of benchmark), based on the following ACO characteristics: ACO average renormalized prospective HCC risk scores for aged/disabled beneficiaries, ACO participation in performance-based risk, and year of entry into the Shared Savings Program. We observed that the current approach would have the greatest adverse effect on ACOs with the highest average risk scores (calculated with the V24 CMS–HCC model), ACOs participating in two-sided models, and ACOs that have been in the Shared Savings Program longer. ACOs that would not have been harmed by the current approach had an average renormalized risk score for their non-ESRD populations roughly equal to 1.00. The 5 percent of ACOs in the modeling with the most adverse impact from the current approach had an average renormalized risk score for their non-ESRD populations of 1.22. For ACOs with the highest average risk scores, the modeling showed the current approach would have resulted in reduced shared savings of about 2 percent (relative to benchmark) per ACO, as compared to the alternative approach. The most adversely impacted ACOs in the modeling also were roughly 40 percent more likely to participate in a two-sided model and to have participated in the Shared Savings Program nearly 2 years longer than ACOs not harmed. The modeling demonstrates that the alternative approach would reduce the negative impact that the current approach shows for ACOs with high risk scores, with earlier entry dates into the Shared Savings Program, and with participation in a two-sided model.

TABLE 40: Estimated Impacts on PY 2021 Shared Savings of the V28 CMS-HCC Model under Current and Alternative Approaches to BY3 and PY Risk Score Calculation, Based on ACO Characteristics (Expressed as Percent of Benchmark)

	Current Approach BY3 V24, PY V28	Alternative Approach BY3 V28, PY V28	Current minus Alternative
Average HCC (Aged/Disabled)			
>1.20	-2.0%	0.0%	-2.1%
1.10 to 1.20	-0.5%	-0.1%	-0.4%
1.025 to 1.10	-0.4%	0.0%	-0.4%
0.975 to 1.025	-0.1%	0.1%	-0.2%
0.90 to 0.975	0.2%	0.2%	0.1%
<0.90	0.5%	0.2%	0.3%
PY21 Track/Level			
Two-sided Model	-0.5%	0.0%	-0.5%
One-sided Model	0.1%	0.1%	0.0%
Program Entry			
On/before 2013	-0.6%	0.1%	-0.7%
On/after 2014	-0.1%	0.1%	-0.1%

In the context of the transition to the V28 CMS–HCC model, the results of this analysis show that the current approach to calculating prospective HCC risk scores is expected to adversely impact ACO financial performance, particularly for ACOs that serve a high-risk beneficiary population, when compared to the stated alternative approach. The factors discussed in section III.G.4.e.(2) of this proposed rule—renormalizing risk scores to the national assignable FFS population, risk-adjusted regional expenditures providing a counterbalance to how risk ratios impact the benchmark, and the phased transition from V24 to V28 by means of a blended risk model—will reduce the impact of a risk adjustment model transition. However, these factors will be insufficient to prevent adverse effects on ACO financial performance due to the larger impact from the transition to V28 relative to prior CMS–HCC model transitions. The alternative policy under which CMS would apply the same CMS–HCC risk adjustment model used in the performance year to calculate prospective HCC risk scores for all benchmark years would strengthen risk adjustment in the Shared Savings Program and consistently apply the CMS–HCC model in the Shared Savings Program context as it is applied in MA.

(4) Proposed Revisions

The adoption of the alternative approach to calculating prospective HCC risk scores for the performance year and each benchmark year of an ACO's agreement period would allow us to more accurately measure the change in severity and case mix for an ACO's assigned beneficiary population or the assignable beneficiary population. Under such an approach, there would be no potential for distortion from using different CMS–HCC risk adjustment models in calculating prospective HCC risk scores for benchmark years and the performance year that could occur under the current policy. For this reason, we propose to modify our current use of the CMS–HCC risk adjustment model and adopt the alternative approach to calculating prospective HCC risk scores for a performance year and the relevant benchmark years for agreement periods beginning on January 1, 2024, and in subsequent years.

We propose to add a new section to our regulations at § 425.659, which would codify our existing framework for calculating risk scores used in Shared Savings Program benchmark calculations and adopt the alternative approach to calculating prospective HCC risk scores for a performance year and the relevant benchmark years discussed in this section of this proposed rule. We propose in paragraph (a) of § 425.659 to codify our current practice of accounting for differences in severity and case mix of the ACO's assigned beneficiaries and assignable beneficiaries (as defined under § 425.20) in calculations used in establishing, adjusting and updating the ACO's historical benchmark.

We propose to set forth in paragraph (b) of § 425.659 our approach to determining Medicare FFS beneficiary prospective HCC risk scores for Shared Savings Program benchmark and performance year calculations. In paragraph (b)(1) of § 425.659, we propose to codify our current policy under which CMS specifies the CMS–HCC risk adjustment methodology used to calculate prospective HCC risk scores for Medicare FFS beneficiaries (as defined under § 425.20) for use in Shared Savings Program calculations. Additionally, we propose:

- To codify our current practice of calculating risk scores for Medicare FFS beneficiaries for a performance year, which provides that CMS uses the CMS–HCC risk adjustment methodology applicable for the corresponding calendar year.
- To codify our current practice for agreement periods beginning before January 1, 2024, of applying the CMS–HCC risk adjustment methodology for the calendar year corresponding to benchmark year in calculating risk scores for Medicare FFS beneficiaries

for each benchmark year of the agreement period.

- For agreement periods beginning on January 1, 2024, and in subsequent years, CMS would apply the CMS–HCC risk adjustment methodology for the calendar year corresponding to the performance year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year of the agreement period.

We propose at § 425.659(b)(2) to codify our current practices for calculating prospective HCC risk scores for a benchmark or performance year. Specifically, in calculating prospective HCC risk scores, we would remove the MA coding intensity adjustment, if applicable. Further, we would renormalize prospective HCC risk scores by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) based on a national assignable FFS population for the relevant benchmark or performance year. We would calculate the average prospective HCC risk score by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) in order to risk adjust benchmark calculations also performed by Medicare enrollment type.

We note that at this time we are not proposing to modify the current approach to calculating demographic risk scores under the Shared Savings Program, as described in section III.G.4.e.(1) of this proposed rule.

We also propose to adjust the benchmark to account for CMS–HCC risk adjustment model changes during the term of the agreement period to maintain uniformity between the calculation of prospective HCC risk scores for the performance year and each benchmark year. We propose to revise the list of circumstances for adjusting the historical benchmark for the second and each subsequent performance year during the term of the agreement period at § 425.652(a)(9) to include a change in the CMS–HCC risk adjustment methodology used to calculate prospective HCC risk scores under proposed, new § 425.659. We further propose to add a new paragraph (a)(9)(vi) to § 425.652 to specify that we would redetermine factors based on prospective HCC risk scores calculated for benchmark years by calculating the prospective HCC risk scores using the CMS–HCC risk adjustment methodology that applies for the calendar year corresponding to the applicable performance year in accordance with proposed § 425.659(b)(1).

We also propose a technical and conforming change to § 425.650(a), which generally describes the organization of the sections on the benchmarking methodology within subpart G of the Shared Savings Program regulations. In the description of the benchmarking methodology applicable for agreement periods beginning before January 1, 2024, we propose to update the list of referenced sections to include the proposed new § 425.659.

This proposed policy would address the concerns of ACOs and other interested parties regarding the transition to the V28 CMS–HCC model or other similar future changes to CMS–HCC risk adjustment methodology that could occur during the term of an ACO's agreement period. Under this proposal, both the numerator and denominator in the PY/BY3 risk ratio would be calculated using a consistent risk model, and any distributional impacts should, on average, be balanced. This would prevent distortion to historical benchmarks resulting from model changes. This conclusion is informed by the data analysis described in section III.G.4.e.(3) of this proposed rule, which shows that on average ACOs would have earned roughly 0.2 percent in additional PY 2021 shared savings payments relative to benchmark when both benchmark year and performance year prospective HCC risk scores are calculated under V28 compared to calculations under both V24 and V28.

Our analysis shows that ACOs with high risk scores would benefit from using the proposed approach to calculate BY and PY prospective HCC risk scores relative to the current policy. This proposal would therefore help the Shared Savings Program retain ACOs serving the highest risk beneficiaries. This is a priority for CMS as high risk beneficiaries may benefit the most from better care coordination and quality improvement activities, particularly by ACOs with above average duration of participation in the program. Similarly, the proposed approach would support potential participation from new ACOs that would consider whether risk adjustment calculations in the Shared Savings Program benchmarking methodology would be adequate for beneficiaries with the highest risk.

This proposal would not affect how prospective HCC risk scores are calculated for ACOs in agreement periods that began prior to January 1, 2024, consistent with our historical practice of incorporating changes to the benchmarking methodology only at the start of an ACO's agreement period. ACOs in an existing agreement period that includes performance year 2024, 2025 or 2026 may benefit from the factors discussed in section III.G.4.e.(2) of this proposed rule—renormalizing risk scores to the national assignable FFS population, risk-adjusted regional expenditures providing a counterbalance to how risk ratios impact the benchmark, and the phased transition from V24 to V28 by means of a blended risk model. These factors would diminish adverse effects of using the new CMS–HCC risk adjustment methodology in Shared Savings Program calculations.

If we finalize the proposed approach for agreement periods beginning on January 1, 2024, and in subsequent years, we note that an ACO in an existing agreement period may choose to terminate its participation agreement early in order to early renew under a new participation agreement to be under the revised approach. For instance, an ACO under an existing agreement period with the current methodology (with a 2022 or 2023 start date) could apply to early renew with the application cycle for the January 1, 2025 agreement period start date, which would occur during CY 2024. For an existing ACO that applied to early renew and enters a new agreement period beginning on January 1, 2024, the proposed policy, if finalized, would apply to the ACO's new agreement period. Any ACO that early renews would have its benchmark rebased at the start of the new agreement period.

The following examples, based on the first three years of a 5-year agreement period beginning on January 1, 2024, illustrate the applicability of the current approach to calculating BY and PY prospective HCC risk scores using different CMS–HCC risk adjustment model(s), as compared to the proposed approach to calculating both BY and PY prospective HCC risk scores using the same CMS–HCC risk adjustment model(s). Under the current policy an ACO beginning a new agreement period on January 1, 2024, would have its prospective HCC risk scores for BY1 (2021) calculated using a blend of 25 percent under the 2014 CMS–HCC model, Version 22 (V22), and 75 percent V24,[204] and for BY2 (2022) and BY3 (2023) calculated using V24.[205] [206] For

[204] For more details, refer to Announcement of Calendar Year (CY) 2021 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (April 6, 2020), available at *https://www.cms.gov/files/document/2021-announcement.pdf*.

[205] For more details, refer to Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA)

PY1 (2024), prospective HCC risk scores would be calculated using a blend of 67 percent V24 and 33 percent V28. For PY2 (2025), prospective HCC risk scores are expected to be calculated using a blend of 33 percent V24 and 67 percent V28. For PY3 (2026), prospective HCC risk scores are expected to be calculated using V28. Under the current methodology, the risk ratios used to risk adjust expenditures would have the numerator and denominator calculated using different underlying CMS–HCC risk adjustment models. Specifically, to risk adjust BY1 expenditures to BY3 when establishing or adjusting the ACO's historical benchmark, the risk ratio would include risk scores calculated under V24 (BY3) and a blend of 25 percent V22 and 75 percent V24 (BY1). To risk adjust BY3 expenditures to the performance year when updating the historical benchmark during financial reconciliation, risk ratios would include risk scores calculated under V24 (as applicable to BY3) and either a blend of V24 and V28 (for PY1 and as expected for PY2) or fully calculated with V28 (as expected for PY3).

Under the proposed approach, BY and PY prospective HCC risk scores would be calculated under the CMS–HCC risk adjustment model(s) applicable to the calendar year corresponding to the relevant performance year. For an ACO beginning a new agreement period on January 1, 2024, in PY1 (2024) all benchmark year and PY1 prospective HCC risk scores would be calculated using a blend of 67 percent V24 and 33 percent V28. In PY2 (2025), all benchmark year and PY2 prospective HCC risk scores are expected to be calculated using a blend of 33 percent V24 and 67 percent V28. In PY3 (2026), all benchmark year and performance year prospective HCC risk scores are expected to be calculated using V28. In the case of an ACO in an existing agreement period that early renews for a new agreement period beginning on January 1, 2025, the calculations described in this paragraph regarding the blend of V24 and V28 for 2025 and the fully phased-in V28 CMS–HCC model for 2026 would be expected to apply for the ACO's first and second performance years (respectively).

We seek comment on these proposals regarding the prospective HCC risk scores to be used in risk adjustment for purposes of benchmark calculations under the Shared Savings Program.

5. Proposed Modifications to Advance Investment Payments Policies

a. Overview

In the CY 2023 PFS final rule (87 FR 69782 through 69805), we finalized a new payment option for eligible Shared Savings Program ACOs entering agreement periods beginning on or after January 1, 2024, to receive advance shared savings payments. This payment option is referred to as advance investment payments (AIP) and the payments themselves are referred to as advance investment payments.

In that final rule, we explained that section 1899(i) of the Act authorizes the Secretary to use other payment models instead of the one-sided model described in section 1899(d) of the Act so long as the Secretary determines that the other payment model would improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures (87 FR 69783 and 69784). In accordance with section 1899(i) of the Act, we determined that making advance investment payments to certain ACOs participating in the Shared Savings Program would improve the quality and efficiency of items and services furnished to Medicare beneficiaries by enhancing the accessibility of the Shared Savings Program (*Id.*).

We established standards for an ACO's receipt and use of advance investment payments within the Shared Savings Program regulations at § 425.630 and also specified requirements in connection with AIP in other sections within 42 CFR part 425. Such standards include: eligibility criteria to limit AIP to new, low revenue ACOs that are inexperienced with performance-based risk; application procedures and contents, including submission of a spend plan; policies governing use and management of payments; amount and frequency of advance investment payments, which are comprised of a one-time $250,000 upfront payment and up to 8 quarterly payments; the methodology for calculation of the quarterly payment amount based on the ACO's assigned population; termination of advance investment payments, as well as recoupment and recovery of advance investment payments; policies to monitor ACO eligibility for AIP; and ACO public reporting requirements regarding the use of advance investment payments.

Within this section of this proposed rule, we propose modifications to refine AIP policies to better prepare for initial implementation of AIP beginning with ACOs entering agreement periods on January 1, 2024. In summary, we are proposing to better support ACOs that are prepared to progress to performance-based risk by allowing ACOs to advance to two-sided model Levels within the BASIC track's glide path beginning in PY3 of the agreement period in which they receive advance investment payments (section III.G.5.b of this proposed rule). We are also proposing to recoup advance investment payments from shared savings for ACOs that wish to early renew to continue their participation in the Shared Savings Program (section III.G.5.c of this proposed rule). We propose to specify that CMS would terminate advance investment payments for future quarters to ACOs that elect to terminate their participation in the Shared Savings Program (section III.G.5.d. of this proposed rule). We propose to require ACOs to report spend plan updates and actual spend information to CMS in addition to publicly reporting such information (section III.G.5.e. of this proposed rule). We propose to codify that ACOs receiving advance investment payments may seek reconsideration review of all payment calculations (section III.G.5.f. of this proposed rule). If finalized, these policies would be effective beginning January 1, 2024.

b. Proposal To Modify AIP Eligibility Requirements To Allow ACOs To Advance to Performance-Based Risk During the 5-Year Agreement Period

(1) Background

The policies we finalized with the CY 2023 PFS final rule require an ACO to remain under a one-sided model for the duration of its agreement period in which it receives advance investment payments to remain compliant with AIP requirements. The ACO would otherwise face potential compliance action and may be required to repay all advance investment payments within 90 days of receiving written notification from CMS. This limits an ACO's ability to select participation options that include progression along the BASIC track's glide path to a performance-based two-sided risk model. This policy arises from the interaction of numerous standards.

First, an ACO is eligible to receive advance investment payments if CMS determines that all of the following criteria are met: (1) the ACO is not a

Capitation Rates and Part C and Part D Payment Policies (January 15, 2021), available at *https://www.cms.gov/files/document/2022-announcement.pdf.*

[206] For more details, refer to Announcement of Calendar Year (CY) 2023 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (April 4, 2022), available at *https://www.cms.gov/files/document/2023-announcement.pdf.*

renewing or a re-entering ACO; (2) the ACO has applied to participate in the Shared Savings Program under any level of the BASIC track's glide path and is eligible to participate in the Shared Savings Program; (3) the ACO is inexperienced with performance-based risk Medicare ACO initiatives; and (4) the ACO is a low revenue ACO (§ 425.630(b)). An eligible ACO will receive a one-time upfront payment of $250,000 and quarterly payments each quarter for the first 2 performance years of the ACO's 5-year agreement period, totaling no more than 8 quarterly payments (§ 425.630(f)).

Second, under § 425.630(h), CMS will terminate an ACO's advance investment payments in accordance with § 425.316(e) if the ACO is no longer inexperienced with performance-based risk Medicare ACO initiatives or is no longer a low revenue ACO. Section 425.316(e) specifies that if CMS determines during any performance year of the agreement period that an ACO receiving advance investment payments is experienced with performance-based risk Medicare ACO initiatives or is a high revenue ACO, and the ACO remains experienced with performance-based risk Medicare ACO initiatives or a high revenue ACO after a deadline specified by CMS pursuant to compliance action, the ACO must repay all advance investment payments it received.

An eligible ACO that joins the Shared Savings Program in Level A of the BASIC track and opts to receive advance investment payments will be eligible for all 8 quarterly payments to be paid over PY1 and PY2, so long as the ACO remains in Level A (or progresses to Level B) in PY2 and remains inexperienced with performance-based risk Medicare ACO initiatives and a low revenue ACO. An ACO that joins the Shared Savings Program at Levels B through E of the BASIC track, however, will not be eligible to receive all 8 quarters of advance investment payments because current program regulations require that an ACO remain inexperienced with performance-based risk Medicare ACO initiatives while receiving advance investment payments (§ 425.630(h)(2)). More specifically, if an ACO receiving advance investment payments elects to participate at Level B of the BASIC track in PY1 progresses along the glide path to Level C for PY2, CMS would determine that the ACO is experienced with performance-based risk in PY2 and the ACO would no longer be eligible to receive advance investment payments during PY2.

In the CY 2023 final rule (87 FR 69787), we stated that advance investment payments were intended to assist smaller, community-based providers in forming high-performing ACO networks by providing much-needed startup capital that can be used to attract and maintain staffing, purchase healthcare delivery infrastructure and IT systems, and develop and implement a strategy to address the health needs of underserved communities. It is for this reason we restricted AIP eligibility to those ACOs that are inexperienced with performance-based risk. ACOs that are experienced with performance-based risk generally would not need advance investment payments to successfully participate in the Shared Savings Program as they have previously participated in the Shared Savings Program or certain Innovation Center models or CMS programs in which the ACO accepted risk for shared losses. In this proposed rule, we propose to modify program regulations to permit an ACO to progress to two-sided risk along the BASIC track's glide path within the agreement period while the ACO continues to benefit from advance investment payments.

(2) Proposed Revisions

We propose to modify AIP eligibility requirements to allow an ACO receiving advance investment payments to transition to two-sided risk within its 5-year agreement period under the BASIC track's glide path. Specifically, we propose to modify § 425.630(b)(2) and (3) to allow an eligible ACO receiving advance investment payments to advance to performance-based risk (by advancing from Level A or B to Level C, D, or E of the BASIC track's glide path) beginning in PY3 of the ACO's agreement period. We also propose to modify § 425.316(e)(2) to specify that CMS would cease payment of advance investment payments if CMS determines that an ACO approved for AIP became experienced with performance-based risk Medicare ACO initiatives during the first or second performance year of its agreement period or became a high revenue ACO during any performance year of the agreement period in which it received advance investment payments. Pursuant to § 425.316(e)(2)(ii), CMS may take compliance action against such ACOs. We also propose to modify § 425.316(e)(2)(i) to specify that CMS will cease payment of advance investment payments no later than the quarter after the ACO became experienced with performance-based risk Medicare ACO initiatives or became a high revenue ACO.

Under the proposed approach, ACOs may choose to move into a two-sided risk participation option within the Shared Savings Program's BASIC track beginning in PY3 (and in subsequent performance years). These ACOs would still be required to repay advance investment payments through earned shared savings over the remaining performance years of its agreement period as prescribed in § 425.630(g). We propose that this policy would be effective January 1, 2024. Under this proposal, an ACO could not use advance investment payments to fund repayment mechanisms or repay shared losses. This limitation also reduces the risk that ACOs stretch themselves beyond their financial capacity while receiving advance investment payments by taking on large amounts of risk. Unlike other ACOs, ACOs receiving advance investment payments will have the additional financial obligation of repaying the advance investment payments if they misjudge their appetite for risk and leave the program mid performance period after incurring shared losses. These policies are intended to align with our goal to support the creation of new ACOs that need time and resource assistance to develop the infrastructure to operate an ACO that effectively manages patient care and lowers costs.

After 2 years of participation, new ACOs may have sufficient experience to be capable of taking on the smaller amounts of downside risk available in levels C–E of the BASIC track. Given that the option to receive advance investment payments was designed for ACOs that are new to the Shared Savings Program, low revenue, and inexperienced with risk, it does not align with broader program goals to permit ACOs of such size or capitalization to take on the high levels of downside risk in the ENHANCED track during their first agreement period in the Shared Savings Program. As proposed, these modifications balance the risk of a new ACO taking on too much risk too quickly while allowing them to take on moderate risk as they develop more experience with the program.

Specifically, we propose to amend the eligibility criteria specified in § 425.630(b) as follows. We propose to revise the eligibility criterion at § 425.630(b)(2) to remove language stating that the ACO has applied to participate in the Shared Savings Program ''under any level of the BASIC track's glide path''; the revised provision would simply state that ''CMS has determined that the ACO is eligible to participate in the Shared Savings

Program.'' Further, we propose to amend the criterion in § 425.630(b)(3) to specify that the ACO must be inexperienced with performance-based risk Medicare ACO initiatives during its first 2 performance years but may participate in Levels of the BASIC track that would make them experienced with performance-based risk Medicare ACO initiatives starting with the third year of its first agreement period. Specifically, we propose to specify in revisions to § 425.630(b)(3), that the ACO may participate in the Levels of the BASIC track's glide path as follows during the agreement period in which the ACO receives advance investment payments:

- For performance year 1, the ACO must participate in Level A of the BASIC track's glide path.
- For performance year 2, the ACO may participate in Level A of the BASIC track's glide path (in accordance with § 425.600(a)(4)(i)(C)(*3*)) or Level B.
- For performance years 3 through 5, the ACO may participate in Level A of the BASIC track's glide path (in accordance with § 425.600(a)(4)(i)(C)(*3*)), or Levels B through E.

To illustrate the proposed policy, consider an ACO entering an agreement period beginning on January 1, 2024, that applies for and is determined to be eligible to receive advance investment payments. The ACO must participate in Level A for PY1. In PY2, the ACO may remain under Level A for all subsequent years of the agreement period in accordance with § 425.600(a)(4)(i)(C)(*3*) or may move to Level B. The ACO would receive advance investment payments for PY1 and PY2, receiving the one-time payment of $250,000 and the 8 quarterly payments. If the ACO remained at Level A for PY2, it could then transition to a higher level of risk and potential reward within the glide path for PY3 (that is, Levels B, C, D, or E) in accordance with § 425.600(a)(4)(i)(C)(*3*)(*iii*). If the ACO participated in Level B for PY2, it could automatically progress for PY3 to Level C (in accordance with § 425.600(a)(4)(i)(C)(2)) or elect to transition to Level D (in accordance with § 425.600(a)(4)(i)(C)(2)(i) and § 425.226(a)(2)(i)) or Level E (in accordance with § 425.600(h)(2)(i) and § 425.226(a)(2)(i)) beginning with PY3.

Under this proposed modification, CMS would continue to recoup from future shared savings. In contrast to what is required under existing § 425.316(e)(3), the ACO would not be immediately obligated to repay all advance investment payments it received by virtue of its transition to a two-sided model in its third performance year or any subsequent performance year. We note that under our proposal if an ACO opts to progress to a two-sided risk model (BASIC track's glide path Levels C through Level E) in PY2, CMS would terminate the ACO's advance investment payments, the ACO may be subject to compliance actions specified in §§ 425.216 and 425.218, and CMS may seek repayment of advance investment payments as set forth at § 425.316(e).

We seek comment on our proposals to amend AIP policies and require that all AIP ACOs be inexperienced with performance-based risk Medicare ACO initiatives while the ACO receives advance investment payments—that is, during PY1 and PY2 of the agreement period—and to allow ACOs to progress to performance-based risk under the BASIC track's glide path beginning with PY3 of the same agreement period.

c. Proposal To Modify AIP Recoupment and Recovery Policies for Early Renewing ACOs

(1) Background

In the CY 2023 PFS final rule (87 FR 69803 through 69805), CMS finalized program policies regarding recoupment and recovery of advance investment payments. In accordance with § 425.630(g)(4), if an ACO terminates its participation agreement during the agreement period in which it received an advance investment payment, the ACO must repay all advance investment payments it received. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

Paragraph (2) of the definition of ''renewing ACO'' at § 425.20 includes an ACO that continues its participation in the Shared Savings Program for a consecutive agreement period, without a break in participation, because it is 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. In prior rulemaking (see, for example, 83 FR 67885 through 67890), we have referred to this provision as allowing for an ''early renewal'' option. In developing the AIP policies in the PFS rulemaking for CY 2023, we did not address the potential interactions between the policy on recovery of advance investment payments specified in § 425.630(g) and a voluntary termination of the participation agreement by an ACO that is seeking to early renew.

(2) Proposed Revisions

We propose to amend § 425.630(g)(4) to create a limited exception to CMS's policy of recovering advance investment payments from an ACO that voluntarily terminates its participation agreement for the agreement period during which it received advance investment payments. Under this proposal, we would not seek to collect all advance investment payments received from an ACO in accordance with § 425.630(g)(4) if the ACO voluntarily terminates its participation agreement at the end of PY2 or later during the agreement period in which it received advance investment payments, provided that the ACO immediately enters into a new participation agreement with CMS under any level of the BASIC track's glide path or the ENHANCED track. Rather, we would carry forward any remaining balance of advance investment payments owed by the early renewing ACO into the ACO's new agreement period.

We propose to allow an ACO approved for AIP to early renew its participation agreement before the expiration of its current agreement, as long as the ACO terminates its current participation agreement effective on or after December 31 of the ACO's second performance year. By requiring the ACO to maintain its current agreement period for the first 2 years, the ACO will receive all of its advance investment payments prior to renewing its participation agreement. We further propose that in such circumstances, the early renewing ACO must continue to repay the advance investment payments through shared savings earned in the subsequent agreement period. If an ACO early renews prior to PY3, it will no longer comply with the eligibility requirements for receiving payments in § 425.630(b)(1) and may be subject to compliance actions under §§ 425.216 and 425.218.

Section 425.630(e)(3) specifies that an ACO may spend an advance investment payment over its entire agreement period and must repay to CMS any unspent funds remaining at the end of the ACO's agreement period. We propose to amend § 425.630(e)(3) to permit an early renewing ACO to spend advance investment payments in its second agreement period so long as the advance investment payments are spent within 5 performance years of when it began to receive advance investment payments. If the ACO does not spend all of the advance investment payments received by the end of the fifth performance year, the ACO must repay any unspent funds to CMS. The

duration of spending advance investment payments was discussed in the CY 2023 PFS final rule (87 FR 69801).

We believe these policy proposals would be most relevant to an ACO that is receiving advance investment payments and seeks to early renew to enter a new participation agreement to participate under modified Shared Savings Program policies that are not applicable to the ACO's current agreement period. For such an ACO, any remaining balance of advance investment payments owed would continue to be recouped from any shared savings the ACO earns in its new agreement period. Further, such an ACO would continue its participation in the Shared Savings Program without a lapse in participation and would be required to continue to adhere to all AIP requirements. We believe continued program participation aligns with our goals to improve the quality and efficiency of care. These policies provide ACOs the flexibility to participate in the Shared Savings Program in a manner that may work best for their structure and patient population without having to choose between immediately paying back the advance investment payment funds they received and being able to enter a new agreement with the Shared Savings Program. Some policy changes are applicable to new agreement periods, and we believe ACOs approved for AIP should have the opportunity to enter a new agreement to experience those changes. This proposed modification, if finalized, would be effective January 1, 2024.

We seek comment on the proposed changes to § 425.630(e)(3) and § 425.630(g)(4).

d. Proposal To Amend Termination Policies To Allow CMS To Cease Distribution of Advance Investment Payments Following an ACO's Notification of Voluntary Termination

(1) Background

In the CY 2023 PFS final rule (87 FR 69803), we finalized policies for termination of advance investment payments at § 425.630(h). Section 425.630(h)(1) specifies that CMS may terminate an ACO's advance investment payments if the ACO fails to comply with the requirements of § 425.630 or meets any of the grounds for ACO termination set forth in § 425.218(b). However, we did not address the termination of advance investment payments if an ACO voluntarily terminates its participation agreement in accordance with § 425.220(a). This created ambiguity regarding whether CMS would continue to make quarterly advance investment payments to an ACO that voluntarily terminates its participation agreement in accordance with § 425.220(a) and does not immediately enter a new agreement period. We are concerned that the continued payment of advance investment payments in such a case would not serve the purpose for which CMS is making such payments and would create unnecessary program integrity risks for the Shared Savings Program. In such a case, CMS would be knowingly paying funds to an ACO that will need to be repaid upon termination.

(2) Proposed Revisions

We propose to permit CMS to terminate advance investment payments for future quarters to an ACO that has provided CMS with notice of termination in accordance with § 425.220(a) if the ACO will not immediately enter a new agreement period. This avoids distributing advance investment payments to an ACO from which CMS would subsequently need to recover such payments. Specifically, we propose to add § 425.630(h)(1)(iii), which allows CMS to terminate an ACO's advance investment payments when the ACO voluntarily terminates its participation agreement in accordance with § 425.220(a). We are also proposing conforming changes to the punctuation of the list of factors in paragraphs (h)(1)(i) and (ii) of § 425.630. If finalized, these proposed changes would be effective January 1, 2024.

In summary, if finalized, CMS will cease paying advance investment payments to an ACO that voluntarily terminates its participation in the Shared Savings Program if the ACO will not immediately enter a new agreement period. In accordance with § 425.630(g)(4), the ACO would still be obligated to repay all advance investment payments within the 90-days after receiving notice of the amount due to CMS. We seek comment on this proposal.

e. Proposal To Require ACOs To Report to CMS Spend Plan Updates and Use of Advance Investment Payments

In the CY 2023 PFS final rule (87 FR 69786 through 69788), CMS finalized program policies to require ACOs that receive advance investment payments to submit a spend plan to CMS as a part of their Shared Savings Program application (§ 425.630(d)(1)). In accordance with § 425.630(d)(3), CMS may review an ACO's spend plan at any time and require the ACO to modify its spend plan to comply with the spend plan requirements specified at § 425.630(d)(2) and the requirements for use and management of advance investment payments at § 425.630(e).

In the CY 2023 PFS final rule (87 FR 69801 and 69802), we also finalized requirements at § 425.308(b)(8) that an ACO receiving advance investment payments must publicly report information, updated annually, about the ACO's use of advance investment payments for each performance year, including the following:

- The ACO's spend plan.
- The total amount of any advance investment payments received from CMS.
- An itemization of how advance investment payments were spent during the year, including expenditure categories, the dollar amounts spent on the various categories, any changes to the spend plan submitted under § 425.630(d), and such other information as may be specified by CMS.

These provisions do not require an ACO to submit this same information to CMS. To support CMS's ability to monitor AIP efficiently, we propose that an ACO must report to CMS the same information about its use of advance investment payments that it is required to publicly report under § 425.308(b)(8).

To ensure that § 425.630 sets forth the complete requirements applicable to an ACO's obligation to report information on its receipt and use of advance investment payments, we propose to add a new provision at § 425.630(i) specifying that an ACO must (1) publicly report information about the ACO's use of advance investment payments for each performance year in accordance with § 425.308(b)(8); and (2) in a form and manner and by a deadline specified by CMS, report to CMS the same information it is required to publicly report in accordance with § 425.308(b)(8).

We believe that these proposed changes would help ensure that CMS efficiently obtains information in a consistent manner from all ACOs receiving advance investment payments and thereby support CMS's monitoring and analysis of the use of advance investment payments. CMS believes that these proposed changes will impose little to no administrative burden on participating ACOs, which are already required to publicly report this information by § 425.308(b)(8). Further, CMS expects to use the submitted data as the template that ACOs can use to populate their public reporting web page early in each performance year to minimize administrative burden for ACOs.

If finalized, these proposed changes would be effective January 1, 2024. We seek comment on these proposals.

f. Proposal To Permit Reconsideration Review of Quarterly Payment Calculations

(1) Background

In the CY 2023 PFS final rule (87 FR 69795 and 69796), we specified that an ACO can request a reconsideration review if CMS does not make an advance investment payment to the ACO pursuant to subpart I of part 425 (§ 425.630(f)). However, we did not specify that an ACO could request reconsideration of the advance investment payment amount received.

(2) Proposed Revisions

We propose to permit an ACO to request a reconsideration review for all advance investment payment quarterly payment calculations, not just instances where no payments are distributed. We propose to revise § 425.630(f) to provide that CMS would notify in writing each ACO of its determination of the amount of advance investment payment it will receive and that such notice would inform the ACO of its right to request reconsideration review in accordance with the procedures specified under subpart I of the regulations. We seek comment on this proposal.

6. Shared Savings Program Eligibility Requirements

a. Overview

We are proposing two modifications to the Shared Savings Program eligibility requirements that, if finalized, would be implemented on January 1, 2024. Specifically, we propose the following, which are discussed in more detail in sections (b) and (c) below:

- Remove the option for ACOs to request an exception to the shared governance requirement that 75 percent control of an ACO's governing body must be held by ACO participants.
- Codify the existing Shared Savings Program operational approach to specify that CMS determines that an ACO participant TIN participated in a performance-based risk Medicare ACO initiative if it was or will be included on a participant list used in financial reconciliation for a performance year under performance-based risk during the 5 most recent performance years.

b. Shared Governance Requirement

(1) Background

In the November 2011 final rule (76 FR 67819), we finalized policies that require an ACO to establish and maintain a governing body with adequate authority to execute the statutory functions of an ACO, and we codified the governing body policies at § 425.106. Specifically, § 425.106(c)(3) mandates that at least 75 percent control of an ACO's governing body must be held by ACO participants. An ACO's governing body is responsible for providing ACO leadership, strategic direction, and oversight for operational management towards meeting the goals of the ACO, including better care, healthy communities, and reduced spending. This responsibility incorporates not only the delivery of improved healthcare, but also the promotion of evidence-based healthcare practices, improved engagement of patients and caregivers, reporting on quality and cost, provision of high-quality care to beneficiaries, and the distribution of shared savings, among other functions. In the November 2011 final rule (76 FR 67819), we indicated our belief that this requirement allowed for Medicare-enrolled entities that directly provide health care services to beneficiaries to drive decision-making, while recognizing that partnerships with non-Medicare enrolled entities outside this 75 percent composition allow these participants access to capital and infrastructure needed for an ACO. This physician-driven leadership is balanced by the remaining percentage of the governing body that is made up of patient advocates, accounting, legal and other professionals that support administrative duties and other functions of the ACO.

We affirmed in the November 2011 final rule (76 FR 67820) our belief that the 75 percent participant control requirement is necessary to ensure that ACOs are provider-driven, innovative in care delivery and strike an appropriate balance to incentivize and empower ACO participants to be accountable for the success of the ACO's operations and improve the health outcomes of their beneficiaries. Previously, commenters expressed concern that the 75 percent participant control threshold is overly prescriptive and may hinder operations, conflict with IRS and State tax laws, and restrict access to capital for the ACO. ACOs requested flexibility to develop their own governing body composition to meet the unique leadership needs of the ACO. In response to these comments, CMS granted an exception process for an ACO that wishes to structure its governing body in a manner that does not meet the 75 percent participant control threshold as required under § 425.106(c)(3). Under the exception process defined at § 425.106(c)(5), an ACO must describe why it seeks to differ from the 75 percent participant control threshold and how the ACO will involve ACO participants in innovative ways in ACO governance. If the exception is granted by CMS, an ACO can form a governing body with less than 75 percent participant control.

In the December 2014 Medicare Shared Savings Program proposed rule (79 FR 72776) we proposed to revise § 425.106(c)(5) to remove the flexibility for ACOs to deviate from the requirement that at least 75 percent control of an ACO's governing body must be held by ACO participants. We stated that, through program implementation, we learned that ACO applicants do not have difficulty meeting the requirements under § 425.106(c)(3) that ACO participants maintain 75 percent control of the governing body. We also noted that since CY 2012, we had not denied participation to any ACO applicants solely based on failure to comply with this requirement and no exceptions have been granted by CMS under § 425.106(c)(5). Furthermore, we affirmed the 75 percent participant control requirement to be ''necessary and protective of the ACO participant's interests'' and thus, that there was no reason to continue to offer an exception to the rule.

During the public comment period for the December 2014 Medicare Shared Savings Program proposed rule, several commenters advocated for retaining the flexibility offered at § 425.106(c)(5), stating that an ACO may elect to utilize the exception in the future. In our response, we noted that our program experience thus far had not suggested that commenters' concerns that laws concerning the composition of tax-exempt or State-licensed entities would interfere with their ability to meet the 75 percent participant control threshold would impact their compliance with this requirement. However, since implementation of the requirement remained in the early stages and we had limited applicability with ACOs in two-sided risk tracks, we declined to finalize the proposal in the June 2015 final rule (80 FR 32719) and elected to retain the flexibility at § 425.106(c)(5). In the final rule, we noted that we anticipated granting such exceptions only in limited circumstances (that is, an ACO being unable to meet the 75 percent participant control requirement because it conflicts with other laws) and might revisit this issue in future rulemaking.

(2) Proposed Revisions

We continue to believe that ACO participants should drive ACO

leadership to move toward improved quality of care and patient outcomes, and that this is a key component of ACO success and ability to earn shared savings. The 75 percent participant control threshold is critical to ensuring that governing bodies are participant-led and best positioned to meet program goals, while allowing for partnership with non-Medicare enrolled entities to provide needed capital and infrastructure for ACO formation and administration.

Over the years, a few ACOs have requested an exception to form a governing body with less than 75 percent participant control. CMS discussed the exemption requests with the interested ACOs and ultimately the ACOs made adjustments to comply with the 75 percent participant control requirement. To date, CMS has not granted an ACO an exception to this requirement, despite the flexibility provided in current regulation. Accordingly, we believe that there is no reason to continue to offer an exception to the requirement, as ACOs have demonstrated that they can appropriately meet the 75 percent participant control requirement without utilizing this flexibility since its establishment in the November 2011 final rule. Thus, we propose to remove the option under § 425.106(c)(5) for ACOs to request an exception to the requirement specified in § 425.106(c)(3) that 75 percent control of the ACO's governing body must be held by ACO participants. Additionally, we propose a corresponding revision to § 425.204(c)(3) to remove the option for ACOs to request an exception to the 75 percent control requirement under § 425.106(c)(3) as part of their Shared Savings Program applications.

We are seeking public comments on the appropriateness of our proposed policy refinement and elimination of the exception process. If finalized, our proposed modification to § 425.106(c) would make no changes to paragraphs (c)(2), (3) and (4). CMS would amend § 425.106(c)(5) to remove reference to paragraph (c)(3) and the procedure for submitting a request for an exception to the 75 percent requirement. Specifically, the revised regulation text would state: ''In cases in which the composition of the ACO's governing body does not meet the requirements of paragraph (c)(2) of this section, the ACO must describe why it seeks to differ from these requirements and how the ACO will provide meaningful representation in ACO governance by Medicare beneficiaries.'' Additionally, CMS would amend § 425.204(c)(3) to remove references to § 425.106(c)(3) and the procedure for submitting a request for an exception to the 75 percent requirement. Specifically, the revised regulation text would state: ''If an ACO requests an exception to the governing body requirement in § 425.106(c)(2), the ACO must describe—(i) Why it seeks to differ from the requirement; and (ii) How the ACO will provide meaningful representation in ACO governance by Medicare beneficiaries.'' If finalized, this policy would be effective beginning January 1, 2024.

c. Identifying ACOs Experienced With Risk Based on TINs' Prior Participation

(1) Background

In the December 2018 final rule, we added a new paragraph (d) under § 425.600 to set forth the participation options for ACOs that are experienced or inexperienced with ''performance-based risk Medicare ACO initiatives'' (which is defined at § 425.20 to include certain Innovation Center ACO models as well as two-sided risk tracks of the Shared Savings Program). We also finalized the definitions of ''experienced with performance-based risk Medicare ACO initiatives'' and ''inexperienced with performance-based risk Medicare ACO initiatives'' (83 FR 68062). These definitions classify ACOs by experience level based on the percentage of ACO participant TINs that participated in performance-based risk Medicare ACO initiatives during a 5-year lookback period. However, current regulation text does not specify how CMS determines whether an ACO participant TIN has ''participated'' in a performance-based risk Medicare ACO initiative. To improve clarity of the regulations, we propose to codify our existing program policy under which an ACO participant TIN is considered to have participated in a performance-based risk Medicare ACO initiative if it was or will be included in financial reconciliation for a performance year under such initiative during any of the 5 most recent performance years.

Under the December 2018 final rule, an ACO is ''inexperienced with performance-based risk Medicare ACO initiatives'' (and therefore eligible to enter an agreement period under the BASIC track's glide path), if less than 40 percent of its ACO participants has participated in a performance-based risk Medicare ACO initiative in ''each'' of the 5 most recent performance years prior to its Shared Savings Program agreement start date, and the ACO legal entity has not participated in any performance-based risk Medicare ACO initiative (83 FR 67895). Similarly, an ACO is ''experienced with performance-based risk Medicare ACO initiatives'' if 40 percent or more of its ACO participants has participated in a performance-based risk Medicare ACO initiative in ''any'' of the 5 most recent performance years prior to its Shared Savings Program agreement start date (83 FR 67895). Thus, if 40 percent or more of the entities on an ACO participant list participated in a performance-based risk Medicare ACO initiative in a single performance year within the 5 most recent performance years, we would determine that the ACO meets the definition of ''experienced with performance-based risk Medicare ACO initiatives.'' Conversely, we would determine that an ACO satisfies the definition of ''inexperienced with performance-based risk Medicare ACO initiatives'' only if it is below the 40 percent threshold in all of the 5 most recent performance years prior to the ACO's agreement start date. In other words, an ACO is inexperienced with performance-based risk Medicare ACO initiatives as long as it does not meet the definition of ''experienced with performance-based risk Medicare ACO initiatives'' in any of the five most recent performance years prior to the ACO's agreement start date. We chose to use a 5-year lookback period for determining whether an ACO is experienced or inexperienced with performance-based risk Medicare ACO initiatives for a number of reasons, including that it could reduce the incentive for organizations to wait out the period in an effort to establish a new legal entity with the same or very similar composition of ACO participants for purposes of gaming program policies.

We recognize that some ACOs or TINs in performance-based risk Medicare ACO initiatives participate for only part of a performance year, but our current regulation text does not specify the duration of participation required for CMS to determine that an ACO participant TIN has participated in a performance-based risk Medicare ACO initiative.

(2) Proposed Revisions

We propose to codify the current operational approach for determining whether an ACO participant has participated in a performance-based risk Medicare ACO initiative. Under our current operational approach, an ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if its TIN was or will be used to calculate financial reconciliation for the entity participating in such ACO initiative (''Initiative ACO''). In general, if an ACO

participant was included on an Initiative ACO's participant list for a performance year during the 5 most recent performance years before the ACO's agreement start date, and the Initiative ACO is, or will be, financially reconciled for that performance year, the ACO participant will be considered to have participated in the Initiative ACO. This will generally be true regardless of whether the entity leaves the Initiative ACO mid-performance year, because its claims experience would still be used in the Initiative ACO's alignment and financial reconciliation for that performance year. If the ACO participant was included on an Initiative ACO's participant list for a performance year during the lookback period, but the ACO voluntarily terminates before the deadline for reconciliation or is otherwise not eligible for reconciliation, the ACO participant will not be considered to have experience with risk because its claims experience would not be used for financial reconciliation.

Except for determinations made regarding AIP ACOs for purposes of § 425.316(e)(2), we determine whether an ACO is experienced with performance-based risk Medicare ACO initiatives prior to the start of an ACO's agreement start date. At the time we make these determinations, the ACO may be in the middle of a PY for which reconciliation has not yet occurred. Nevertheless, we believe that at the time we make these determinations, we have the information necessary to determine whether an ACO or ACO participant TIN will be included in financial reconciliation for a PY in the relevant Medicare ACO initiative because this issue is addressed in the terms of each Medicare ACO initiative. For example, as outlined in § 425.221(b)(2)(ii)(A), if an ACO in a two-sided model terminates from the Shared Savings Program after June 30th of a PY, they will be held responsible for a pro-rated share of any shared losses determined for the performance year during which the termination becomes effective. Any ACO participant TIN that was included on the participant list for that performance year will have been included in beneficiary alignment and their claims experience used to calculate the benchmark and performance year expenditures. For other Medicare ACO initiatives, the terms of the participation agreement specify when the ACO is subject to reconciliation and which TINs will be included in reconciliation.

We propose to modify the existing definitions for ''experienced with performance-based risk Medicare ACO initiatives'' and ''inexperienced with performance-based risk Medicare ACO initiatives'' at § 425.20 to include the following new sentence at the end of each definition: ''An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for a performance year under such initiative during any of the 5 most recent performance years.'' We also propose a technical correction to remove the language ''as defined under this section'' from both definitions. We propose that these amendments would become effective on January 1, 2024.

We seek comments on the proposed regulation text.

7. Proposed Technical Changes to References in Shared Savings Program Regulations

a. References to an ACO's Assignment Methodology Selection

Section 1899(c)(2)(A) of the Act, as amended by the Bipartisan Budget Act of 2018, provides all ACOs with a choice of prospective assignment for agreement periods beginning on or after January 1, 2020. In the December 2018 final rule (83 FR 67859 through 67863), we finalized modifications to the Shared Savings Program's regulations, to separate the choice of beneficiary assignment methodology from the choice of participation track (financial model). We also added a new section of the Shared Savings Program regulations at § 425.226 to govern annual participation elections. In accordance with § 425.226, before the start of a performance year an ACO may make elections related to its participation in the Shared Savings Program, including selection of its beneficiary assignment methodology, which will be effective at the start of the applicable performance year and for the remaining years of the agreement period, unless superseded by a later election. Section 425.226(a)(1) specifies that an ACO may select the assignment methodology that CMS employs for assignment of beneficiaries under subpart E of the Shared Savings Program regulations. An ACO may select either of the following: (i) preliminary prospective assignment with retrospective reconciliation, as described in § 425.400(a)(2); or (ii) prospective assignment, as described in § 425.400(a)(3).

For consistency, in the December 2018 final rule (83 FR 67991), we also finalized conforming changes to regulations that previously identified assignment methodologies according to program track. Among other changes to the Shared Savings Program regulations, we added § 425.400(a)(4)(ii) to establish that for agreement periods beginning on July 1, 2019, and in subsequent years, the ACO may select the assignment methodology CMS employs for the assignment of beneficiaries. As specified in § 425.400(a)(4)(ii)(B), this selection of assignment methodology is made prior to the start of each agreement period, and may be modified prior to the start of each performance year as specified in § 425.226 (83 FR 67863).

Although §§ 425.226(a)(1) and 425.400(a)(4)(ii) both reference assignment methodology selection, there are key differences in the purpose each section serves in directing action from the ACO versus action that CMS initiates. Section 425.226 states that the initial selection of, and any annual selection for a change in, beneficiary assignment methodology by an ACO, must be made in the form and manner, and according to the timeframe, that we establish. Therefore, § 425.226(a)(1) is the relevant regulation for referencing the ACO's option to select and to change its selection of assignment methodology. That is, § 425.226 describes actions for which the ACO is responsible because the ACO is selecting the assignment methodology that will be effective at the beginning of the ACO's agreement period or making a change to the ACO's prior assignment methodology selection that will become effective at the beginning of the next performance year.

In comparison, § 425.400 outlines how we employ the assignment methodology described in §§ 425.402 and 425.404 for purposes of benchmarking, preliminary prospective assignment (including quarterly updates), retrospective reconciliation, and prospective assignment. Therefore, § 425.400(a)(4)(ii) is the relevant regulation for referencing how we determine the assignment methodology to be used in the referenced program operations or program calculations. That is, § 425.400(a)(4)(ii) governs actions undertaken by us because we are applying the ACO's selected assignment methodology when determining benchmarking, preliminary prospective assignment, retrospective reconciliation, and prospective assignment.

Throughout the current Shared Savings Program regulations text, there are various references to § 425.226(a)(1) or § 425.400(a)(4)(ii). We conducted a review of the Shared Savings Program regulations text to determine whether the existing twelve references to either § 425.226(a)(1) or § 425.400(a)(4)(ii) align with provisions' intended purposes. We also considered the intended purposes of the provisions in

identifying the appropriate cross-reference to include in the proposed new regulation at § 425.655, which is described in section III.G.4.b. of this proposed rule.

We believe the following five references to § 425.400(a)(4)(ii) are consistent with the intended purpose of § 425.400(a)(4)(ii), in referring to how we determine the ACO's chosen assignment methodology for purposes of determining beneficiary assignment or performing certain program calculations: § 425.609(c)(1); § 425.652(a)(5)(v)(A); § 425.652(b)(2)(iv)(A); § 425.654(a)(1)(i); and § 425.656(b)(3).

We believe the following two references to § 425.226(a)(1) are consistent with the intended purpose of § 425.226(a)(1) because the references are used when referring to the ACO's option to change its selection of assignment methodology: § 425.601(a)(9) introductory text; and § 425.652(a)(9) introductory text.

We identified five inconsistencies in references to §§ 425.226(a)(1) and 425.400(a)(4)(ii) that we are proposing to revise in this proposed rule. To follow is a description of the five references we are proposing to revise and the proposed technical changes to the applicable provisions in 42 CFR part 425, subpart G to ensure that the appropriate assignment selection reference is being cited for clarity and consistency.

For performance years starting on January 1, 2019, and subsequent performance years, CMS adds beneficiaries to an ACO's list of assigned beneficiaries based on a beneficiary's designation of an ACO professional as the provider or supplier they consider responsible for coordinating their overall care, if certain conditions are satisfied, including the conditions specified in § 425.402(e)(2)(ii)(A). In accordance with § 425.402(e)(2)(ii)(A), the beneficiary must meet the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b). Further, the provision specifies that the exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for alignment to an ACO based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under § 425.402(e), regardless of the ACO's assignment methodology selection under § 425.400(a)(4)(ii). The reference to § 425.400(a)(4)(ii) in § 425.402(e)(2)(ii)(A) is not consistent with the intended purpose of the reference the ACO's selected assignment methodology. Therefore, we are proposing to amend § 425.402(e)(2)(ii)(A) by removing the reference to § 425.400(a)(4)(ii) and adding in its place a reference to § 425.226(a)(1), for clarity and consistency.

The introductory text of § 425.601(a) (applicable to agreement periods beginning on or after July 1, 2019, and before January 1, 2024) and § 425.652(a) (applicable to agreement periods beginning on January 1, 2024, and in subsequent years) specifies that in computing an ACO's historical benchmark for its first agreement period under the Shared Savings Program, CMS determines the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period using the ACO participant TINs identified before the start of the agreement period as required under § 425.118(a) and the beneficiary assignment methodology selected by the ACO for the first performance year of the agreement period as required under § 425.226(a)(1). Accordingly, the introductory text of § 425.601(a) and § 425.652(a) is describing how we will compute expenditures for beneficiaries that would have been assigned to the ACO based on the assignment methodology selected by the ACO. This provision is referring to how we determine the assignment methodology to be used to identify the beneficiary population that would have been assigned in the three benchmark years, not to the ACO's act of selecting the assignment methodology. Therefore, we are proposing to amend the introductory text of § 425.601(a) and § 425.652(a) by removing the reference to § 425.226(a)(1) and adding in its place a reference to § 425.400(a)(4)(ii), for clarity and consistency.

Section 425.652(a)(9)(ii) specifies that for agreement periods beginning on January 1, 2024, and in subsequent years, when adjusting the benchmark for certain changes during the agreement period, we redetermine the regional adjustment amount under § 425.656 according to the ACO's assigned beneficiaries for BY3, and based on the assignable population of beneficiaries identified for the assignment window corresponding to BY3 that is consistent with the assignment window that applies under the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.226(a)(1). In § 425.652(a)(9)(ii) the reference to § 425.226(a)(1) is not consistent with the intended purpose of the reference, which is to specify how we determine the assignment methodology that will be used to identify the assigned beneficiary and assignable beneficiary populations which are in turn used to redetermine the regional adjustment in the event the ACO changes its selected assignment methodology. Therefore, we are proposing to amend § 425.652(a)(9)(ii) by removing the reference to § 425.226(a)(1) and adding in its place the reference to § 425.400(a)(4)(ii), for clarity and consistency.

Section 425.652(a)(9)(iv) describes that for agreement periods beginning on January 1, 2024, and in subsequent years, when adjusting the benchmark for certain changes during the agreement period, we redetermine the proration factor used in calculating the prior savings adjustment under § 425.658(b)(3)(ii) to account for changes in the ACO's assigned beneficiary population in the benchmark years of the ACO's current agreement period due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.400(a)(4)(ii), or changes to the beneficiary assignment methodology under 42 CFR part 425, subpart E. In § 425.652(a)(9)(iv) the reference to § 425.400(a)(4)(ii), is not consistent with the intended purpose of provision, which is to specify that we will redetermine the proration factor used in calculating the prior savings adjustment if the ACO changes its beneficiary assignment methodology selection. Therefore, we are proposing to amend § 425.652(a)(9)(iv) by removing the reference to § 425.400(a)(4)(ii) and adding in its place a reference to § 425.226(a)(1), for clarity and consistency.

We seek comments on these proposed technical changes.

b. Definition of Rural Health Clinic

In the November 2011 final rule, we established a definition for the term ''Rural health center (RHC)'' for the Shared Savings Program at § 425.20.[207] The definition of ''Rural health center (RHC)'' at § 425.20 states that this term has the same meaning given to this term under § 405.2401(b). The term ''Rural health clinic (RHC)'' is defined at § 405.2401(b) to mean a facility that has—

- Been determined by the Secretary to meet the requirements of section

[207] See, for example, 76 FR 67930 through 67932 (discussion of our proposal to define FQHCs and RHCs as these terms are defined in § 405.2401(b)), and 76 FR 67974 and 67975 (finalized regulations text for § 425.20).

1861(aa)(2) of the Act and 42 CFR part 491 concerning RHC services and conditions for approval; and

• Filed an agreement with CMS that meets the requirements in § 405.2402 to provide RHC services under Medicare.

This inconsistency between § 425.20, which inaccurately uses the word ''center,'' and § 405.2401(b), which accurately uses the word ''clinic,'' recently came to our attention. We note that the term ''rural health clinic'' was in use and defined at § 405.2401(b) when we established the term and definition for ''Rural health center (RHC)'' under part 425 with the November 2011 final rule. Furthermore, in the November 2011 final rule (76 FR 67803) we separately established an acronym ''RHCs'' for ''Rural Health Clinics'' in the acronyms list reflecting the accurate term.

To ensure clarity and accuracy, we are proposing to correct the error in the definition for ''Rural health center (RHC)'' at § 425.20 by replacing the word ''center'' with the word ''clinic''. We would like to clarify that all uses of the acronym ''RHC'' or ''RHCs'' throughout Part 425—including in the definition of ''primary care physician'' in § 425.20 as well as in §§ 425.102 and 425.304 and throughout 42 CFR part 425, subpart E—have been interpreted to refer to ''rural health clinic'' or ''rural health clinics'' as defined at § 405.2401(b). Further, we propose to revise the definition of rural health center in § 425.20 to specify that the referenced provision at § 405.2401(b) is within Title 42, Chapter IV of the Code of Federal Regulations. We seek comments on these proposed technical changes.

c. Definition of At-Risk Beneficiary

In the November 2011 final rule (see 76 FR 67974), we established the definition of ''At-risk beneficiary'' at § 425.20, the meaning of which includes, but is not limited to, a beneficiary who—

• Has a high risk score on the CMS–HCC risk adjustment model;

• Is considered high cost due to having two or more hospitalizations or emergency room visits each year;

• Is dually eligible for Medicare and Medicaid;

• Has a high utilization pattern;

• Has one or more chronic conditions;

• Has had a recent diagnosis that is expected to result in increased cost;

• Is entitled to Medicaid because of disability; or

• Is diagnosed with a mental health or substance abuse disorder.

In finalizing modifications to the proposed definition of at-risk beneficiary, we explained that we agreed with commenters that our proposed definition should be expanded to include patients who are entitled to *Medicare* (emphasis added) because of disability (see 76 FR 67950). However, in codifying the relevant regulation text at § 425.20, we inadvertently referred to patients who are entitled to *Medicaid* because of disability (emphasis added). We note that an individual who is entitled to Medicare because of disability and who is also entitled to Medicaid, would be included under the category ''Is dually eligible for Medicare and Medicaid.''

We are proposing to correct the typographical error in the definition for ''At-risk beneficiary'' at § 425.20 by replacing the word ''Medicaid'' in paragraph (7) with the word ''Medicare''. We also propose to adjust inaccurate punctuation in the list of paragraphs within this definition by replacing the period at the end of paragraphs (5) and (6) with a semi-colon. We seek comment on these proposed changes.

d. Updating Terminology in Regulations on Data Sharing With ACOs

It has come to our attention that certain terminology that is used in the data sharing regulations for the Shared Savings Program in 42 CFR part 425, subpart H is outdated or inconsistent with the terminology used elsewhere in the Medicare program and in the HIPAA regulations in 45 CFR part 164. We are proposing technical and conforming changes to § 425.702(c)(1)(ii)(A)(*3*) and § 425.702(c)(1)(ii) for clarity and consistency.

In accordance with the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), CMS discontinued the use of Social Security Number-based Health Insurance Claim Numbers (HICNs) as the beneficiary identifier on Medicare cards and replaced that identifier type with Medicare Beneficiary Identifiers (MBIs) by April 2019. MBIs are now used for Medicare transactions like billing, eligibility status, and claim status. All claims with a date of service on or after January 1, 2020, must use the beneficiary's MBI, rather than the HICN.[208] [209] To accommodate this change from HICN to MBI, starting in PY 2018 we revised Shared Savings Program reports providing beneficiary-identifiable information under § 425.702, and claim and claim line feed files with beneficiary identifiable claims data provided under § 425.704, to include a field for the beneficiary's MBI. By the end of PY 2019 we discontinued populating data in the HICN fields. However, when we made this operational update we did not make conforming changes to the regulations text at § 425.702(c)(1)(ii)(A) to revise the list of the four data elements we provide to ACOs on their fee-for-service beneficiary population: (1) beneficiary name; (2) date of birth; (3) HICN; and (4) sex. Therefore, because CMS has discontinued use of the HICN, we propose to revise § 425.702(c)(1)(ii)(A)(*3*) to refer to ''Beneficiary identifier'' instead of ''Health Insurance Claim Number (HICN).'' This change to the regulations text will not change the information that is provided to ACOs pursuant to § 425.702(c)(1)(ii).

Further, we propose to revise the list of purposes in § 425.702(c)(1)(ii) for which an ACO may request certain beneficiary-identifiable data for purposes of population-based activities to better align with the terminology used in the first paragraph of the definition of health care operations at 45 CFR 164.501. Specifically, we propose to remove the reference to ''process development'' and to add in its place a reference to ''protocol development.'' In prior rulemaking, we indicated that ACOs could request beneficiary-identifiable data under § 425.702(c)(1)(ii) for purposes of carrying out population-based activities, including process development, and referred to care coordination processes and required process development under § 425.112 (see 80 FR 32734 and 32735). We do not believe the revision we are proposing would impact ACOs' ability to request data for these types of process development. Rather, activities related to care coordination processes and the development of required processes under § 425.112 would continue to fall within the population-based activities listed in § 425.702(c)(1)(ii) for which an ACO may request data, including protocol development (as added by this proposed revision) and care coordination. This proposed revision would also ensure that the terminology used in § 425.702(c)(1)(ii) is consistent with the language of the proposed new provision at § 425.702(c)(1)(iii) discussed in

[208] CMS, MLN Matters, ''New Medicare Beneficiary Identifier (MBI) Get It, Use It''. Article number SE18006, revised March 19, 2020. Available at *https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se18006.pdf.*

[209] *CMS.gov* website, Medicare Beneficiary Identifiers (MBIs), at *https://www.cms.gov/Medicare/New-Medicare-Card.*

section III.G.2.b.(2) of this proposed rule.

We seek comment on these proposed changes.

8. Seeking Comments on Potential Future Developments to Shared Savings Program Policies

a. Background

In an article published on the New England Journal of Medicine's website on April 27, 2022,[210] CMS lays out a vision for how Accountable Care Organizations (ACOs) participating in the Shared Savings Program and in Center for Medicare and Medicaid Innovation (Innovation Center) models can help CMS achieve its goal of having all beneficiaries in the traditional Medicare program cared for by health care providers who are accountable for costs and quality of care by 2030. This article describes a vision for the Shared Savings Program and new Innovation Center models to expand participation in ACOs, strengthen incentives for savings for participants and for Medicare, and make access to ACOs more equitable, including: (1) aligning features of new Center for Medicare and Medicaid Innovation (Innovation Center) models and features in the Shared Savings Program; (2) adopting lessons from the ACO Investment Model to help provide upfront investments for small ACOs that lack experience with performance-based risk; (3) examining benchmarking approaches that could support increased participation, including among organizations serving patients with high costs of care and address the effects of rebasing and regional benchmark adjustments; and (4) examining the use of incentives to recruit health care providers that care for underserved populations to join ACOs, with the goal of closing gaps in outcomes, and asking health care providers to consider beneficiaries' social needs in care plans.

CMS adopted several policies as part of the CY 2023 PFS final rule to advance these goals, including providing advance shared savings payments in the form of advance investment payments to certain new, low-revenue ACOs that they can use to build the infrastructure needed to succeed in the Shared Savings Program and promote equity by holistically addressing beneficiary needs, including social needs; reinstating a sliding scale reflecting an ACO's quality performance for use in determining shared savings for ACOs and shared losses for ENHANCED track ACOs; modifying the benchmarking methodology to strengthen financial incentives for long-term participation by reducing the impact of ACOs' performance and market penetration on their benchmarks; support the business case for ACOs serving high-risk and a high proportion of dually eligible populations to participate; and mitigate bias in regional expenditure calculations for ACOs electing prospective assignment; and expanding opportunities for certain low-revenue ACOs participating in the BASIC track to share in savings.

CMS has also continued to receive significant input from interested parties regarding opportunities to increase participation in ACO initiatives. One such option would be to identify ways that the Shared Savings Program can support ACOs' efforts to strengthen primary care, such as by providing prospective payments for primary care that would reduce reliance on fee-for-service payments and support innovations in care delivery that better meet beneficiary needs and increase access to primary care in underserved communities. Empirical data support the notion that primary care serves as the foundation of high-performing ACOs. ACO performance results have indicated that ACOs comprised of 75 percent or more of primary care clinicians share in savings at almost twice the rate of those ACOs comprised of less than 75 percent primary care clinicians.[211] Another option would be to offer a higher risk track in the Shared Savings Program, on which CMS requests input below.

b. Incorporating a Higher Risk Track Than the ENHANCED Track

Over time, CMS has considered a higher risk Shared Savings Program track under which the shared savings/loss rate would be somewhere between 80 percent and 100 percent (that is, a rate higher than that currently offered under the ENHANCED track) that builds on the experience of the Next Generation ACO (NGACO) and ACO Realizing Equity, Access, and Community Health (ACO REACH) Models. ''Higher risk'' sharing provides a higher level of potential reward which may encourage ACOs that would not otherwise have participated in the Shared Savings Program because of current limitations on potential upside to consider participating. Also, a higher risk sharing model may incentivize participating ACOs to take on more risk (and potential reward) and incentivize ACOs to improve performance in the program, which may result in reduced healthcare costs for Medicare, and more effective, efficient care for beneficiaries. In addition, higher risk sharing may incentivize ACOs to develop new care delivery strategies, such as a focus on specialty care integration and reduced care fragmentation. Offering a higher risk sharing track may also help CMS reach our goal of having all beneficiaries in the traditional Medicare program in a care relationship with a health care provider who is accountable for the costs and quality of their care by 2030 by encouraging efficient ACOs to continue participation in the Shared Savings Program.

Currently, under the Shared Savings Program, ACOs may enter participation agreements under one of two tracks—the BASIC track or the ENHANCED track. The BASIC track allows eligible ACOs to begin under a one-sided model and incrementally transition to higher levels of risk and potential reward through the BASIC track's glide path. The ENHANCED track is a two-sided model that represents the highest level of risk and potential reward currently offered under the Shared Savings Program. The rules governing the participation options available to ACOs and the progression from lower to higher risk for ACOs entering the program are described in § 425.600 of the regulations.

Under the BASIC track, eligible ACOs operate under either a one-sided model or a two-sided model, either sharing savings only or sharing both savings and losses with the Medicare program. Under the BASIC track's glide path, the level of risk and potential reward phases in over the course of an agreement period with the ACO beginning participation under a one-sided model and progressing to incrementally higher levels of risk and potential reward, unless the ACO chooses to begin under a two-sided model and/or progress more quickly than the glide path would require.[212] The glide path includes five levels (Levels A through E). Levels A and B are one-sided models (shared savings only); [213] and Levels C, D, and E are two-sided models (shared savings and shared losses) that provide for

[210] Jacobs D, Rawal P, Fowler L, Seshamani M. Expanding Accountable Care's Reach among Medicare Beneficiaries. *NEJM.org,* April 27, 2022, available at *https://www.nejm.org/doi/full/10.1056/NEJMp2202991.*

[211] Refer to ''Medicare Shared Savings Program Saves Medicare More Than $1.6 Billion in 2021 and Continues to Deliver High-quality Care''—As of August 30, 2022, available at *https://www.cms.gov/newsroom/press-releases/medicare-shared-savings-program-saves-medicare-more-16-billion-2021-and-continues-deliver-high.*

[212] Refer to § 425.600(a)(4)(i).

[213] Refer to §§ 425.600(a)(4)(i)(A)(1), 425.605(d)(1)(i) (Level A); §§ 425.600(a)(4)(i)(A)(2), 425.605(d)(1)(ii) (Level B).

incrementally higher performance-based risk.[214] An ACO in the ENHANCED track operates under a two-sided model, sharing both savings and losses with the Medicare program, for all 5 performance years of the agreement period.

To qualify for a shared savings payment, an ACO must meet a minimum savings rate (MSR) requirement, meet the quality performance standard or alternative quality performance standard established under § 425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under 42 CFR part 425.[215] For ACOs meeting the applicable quality performance standard established under § 425.512(a)(2) or § 425.512(a)(4)(i) (for PY 2022 and PY 2023) or § 425.512(a)(5)(i) (for PY 2024 and subsequent performance years), the final shared savings rate is equal to the maximum sharing rate specific to the ACO's track/level of participation as follows: 40 percent for ACOs participating in Level A or Level B of the BASIC track,[216] 50 percent for ACOs participating in Levels C, D, or E of the BASIC track,[217] and 75 percent for ACOs participating in the ENHANCED track.[218] Beginning in PY 2023, ACOs meeting the MSR requirement that do not meet the applicable quality performance standard established under § 425.512(a)(2) or § 425.512(a)(4)(i) or § 425.512(a)(5)(i), as applicable, but meet the alternative quality performance standard described in § 425.512(a)(4)(ii) (for PY 2023) or § 425.512(a)(5)(ii) (for PY 2024 and subsequent performance years) will have the opportunity to share in savings at a lower rate that is scaled by the ACO's quality performance. Additionally, beginning in PY 2024, certain ACOs participating in the BASIC track that do not meet the MSR have the opportunity to share in savings at a rate that is equal to half of the rate to which they would have otherwise been entitled had they met the MSR.[219] CMS computes an ACO's shared savings payment by applying the final sharing rate to the ACO's savings on a first dollar basis (meaning the final sharing rate is applied to the ACO's full total savings amount), with the payment subject to a cap that is equal to 10 percent of the updated benchmark for an ACO in the BASIC track or 20 percent of the updated benchmark for an ACO in the ENHANCED track.[220]

ACOs that operate under a two-sided model and have losses that meet or exceed a minimum loss rate (MLR) must share losses with the Medicare program.[221] Once this MLR is met or exceeded, the ACO will share in losses at a rate determined according to the ACO's track/level of participation, up to a loss recoupment limit (also referred to as the loss sharing limit).[222] In determining shared losses, ACOs participating in 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.[223] ENHANCED track ACOs are subject to a loss rate that is scaled by the ACO's quality performance, subject to a minimum of 40 percent and a maximum of 75 percent.[224]

For agreement periods beginning before January 1, 2024, certain ACOs were only allowed to enter the program in the ENHANCED track, and ACOs entering the program in the BASIC track were limited in how many agreement periods they could participate in the BASIC track before being required to transition to the ENHANCED track. Based on changes finalized in the CY 2023 PFS final rule, for agreement periods starting on January 1, 2024, and in subsequent years, participation in the ENHANCED track will be optional (see 87 FR 69818).

In the NGACO Model, NGACOs were offered the choice between two risk arrangements, partial risk or full risk. Under both arrangements, the NGACO was responsible for 100 percent of performance year expenditures, for services rendered to the NGACO's aligned beneficiaries.[225] Under the partial risk arrangement, the NGACO could receive or owe up to 80 percent of savings/losses, whereas under the full risk arrangement, the NGACO could receive or owe up to 100 percent of savings/losses. To mitigate the ACO's risk of large shared losses, as well as to protect the Medicare Trust Funds against paying out excessive shared savings, NGACOs were required to choose a cap on gross savings/losses. The cap, expressed as a percentage of the benchmark, ranged from 5 percent to 15 percent. The risk arrangement chosen by the NGACO (80 or 100 percent) was applied to gross savings or losses after the application of the cap. In PYs 1–3, a discount was applied to the NGACO's benchmark that was set at a standard 3 percent, with various adjustments, that allowed the final discount to vary from 0.5 percent to 4.5 percent. In PYs 4–6, a discount of 0.5 percent was applied to the benchmark under the partial risk arrangement, and a discount of 1.25 was applied to the benchmark under the full risk arrangement. The purpose of the discount was to ensure that CMS received a financial benefit from any savings achieved by the NGACOs participating in the model.

Under the ACO REACH Model, REACH ACOs are offered the choice of participating under the Global or the Professional Risk Options. As in the NGACO Model, under both risk sharing options, the ACO REACH ACO is responsible for 100 percent of performance year expenditures for services rendered to aligned beneficiaries. Because ACOs electing the Global Risk Option retain up to 100 percent of the savings/losses, a discount is applied to the benchmark to ensure savings are also generated for CMS. Consequently, for ACOs in the Global Risk Option, the benchmark is reduced by a fixed percentage based on the performance year.[226] The benchmark for ACOs participating in the Professional Option does not include this discount, and these ACOs are only eligible to retain 50 percent of savings or owe 50 percent of any losses.

When considering including a higher risk track in the Shared Savings Program, we must balance several factors to protect beneficiaries, ACOs, and the Medicare trust funds. One factor to consider is that there may be selective participation with regard to which ACOs would choose to participate in a

[214] Refer to §§ 425.600(a)(4)(i)(A)(3), 425.605(d)(1)(iii) (Level C); §§ 425.600(a)(4)(i)(A)(4), 425.605(d)(1)(iv) (Level D); §§ 425.600(a)(4)(i)(A)(5), 425.605(d)(1)(v) (Level E).

[215] Refer to §§ 425.100(b), 425.604(c), 425.605(c), 425.606(c), 425.610(c).

[216] Refer to § 425.605(d)(1)(i)(A), (d)(1)(ii)(A).

[217] Refer to § 425.605(d)(1)(iii)(A), (d)(1)(iv)(A), (d)(1)(v)(A).

[218] Refer to § 425.610(d).

[219] Refer to § 425.605(h).

[220] Refer to § 425.605(d); § 425.610(e).

[221] Refer to § 425.100(c).

[222] Refer to § 425.605(d); § 425.610(f), (g).

[223] Refer to § 425.605(d)(1)(iii)(C), (d)(1)(iv)(C), (d)(1)(v)(C).

[224] Refer to § 425.610(f).

[225] In 2020, due to the impacts of the COVID–19 pandemic, NGACOs were offered an optional amendment to the Participation Agreement (PA) for 2020 (PY5). For NGACOs that signed the amendment, CMS removed all beneficiary experience associated with COVID–19 related admissions and retrospectively updated the prospective trend with a regional observed trend. For 2021, CMS modified the NGACO financial methodology to provide financial protection to all NGACOs continuing in the model for PY6. PY6 financial protections included: adoption of an extreme and uncontrollable circumstances policy, under which any shared losses were prorated based on the number of months during the PHE and the number of beneficiaries residing in an impacted area, and all expenses associated with COVID–19 related admissions were removed from both PY expenditures and retrospective trend.

[226] For more details, refer to CMS, ACO Realizing Equity, Access, and Community Health (REACH) Model, PY2023 Financial Settlement Overview, available at: *https://innovation.cms.gov/media/document/aco-reach-py2023-fncl-settlement* (see Table 4: Schedule of Discounts by Risk Arrangement).

higher risk track, if offered. For example, Shared Savings Program ACOs that have a history of high levels of shared savings or have received a favorable high regional adjustment to their benchmark may be more likely than other ACOs to switch to the higher risk track upon renewing or early renewing their participation in the program so they can receive additional benefit from the higher levels of potential reward offered in a higher risk track. 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 Medicare and the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model under section 1899(d). We have concerns that introducing a higher risk track would lead to only select ACOs participating, creating benefits limited almost entirely to those ACOs and limited to no benefits gained for beneficiaries or CMS.

Another consideration is that ACOs in a higher risk track could have an increased incentive (relative to existing Shared Savings Program risk models) to avoid high-cost beneficiaries in the performance year in order to maximize their potential shared savings payment or avoid or reduce potential shared losses. The Shared Savings Program truncates individual beneficiary expenditures at the 99th percentile of national Medicare fee-for-service expenditures by enrollment type, which can help to protect ACOs from the impact of expenditure outliers (*i.e.,* prevent a small number of extremely costly beneficiaries from significantly affecting the ACO's per capita expenditures) and reduce the incentive for ACOs to avoid high-cost beneficiaries. As described earlier in this section of this proposed rule, the Shared Savings Program also caps the amount of shared savings an ACO may receive or the amount of shared losses it may owe, which can further discourage beneficiary selection. If introducing a higher risk-track to the program, we would need to consider whether the program's existing approach to expenditure truncation and capping shared savings and shared losses would be sufficient in curbing incentives for ACOs to engage in beneficiary selection in light of the higher potential risk and reward, while ensuring that the new risk model will still be attractive to ACOs and improve the quality and efficiency of the care their assigned beneficiaries receive.

When considering a higher risk track, CMS would need to balance the incentives for ACOs to transition to higher levels of risk and potential reward only when they are very confident it is in their financial interest to do so, with the benefits of increasing ACO participation in the Shared Savings Program and in two-sided accountable care tracks, all while ensuring sufficient financial safeguards against inappropriately large shared losses for ACOs coordinating and improving quality of care for high-cost beneficiaries. We are seeking comment on the following: (1) policies/model design elements that could be implemented so that a higher risk track could be offered without increasing program expenditures; (2) ways to protect ACOs serving high-risk beneficiaries from expenditure outliers and reduce incentives for ACOs to avoid high-risk beneficiaries; and (3) the impact that higher sharing rates could have on care delivery redesign, specialty integration, and ACO investment in health care providers and practices.

c. Increasing the Amount of the Prior Savings Adjustment

Under section 1899(d)(1)(B)(ii) of the Act, an ACO's benchmark must be reset at the start of each agreement period using the most recent available 3 years of expenditures for Parts A and B services for beneficiaries assigned to the ACO. Section 1899(d)(1)(B)(ii) of the Act provides the Secretary with discretion to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate.'' Pursuant to this authority, as described in the CY 2023 PFS final rule (87 FR 69898 through 69915), we established a prior savings adjustment that will apply when establishing the benchmark for eligible ACOs entering an agreement period beginning on January 1, 2024, or in subsequent years, to account for the average per capita amount of savings generated during the ACO's prior agreement period.

The prior savings adjustment adopted in the CY 2023 PFS final rule is designed to adjust an ACO's benchmark to account for the average per capita amount of savings generated by the ACO across the 3 performance years prior to the start of its current agreement period for re-entering and renewing ACOs. In the final rule, we explained that reinstituting a prior savings adjustment would be broadly in line with our interest in addressing dynamics to ensure sustainability of the benchmarking methodology. Specifically, such an adjustment would help to mitigate the rebasing ratchet effect on an ACO's benchmark by returning to an ACO's benchmark an amount that reflects its success in lowering growth in expenditures while meeting the program's quality performance standard in the performance years corresponding to the benchmark years for the ACO's new agreement period. We also explained our belief that a prior savings adjustment could help address an ACO's effects on expenditures in its regional service area that result in reducing the regional adjustment added to the historical benchmark.

In the CY 2023 PFS final rule (87 FR 69899), we explained that, in order to mitigate the potential for rebased benchmarks for ACOs that are lower-spending compared with their regional service area and that achieved savings in the benchmark period to become overinflated, we believed that adjusting an ACO's benchmark based on the higher of either the prior savings adjustment or the ACO's positive regional adjustment would be appropriate. We also note that elsewhere in this proposed rule, we have proposed to further mitigate the impacts of the negative regional adjustment when the overall adjustment to an ACO's historical benchmark is negative; however, the negative regional adjustments by enrollment type would continue to be factored in when the overall regional adjustment is positive.

In the CY 2023 PFS final rule (87 FR 69902), we finalized a policy to apply a 50 percent scaling factor to the pro-rated positive average per capita prior savings because we believed it would be important to consider a measure of the sharing rate used in determining the shared savings payment the ACO earned in the applicable performance years under its prior agreement period(s). In response to discussion of this policy in the CY 2023 PFS proposed rule, ACOs and other interested parties commented that we should consider using a higher scaling factor that may more closely match the maximum shared savings rate from an ACO's prior agreement period. However, in the CY 2023 PFS final rule, we reiterated our belief that a 50 percent scaling factor would be appropriate because it represents a middle ground between the maximum sharing rate of 75 percent under the ENHANCED track and the lower sharing rates available under the BASIC track (*e.g.,* 40 percent). Additionally, we noted that if we were to finalize a scaling factor that would more closely match the average shared savings rate from an ACO's prior agreement period, many ACOs would

have a scaling factor below 50 percent, which would be less advantageous than the policy that we finalized.

In the CY 2023 PFS final rule (87 FR 69902), we also finalized a policy to calculate the final adjustment to the benchmark by adding the pro-rated average per capita prior savings to the ACO's negative regional adjustment for ACOs that are higher spending relative to their regional service area. Under this policy, we apply the 50 percent scaling factor after offsetting the negative regional adjustment to maximize the portion of the pro-rated average per capita savings that would be added to the negative regional adjustment in determining the final adjustment to the benchmark and strengthen incentives for ACOs to remain in the program.

MedPAC commented on the CY 2023 PFS proposed rule that while the prior savings adjustment is a reasonable policy for mitigating ratcheting effects, implementing both the prior savings adjustment and the regional adjustment policies together would be duplicative. MedPAC also expressed concern that the prior savings adjustment and the regional adjustment could interact in a way that would perpetuate a programmatic bias towards ACOs receiving a positive regional adjustment. In MedPAC's view, many ACOs would receive an inflated prior savings adjustment because the prior savings adjustment would be based on savings achieved using benchmarks already inflated by the regional adjustment. However, we explained in the CY 2023 PFS final rule (87 FR 69913) that because for most ACOs, the positive regional adjustment would exceed the prior savings adjustment, our policy of applying the larger of the regional adjustment and the prior savings adjustment potentially mitigates this concern.

We are seeking comment on potential changes to the 50 percent scaling factor used in determining the prior savings adjustment such as using an average of the ACO's shared savings rates from the 3 years prior to the start of its agreement period, increasing to 75 percent of shared savings achieved if the ACO participated in the ENHANCED track in the 3 years prior to the start of the agreement period, or another value corresponding to the maximum shared savings rate the ACO was eligible to earn in the 3 years prior to the start of the agreement period. We are also seeking comment on potential changes to the positive regional adjustment to reduce the possibility of inflating the benchmark while still mitigating potential ratchet effects on ACO benchmarks.

d. Expanding the ACPT Over Time and Addressing Overall Market-Wide Ratchet Effects

As described in the December 2018 final rule (83 FR 68024 through 68030), we used our statutory authority under section 1899(i)(3) of the Act to adopt the policy under which we update the historical benchmark using a blend of national and regional growth rates. In accordance with § 425.601(b), for agreement periods beginning on July 1, 2019, and before January 1, 2024, we update the historical benchmark for an ACO for each performance year using a blend of national and regional growth rates between BY3 and the performance year.

In the CY 2023 PFS final rule (87 FR 69902), we finalized a policy for agreement periods beginning on January 1, 2024, and in subsequent years to incorporate a prospectively projected administrative growth factor, a variant of the United States Per Capita Cost (USPCC) that we refer to as the Accountable Care Prospective Trend (ACPT), into a ''three-way'' blend with national and regional growth rates to update an ACO's historical benchmark for each performance year in the ACO's agreement period. The three-way blend is calculated as the weighted average of the ACPT (one-third weight) and the existing national-regional ''two-way'' blend (two-thirds weight). The ACPT will be projected for an ACO's entire agreement period near the start of that agreement period, providing a degree of certainty to ACOs.

We explained in the CY 2023 PFS final rule that the ACPT will insulate a portion of the annual benchmark update from any savings occurring as a result of the actions of ACOs participating in the Shared Savings Program and address the impact of increasing market penetration by ACOs in a regional service area on the existing blended national-regional growth factor. Because the ACPT is prospectively set at the outset of an agreement period, any savings generated by ACOs during the agreement period would not be reflected in the ACPT component of the three-way blend. Accordingly, incorporation of the ACPT may allow benchmarks to increase beyond actual spending growth rates as ACOs slow spending growth. By limiting ACOs' ability to slow spending growth for purposes of their own benchmarks, we noted that we believed the use of this three-way blend to update ACOs' benchmarks would incentivize greater savings by ACOs and greater program participation. Additionally, because incorporating the ACPT into the update would reduce the degree to which an ACO's savings negatively impact its benchmark through the regional trend component of the update, we also stated our belief that this change to the update methodology would help to address concerns raised by ACOs and other interested parties regarding the disproportionate impact of an ACO's savings on the benchmark update for ACOs with high market share.

In the final rule, we noted that it was possible that incorporating the ACPT into a three-way blended update factor would have the potential for mixed effects. For example, it may also lower an ACO's benchmark relative to the two-way blend if external factors lead to higher program spending growth than originally projected at the start of an ACO's agreement period. Consequently, we finalized that if an ACO generates losses for a performance year that meet or exceed its MLR (for two-sided model ACOs) or negative MSR (for one-sided model ACOs) under the three-way blend, we would recalculate the ACO's updated benchmark using the two-way blend and the ACO would receive whichever benchmark update minimizes shared losses. However, the ACO would not be eligible to share in savings resulting from use of the two-way blend in updating the benchmark. We also finalized that if unforeseen circumstances such as an economic recession, pandemic, or other factors cause actual expenditure trends to significantly deviate from projections, we would retain discretion to decrease the weight applied to the ACPT in the three-way blend.

In their comments on the proposal to adopt the three-way blend in the CY 2023 PFS proposed rule, ACOs and other interested parties expressed concern that the three-way blend effectively increases the proportion of the benchmark update that is based upon national trends, as opposed to regional trends, noting that the blend may not adequately account for geographic variation in spending growth that is outside of an ACO's control. Over a 5-year agreement period, we recognize some ACOs may be disadvantaged or advantaged in the short term by benchmark updates that give greater weight to a national update factor. However, as we stated in the CY 2023 PFS final rule (87 FR 69891), we believe that the net impact of these deviations will be modest in the context of offsetting considerations. For example, the three-way blend only incorporates the ACPT at a one-third weight and maintains the current two-way blend for the majority weight of the benchmark trend calculation, allowing for a

significant proportion of the benchmark update to reflect expenditure growth in an ACO's regional service area. The ACPT itself is also expected to project spending above realized spending as ACOs generate savings, thereby providing a stable, predictable component of the update factor that will be beneficial for ACOs.

Interested parties who commented on the proposal in the CY 2023 PFS proposed rule to incorporate the ACPT as part of a three-way blend suggested modifications to the three-way blend to further mitigate potential ratchet effects and to better reflect regional variation in spending. These included modifications such as: (1) keeping a two-way national-regional blend and substituting the national component of the two-way blend with the ACPT (see 87 FR 69890); and (2) adjusting the weight of the ACPT in the three-way blend to reflect each ACO's market penetration, as is done with the national component of the two-way blend (see 87 FR 69893). CMS declined to implement these suggestions in the CY 2023 PFS final rule.

We seek comment on the following potential refinements to the ACPT and the three-way blended benchmark update factor as CMS works toward broad implementation of administrative benchmarks: (1) replacing the national component of the two-way blend with the ACPT; and (2) scaling the weight given to the ACPT in a two-way blend for each ACO based on the collective market share of multiple ACOs within the ACO's regional service area.

e. Promoting ACO and CBO Collaboration

Section 1899(b)(2)(G) of the Act requires an ACO to define processes to promote evidence-based medicine and patient engagement; report on quality and cost measures; and coordinate care, such as through the use of telehealth, remote patient monitoring, and other enabling technologies. In the November 2011 final rule (76 FR 67827), we finalized policies to require that a participating Shared Savings Program ACO provide documentation in its application describing its plans to: (1) promote evidence-based medicine; (2) promote beneficiary engagement; (3) report internally on quality and cost metrics; and (4) coordinate care. We emphasized our belief that ACOs should retain the flexibility to establish processes that are best suited to their practice and patient population. As part of these required processes, we explained that ACOs should adopt a focus on patient-centeredness, which could include such activities as: a process for evaluating the needs of the ACO's population, including consideration of diversity in its patient populations, and a plan to address the needs of this population, including how the ACO intends to partner with other interested parties in the community to improve the health of its population; a plan to engage in shared decision making with beneficiaries; and a plan to implement individualized care plans, including taking into account the community resources available to the individual beneficiary.

When establishing these required processes and patient centeredness criteria in the November 2011 final rule (76 FR 67826), we stated that as we learn more about successful strategies in these areas, and as we gain more experience assessing specific critical elements for success, the Shared Savings Program eligibility requirements under section 1899(b)(2)(G) of the Act may be revised. For example, in subsequent rules we underscored the importance of health information technology development and infrastructure within care coordination. In the June 2015 final rule, we finalized two modifications to the care coordination processes required of ACOs under § 425.112(b)(4): (1) adding a new eligibility requirement under § 425.112(b)(4)(ii)(C), which required an ACO to describe in its application how it will encourage and promote the use of enabling technologies for improving care coordination for beneficiaries, and (2) adding a new provision at § 425.112(b)(4)(ii)(D), which required the applicant to describe how the ACO intends to partner with long-term and post-acute care providers to improve care coordination for the ACO's assigned beneficiaries (80 FR 32725). In the CY 2018 PFS final rule (82 FR 53222), we shifted from requiring an ACO to submit documents detailing how it would meet the requirements of § 425.112 as a narrative in its Shared Savings Program application to instead requiring it to certify at the time of application that it has defined the required processes and patient centeredness criteria consistent with the requirements specified in section § 425.112 and to furnish such documentation upon request—thereby reducing ACO burden while maintaining CMS's flexibility to obtain additional documentation when necessary (see § 425.204(c)(ii)).

Additionally, in previous rulemaking (80 FR 32722), we specified that the care coordination processes under § 425.112 could include coordination with CBOs that provide services that address social determinants of health. This coordination could include a plan to partner with interested parties of the community, a plan to engage in shared decision making with beneficiaries, and a plan to implement individualized care plans. In that rulemaking (80 FR 32722), we also confirmed our understanding that ACOs differ in their ability to adopt the appropriate health information exchange technologies, but we continued to underscore the importance of robust health information exchange tools in effective care coordination.

We are seeking comment on ways to improve and incentivize collaboration between ACOs and interested parties in the community or CBOs. As explained in the CY 2023 PFS final rule (87 FR 69790), where we refer to CBOs, we mean public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations. They may include community-action agencies, housing agencies, area agencies on aging, or other non-profits that apply for grants to perform social services. They may receive grants from other agencies in the U.S. Department of Health and Human Services, including Federal grants administered by the Administration for Children and Families (ACF), Administration for Community Living (ACL), or the Centers for Disease Control, or from State-funded grants to provide social services. Generally, we believe such organizations are trusted entities that know the populations they serve and their communities, want to be engaged, and may have the infrastructure or systems in place to help coordinate supportive services that address social determinants of health or serve as a trusted source to share information.[227] We recognize that ACOs wishing to address social needs may want to make investments in goods or social services that would enable their ACO participants and ACO providers/suppliers to work with CBOs that have expertise in identifying and providing the types of social services that the ACO's beneficiary population requires.

It is important to note that the Shared Savings Program does not prohibit ACOs from partnering with CBOs. Currently, if a CBO is enrolled in Medicare, it may already be an ACO participant or an ACO provider/supplier. We believe CBOs could play

[227] U.S. Department of Health & Human Services, Office of the Assistant Secretary for Preparedness and Response, Community-Based Organizations during COVID–19, available at *https://www.phe.gov/emergency/events/COVID19/atrisk/returning-to-work/Pages/default.aspx*.

an important role in identifying and addressing gaps in health equity. As we stated in the CY 2023 PFS final rule, we hope to encourage more ACOs to partner with CBOs whether they provide items and services reimbursed by Medicare or not. We recognized that Federal and other sources of grant funding for social services may be insufficient to fully address the demand for services within a community or broader geography. As we noted in that final rule, contractual arrangements between the health care sector and CBOs providing social services have increased in recent years to meet this demand.

We are seeking comment on approaches, generally, for encouraging or incentivizing increased collaboration between ACOs and CBOs, including any policies specifically designed to encourage ACOs to partner with CBOs and address unmet health-related social needs. We are also seeking comment on potential changes CMS could make to the patient-centered care requirements in § 425.112 to strengthen partnerships between ACOs and interested parties in the community, including CBOs, to address unmet health-related social needs.

H. Medicare Part B Payment for Preventive Vaccine Administration Services (§§ 410.10, 410.57, 410.152)

1. Statutory Background

Under section 1861(s)(10) of the Act, Medicare Part B currently covers both the vaccine and vaccine administration for the specified preventive vaccines—the pneumococcal, influenza, hepatitis B and COVID–19 vaccines. Section 1861(s)(10)(B) of the Act specifies that the hepatitis B vaccine and its administration is only covered for those who are at high or intermediate risk of contracting hepatitis B, as defined at § 410.63. Under sections 1833(a)(1)(B) and (b)(1) of the Act, respectively, there is no applicable beneficiary coinsurance, and the annual Part B deductible does not apply for these vaccines or the services to administer them. Per section 1842(o)(1)(A)(iv) of the Act, payment for these vaccines is based on 95 percent of the Average Wholesale Price (AWP) for the vaccine product, except where furnished in the settings for which payment is based on reasonable cost, such as a hospital outpatient department (HOPD), rural health clinic (RHC), or Federally qualified health center (FQHC). Some other preventive vaccines, such as the zoster vaccine for the prevention of shingles, not specified for Medicare Part B coverage under section 1861(s)(10) of the Act are instead covered and paid for under Medicare Part D.

2. Medicare Part B Payment for the Administration of Preventive Vaccines

a. Pneumococcal, Influenza and Hepatitis B Vaccine Administration

In the CY 2022 PFS final rule (86 FR 65186), we finalized a uniform payment rate of $30 for the administration of a pneumococcal, influenza or hepatitis B vaccine covered under the Medicare Part B preventive vaccine benefit. We explained that since the administration of the preventive vaccines described under section 1861(s)(10) of the Act are finalized independent of the PFS, these payment rates will be updated as necessary, independent of the valuation of any specific codes under the PFS. (Please see COVID–19 vaccine administration payment information in the next section.) The CY 2022 PFS final rule (86 FR 65180 through 65182) provides a detailed discussion on the history of the valuation of the three Level II Healthcare Common Procedure Coding System (HCPCS) codes, G0008, G0009, and G0010, which describes the services to administer an influenza, pneumococcal, and hepatitis B vaccine, respectively.

In the CY 2023 PFS final rule (87 FR 69984), we finalized an annual update to the payment amount for the administration of Part B preventive vaccines based upon the percentage increase in the Medicare Economic Index (MEI). Additionally, we finalized the use of the PFS Geographical Adjustment Factor (GAF) to adjust the payment amount to reflect cost differences for the geographic locality based upon the fee schedule area where the preventive vaccine is administered. These adjustments and updates apply to HCPCS codes G0008, G0009, G0010, and to Level I Current Procedural Terminology (CPT) codes that describe the service to administer COVID–19 vaccines, which we discuss in the next section.[228]

The current payment rates for G0008, G0009, and G0010, as finalized in the CY 2023 PFS final rule, can be found on the CMS Seasonal Influenza Vaccines Pricing website under Downloads.[229] The payment rates for these services with the annual update applied for CY 2024, will be made available at the time of publication of the CY 2024 PFS final rule.

b. COVID–19 Vaccine Administration

In the CY 2022 PFS final rule (86 FR 65181 and 65182), we provide a detailed history regarding the determinations of the initial payment rates for the administration of the COVID–19 vaccines, and how the payment policy evolved to a rate of $40 per dose. We note that in the CY 2022 PFS proposed rule (86 FR 39220 through 39224), we included a comment solicitation requesting information that specifically identifies the resource costs and inputs that should be considered when determining payment rates for preventive vaccine administration. As part of the comment solicitation, we requested feedback specifically related to the circumstances and costs associated with furnishing COVID–19 vaccines, in order to ensure that we took these into consideration when determining our payment policy. In the CY 2022 PFS final rule (86 FR 65185), we stated that, after consideration of all the comments received, it was appropriate to establish a single, consistent payment rate for the administration of all four Part B preventive vaccines in the long term, but to pay a higher, $40 payment rate for administration of COVID–19 vaccines in the short term, while pandemic conditions persisted (86 FR 65185).

In the CY 2023 PFS final rule (87 FR 69988 through 69993), we stated that in light of the timing distinctions between a PHE declared under section 319 of the Public Health Service (PHS) Act and an Emergency Use Authorization (EUA) declaration under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), we reconsidered the policies finalized in the CY 2022 PFS final rule in light of our goal to promote broad and timely access to COVID–19 vaccines. We explained that our goal would be better served if our policies with respect to payment for these products, as addressed in the November 2020 IFC and CY 2022 PFS final rule, continue until the EUA declaration for drugs and biological products with respect to COVID–19 (see 85 FR 18250) is terminated. Therefore, we finalized that we would maintain the current payment rate of $40 per dose for the administration of COVID–19 vaccines through the end of the calendar year in which the March 27, 2020 EUA declaration under section 564 of the FD&C Act (EUA declaration) for drugs and biological products ends. Effective January 1 of the year following the year in which the EUA declaration ends, the COVID–19 vaccine administration

[228] *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.*

[229] *https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice/vaccinespricing.*

payment would be set at a rate to align with the payment rate for the administration of other Part B preventive vaccines, that is, $30 per dose. As mentioned above, we also finalized that, beginning January 1, 2023, we would annually update the payment amount for the administration of all Part B preventive vaccines based upon the percentage increase in the MEI, and that we would use the PFS GAF to adjust the payment amount to reflect cost differences for the geographic locality based upon the fee schedule area where the vaccine is administered.

The current payment rates for the CPT codes that describe the service to administer COVID–19 vaccines, as finalized in the CY 2023 PFS final rule, can be found on the CMS COVID–19 Vaccines and Monoclonal Antibodies website.[230] The payment rates for these services with the annual update applied for CY 2024, will be made available at the time of publication of the CY 2024 PFS final rule.

3. In-Home Additional Payment for Administration of COVID–19 Vaccines

a. Background

In the CY 2022 PFS final rule (86 FR 65187 and 65190), we provide a detailed discussion on the payment policy for COVID–19 vaccine administration in the home. In summary, providers and suppliers that administer a COVID–19 vaccine in the home, under certain circumstances, can bill Medicare for one of the existing COVID–19 vaccine administration CPT codes[231] along with HCPCS code M0201 (*COVID–19 vaccine administration inside a patient's home; reported only once per individual home per date of service when only COVID–19 vaccine administration is performed at the patient's home*). In CY 2022, the Medicare Part B payment amount paid to providers and suppliers administering a COVID–19 vaccine in the home was $75.50 dollars per dose ($40 for COVID–19 vaccine administration and $35.50 for the additional payment for administration in the home). These payment amounts were then geographically adjusted using PFS GPCIs (as discussed in the CY 2023 PFS final rule at 87 FR 69980 through 69983).

Since announcing the add-on payment for in-home COVID–19 vaccine administration in June 2021, we noted that we established these policies on a preliminary basis to ensure access to COVID–19 vaccines during the public health emergency and that we would continue to evaluate the needs of Medicare patients and these policies. In the CY 2022 PFS proposed rule (86 FR 39224 through 39226), we included a comment solicitation to collect feedback on these policies and potential future changes. As part of the comment solicitation, we requested feedback related to our definition of ''home,'' program integrity concerns, changes that we should consider, costs associated with administering COVID–19 vaccines in the home, and whether outside of a PHE there is a need to vaccinate people in the home rather than going to a health care provider or supplier. In the CY 2022 PFS final rule (86 FR 65188 through 65190), we discussed the feedback received, and we noted that commenters overwhelmingly recommended that we continue making the additional payment for COVID–19 vaccines administered in the home beyond the end of the PHE. Many commenters also supported extending the payment to other preventive vaccines, either permanently or until the end of the PHE. Commenters emphasized the importance of increasing vaccination rates and making vaccines available to underserved homebound beneficiaries who face barriers including chronic illness, financial and social precarity, and lack of access to digital resources. We agreed with commenters that the added costs and compelling needs required CMS to adopt the in-home add-on payment rate for COVID–19 vaccine administration. In addition, we stated that since we did not expect those needs or costs to diminish immediately with the end of the PHE, we believed it would be appropriate to leave the in-home add-on payment rate in place through the end of the calendar year in which the PHE ends. We explained that this extension of payment past the end of the PHE would also afford CMS the opportunity to monitor vaccine uptake data (86 FR 65189). We note that in section III.H.3.c. of this proposed rule, we are proposing revisions to § 410.152 that relate to this payment policy.

In the CY 2023 PFS final rule (87 FR 69984 through 69986), we discussed that we had received many comments and requests from interested parties that the in-home add-on payment be applied more broadly to all preventive vaccines. Commenters also expressed concerns that discontinuation of the in-home additional payment would negatively impact access to the COVID–19 vaccine for underserved homebound beneficiaries. We noted that while we agreed with these concerns, we also believed that we need to learn more about the populations served through the current in-home add-on payment, and other potential populations that may not have been able to access a COVID–19 vaccine despite the availability of the in-home add-on payment, in order to understand the barriers in receiving vaccinations in their home versus in the community. We also noted the need to consider potential program integrity concerns. Therefore, we finalized that we would continue the additional payment of $35.50 when a COVID–19 vaccine is administered in a beneficiary's home, under the certain circumstances described in section III.H.3.b of the final rule, only for the duration of CY 2023. We explained that we were continuing the additional payment for at-home COVID–19 vaccinations for another year in order to provide us time to track utilization and trends associated with its use, in order to inform the Part B preventive vaccine policy on payments for in-home vaccine administration for CY 2024.

We also finalized the policy to adjust this payment amount for geographic cost differences as we do the payment for the preventive vaccine administration service, that is, based upon the fee schedule area where the COVID–19 vaccine is administered, by using the PFS GAF. In addition, we finalized an update to the $35.50 payment amount by the CY 2023 MEI percentage increase, consistent with the policy finalized for the other preventive vaccine administration services. We note that in the CY 2023 PFS final rule (87 FR 69688 through 69710), we rebased and revised the MEI to a 2017 base year. Therefore, we finalized (87 FR 69986) that for CY 2023, the in-home additional payment amount for COVID–19 vaccine administration described by HCPCS code M0201 was $36.85 ($35.50 × 1.038 = $36.85), and we established that payment for these services is adjusted for geographic cost differences using the relevant PFS GAF. We note that in section III.H.3.c. of this proposed rule, we are proposing revisions to § 410.152 that relate to these policies.

b. Conditions for Billing HCPCS Code M0201

In establishing the additional payment for COVID–19 vaccine administration in the home, we also established certain conditions for the add-on payment described by HCPCS code M0201. In the CY 2022 PFS final rule, we provide a detailed discussion

[230] *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.*

[231] *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.*

on how we established the certain conditions under which the code can be used, and the situations we contemplated to arrive at our final payment policy (86 FR 65187 and 65188).

For purposes of this add-on payment for in-home COVID–19 vaccine administration, the following requirements apply when billing for HCPCS code M0201: [232] [233]

- The patient has difficulty leaving the home to get the vaccine, which could mean any of these:

++ They have a condition, due to an illness or injury, that restricts their ability to leave home without a supportive device or help from a paid or unpaid caregiver;

++ They have a condition that makes them more susceptible to contracting a pandemic disease like COVID–19; or

++ They are generally unable to leave the home, and if they do leave home, it requires a considerable and taxing effort.

- The patient is hard-to-reach because they have a disability or face clinical, socioeconomic, or geographical barriers to getting a COVID–19 vaccine in settings other than their home. These patients face challenges that significantly reduce their ability to get vaccinated outside the home, such as challenges with transportation, communication, or caregiving.
- The sole purpose of the visit is to administer the COVID–19 vaccine. Medicare will not pay the additional amount if the provider or supplier furnished another Medicare covered service in the same home on the same date.
- A home can be:

++ A private residence, temporary lodging (for example, a hotel or motel, campground, hostel, or homeless shelter);

++ An apartment in an apartment complex or a unit in an assisted living facility or group home (including assisted living facilities participating in the CDC's Pharmacy Partnership for Long-Term Care Program when their residents are vaccinated through this program);

++ A patient's home that is made provider-based to a hospital during the PHE for COVID–19; or

++ Communal spaces of a multi-unit or communal living arrangement.

- A home cannot be:

++ An institution that meets the requirements of sections 1861(e)(1), 1819(a)(1), or 1919(a)(1) of the Act, which includes hospitals and skilled nursing facilities (SNFs), as well as most nursing facilities under Medicaid.[234]

The COVID–19 vaccine must be administered inside an individual's home. For this purpose, an individual unit in a multi-dwelling building is considered a home. For example, an individual apartment in an apartment complex or an individual bedroom inside an assisted living facility or group home is considered a home. HCPCS code M0201, as noted in the code descriptor, can be billed only once per individual home per date of service. Medicare pays the additional payment amount for up to a maximum of 5 vaccine administration services per home unit or communal space within a single group living location; but only when fewer than 10 Medicare patients receive a COVID–19 vaccine dose on the same day at the same group living location.

c. Proposals for CY 2024 and Subsequent Years

Over the past several months, CMS has engaged in an in-depth analysis of the use of HCPCS billing code M0201, which specifically indicates that a COVID–19 vaccine was furnished in the home on a Medicare claim. The analysis found that data for in-home COVID–19 vaccinations among Medicare fee-for-service beneficiaries from June 2021 to June 2022 show the payment code was used at a disproportionately high rate by underserved populations, including persons who are dual eligible for both Medicare and Medicaid and those of advanced age. The data reflect that, between June 2021-June 2022, those 85 years of age and older were over 3 times more likely than younger beneficiaries to have received an in-home COVID–19 vaccination, and persons who are dual eligible for both Medicare and Medicaid were over 2 times more likely than those who are not dual eligible to have received a COVID–19 vaccine provided in their home. The data also showed higher usage of the in-home payment code among those with some common chronic conditions.[235]

In light of the results of our study, we concluded that the in-home additional payment improved healthcare access to vaccines for these often-underserved Medicare populations. From an analysis of the data, it is clear that the in-home additional payment is being billed significantly more frequently for beneficiaries that are harder to reach and that may be less likely to otherwise receive these preventive benefits. Therefore, we propose to maintain the in-home additional payment for COVID–19 vaccine administration under the Part B preventive vaccine benefit. In addition, since our statutory authority at section 1861(s)(10) of the Act to regulate Part B preventive vaccine administration is identical for all four preventive vaccines, and since the payment has been shown to positively impact health equity and healthcare access, we propose to extend the additional payment to the administration of the other three preventive vaccines included in the Part B preventive vaccine benefit—the pneumococcal, influenza, and hepatitis B vaccines. We propose to provide the additional payment for pneumococcal, influenza, hepatitis B and COVID–19 vaccine administrations in the home, when the conditions described in section III.H.3.b of this proposed rule are met. We note that several of the conditions we established for the in-home additional payment, discussed previously in this section of the proposed rule, refer specifically to COVID–19. If we finalize the proposal to expand the in-home additional payment to the other preventive vaccines, we would broaden the conditions for the payment to reflect preventive vaccines for the other diseases.

Further, since expanding this policy could mean that multiple vaccines are administered during the same visit to the home, we propose to limit the additional payment to one payment per home visit, even if multiple vaccines are administered during the same home visit. We emphasize that every vaccine dose that is furnished would still receive its own unique vaccine administration payment. We intend to continue to monitor utilization of the M0201 billing code for the in-home additional payment, and we plan to revisit the policy should we observe inappropriate use or abuse of the code. We propose to modify the regulations at § 410.152(h) to reflect these policies.

We seek comment on the policy condition mentioned in section III.H.3.b of this proposed rule regarding Medicare payment of the in-home additional payment amount for up to a maximum of 5 vaccine administration services per home unit or communal space within a single group living location, but only when fewer than 10 Medicare patients receive a COVID–19 vaccine dose on the same day at the same group living location. We invite feedback on the applicability of this policy to the proposed policy to make

[232] *https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment.*

[233] *https://www.cms.gov/files/document/vaccine-home.pdf.*

[234] 42 CFR 409.42(a).

[235] Common chronic conditions as identified by the CMS Chronic Conditions Data Warehouse, *https://www2.ccwdata.org/web/guest/home/.*

the in-home additional payment available for the administration of all four Part B preventive vaccines.

If finalized as proposed, the in-home additional payment for the administration of pneumococcal, influenza, and hepatitis B vaccines would be effective January 1, 2024, to join the current additional payment for the in-home administration of COVID–19 vaccines that is now being extended. That is, providers and suppliers would continue to bill Medicare Part B for the additional payment for the in-home administration of COVID–19 vaccines, and beginning January 1, 2024, they would also be able to bill Medicare Part B for the in-home administration of pneumococcal, influenza, and hepatitis B vaccines. In addition, like the current in-home additional payment for COVID–19 vaccine administration, the proposed in-home additional payment for the administration of Part B preventive vaccines that would be effective beginning for CY 2024, if finalized, would be geographically adjusted based on the PFS GAF, and annually updated by the CY 2024 MEI percentage increase. For CY 2024, the proposed growth rate of the 2017-based MEI is estimated to be 4.5 percent, based on the IHS Global, Inc. (IGI) first quarter 2023 forecast with historical data through fourth quarter 2022. Therefore, we would multiply the CY 2023 in-home additional payment amount for Part B preventive vaccine administration of $36.85 by the proposed CY 2024 percentage increase in the MEI of 4.5 percent, which would result in a proposed CY 2024 in-home additional payment for Part B preventive vaccine administration of $38.51 ($36.85 x 1.045 = $38.51). We are also proposing that if more recent data are subsequently available (for example, a more recent estimate of the MEI percentage increase), we would use such data, if appropriate, to determine the CY 2024 MEI percentage increase in the CY 2024 PFS final rule; we would apply that new MEI percentage increase to update last year's $36.85 CY 2023 in-home additional payment amount for Part B preventive vaccine administration.

Therefore, in this proposed rule, we propose to amend the Part B payment for preventive vaccine administration regulations at § 410.152(h) to reflect the following:

- Effective January 1, 2022, the Medicare Part B additional payment amount paid to providers and suppliers administering a COVID–19 vaccine in the home, under certain circumstances, is $35.50. For COVID–19 vaccines administered in the home January 1, 2022 through December 31, 2022, the additional payment amount under Medicare Part B is adjusted to reflect geographic cost variations using the PFS GPCIs.
- Effective January 1, 2023, the additional payment amount for the administration of a COVID–19 vaccine in the home is annually updated based upon the percentage change in the MEI. For COVID–19 vaccines administered in the home January 1, 2023 through December 31, 2023, the payment amount is adjusted to reflect geographic cost variations using the PFS GAF.
- Effective January 1, 2024, the payment policy allowing for additional payment for the administration of a COVID–19 vaccine in the home would be extended to include the other three preventive vaccines included in the Part B preventive vaccine benefit, and the payment amount for all four vaccines would be identical. That is, beginning January 1, 2024, the Medicare Part B will pay the same additional payment amount to providers and suppliers that administer a pneumococcal, influenza, hepatitis B, or COVID–19 vaccine in the home, under certain circumstances. This additional payment amount would be annually updated using the percentage increase in the MEI and adjusted to reflect geographic cost variations using the PFS GAF.

We solicit comment on these proposals and the proposed amendments to the regulation text.

4. Other Amendments to Regulation Text

In CY 2023 PFS final rule (87 FR 69987 through 69993), we finalized changes to our policies regarding Part B coverage and payment for COVID–19 monoclonal antibody products and their administration. In that final rule (87 FR 69987), we discussed that all COVID–19 monoclonal antibody products and their administration are covered and paid for under the Part B preventive vaccine benefit through the end of year in which the Secretary terminates the EUA declaration for drugs and biological products with respect to COVID–19. In addition, we explained that, under the authority provided by section 3713 of the CARES Act, we have established specific coding and payment rates for the COVID–19 vaccine, as well COVID–19 monoclonal antibodies and their administration, through technical direction to Medicare Administrative Contractors (MACs) and information posted publicly on the CMS website (87 FR 69987). At 87 FR 69983, we listed the unique payments rates for the administration of COVID–19 monoclonal antibodies in Table 85. We note that at the time of the publication of this proposed rule, there are no COVID–19 monoclonal antibodies approved or authorized for use against the dominant strains of COVID–19 in the United States.

In the CY 2023 PFS final rule, we also established a policy to continue coverage and payment for monoclonal antibodies that are used for pre-exposure prophylaxis (PreP) of COVID–19 under the Part B preventive vaccine benefit, if they meet applicable coverage requirements (87 FR 69992). We explained that we would continue to pay for these products and their administration even after the EUA declaration for drugs and biological products is terminated, so long as after the EUA declaration is terminated, such products have market authorization. Additionally, we established that payments for the administration of monoclonal antibodies that are used for PreP of COVID–19 would be adjusted for geographic cost variations using the PFS GAF. However, we did not codify these policies in our regulations. We now propose revisions to the relevant regulations to include monoclonal antibodies that are used for PreP of COVID–19 under the Part B preventive vaccine benefit. Specifically, we propose to revise the following regulations to reflect policies for monoclonal antibodies for PreP of COVID–19 that we finalized in the CY 2023 PFS final rule:

- At § 410.10, in paragraph (l), we propose to add a phrase regarding monoclonal antibodies used for pre-exposure prophylaxis of COVID–19, and their administration.
- At § 410.57, in paragraph (c), we propose to add a phrase regarding monoclonal antibodies used for pre-exposure prophylaxis of COVID–19, and their administration.

We note again that at the time of the publication of this proposed rule, there are no COVID–19 monoclonal antibodies approved or authorized for use against the dominant strains of COVID–19 in the United States. Therefore, we are not proposing any payment regulations regarding monoclonal antibodies for PreP of COVID–19 at this time. If and when a new monoclonal antibody for PreP of COVID–19 becomes authorized for use, we would use the authority provided by section 3713 of the CARES Act, as discussed in the CY 2023 PFS Final Rule (87 FR 69987), to establish specific coding and payment rates for the administration of that product through technical direction to MACs and information posted publicly on the CMS website. We would subsequently

propose coding and payment rates for the administration of that product via rulemaking.

We also note that, for the purposes of the in-home additional payment discussed above in section III.H.3.c. of this proposed rule, that additional payment is not applicable to the administration of monoclonal antibodies for PreP of COVID–19. With regard to monoclonal antibodies for PreP of COVID–19, as displayed in Table 85 of the CY2023 PFS final rule (87 FR 69983), we set the coding and payment rates for the administration of COVID–19 monoclonal antibodies in the home to be higher than those in other health care settings, and therefore such amounts already account for the higher costs of administering the product in the home. More information on our coding and payment policies for COVID–19 monoclonal antibodies is available at *https://www.cms.gov/monoclonal*.

Also, in the CY 2023 PFS final rule, we codified our payment rates for all four Part B preventive vaccines, and we finalized that the vaccine administration payment rates for all four Part B preventive vaccines would be annually updated by the MEI and geographically adjusted by the PFS GAF. We included these policies in regulation text at § 410.152(h). However, we neglected to include the effective date for the MEI policy in the regulation text. We are proposing the following correction, and we are reorganizing other elements of the regulation text at § 410.152(h) as we codify the in-home additional payment:

- At § 410.152, at paragraph (h)(5), we propose to add that the paragraph is effective beginning January 1, 2023.
- At § 410.152, we propose to combine the existing paragraph (h)(2) and (h)(3) into a new paragraph (h)(2), with subparagraphs (h)(2)(i) and (h)(2)(ii)
- At § 410.152, at a revised paragraph (h)(3), we propose new regulations regarding the in-home additional payment for preventive vaccine administration, as described in this section of the proposed rule in section III.H.3.c.

I. Medicare Diabetes Prevention Program (MDPP)

The Centers for Medicare & Medicaid Services' (CMS) Medicare Diabetes Prevention Program Expanded Model (hereafter, ''MDPP'' or ''expanded model'') is an evidence-based behavioral intervention that aims to prevent or delay the onset of type 2 diabetes for eligible Medicare beneficiaries diagnosed with prediabetes. MDPP is an expansion in duration and scope of the Diabetes Prevention Program (DPP) model test, which was initially tested by CMS through a Round One Health Care Innovation Award (2012–2016). MDPP was established in 2017 as an ''additional preventive service'' covered by Medicare and not subject to beneficiary cost-sharing, in addition to being available once per lifetime to eligible beneficiaries. To facilitate delivery of MDPP in a non-clinical community setting (to align with the certified DPP model test) by non-clinical providers, CMS created through rulemaking in the CY 2017 PFS final rule, a new MDPP supplier type, in addition to requiring organizations that wish to participate in MDPP enroll in Medicare separately, even if they are already enrolled in Medicare for other purposes.

MDPP is a non-pharmacological behavioral intervention consisting of no fewer than 22 intensive sessions using a Centers for Disease Control and Prevention (CDC) approved National Diabetes Prevention Program (National DPP) curriculum. Sessions are furnished over 12 months by a trained Coach who provides training on topics that include long-term dietary change, increased physical activity, and behavior change strategies for weight control and diabetes risk reduction. Suppliers may use the CDC-developed PreventT2 curriculum [236] or an alternate CDC-approved curriculum when delivering MDPP. The primary goal of the expanded model is to help Medicare beneficiaries reduce their risk for developing type 2 diabetes by achieving at least 5 percent weight loss.

Eligible organizations seeking to furnish MDPP began enrolling in Medicare as MDPP suppliers on January 1, 2018 and began furnishing MDPP on April 1, 2018. Through the National DPP Diabetes Prevention Recognition Program (DPRP), the CDC administers a national quality assurance program recognizing eligible organizations that furnish the National DPP through its evidence-based DPRP Standards,[237] which are updated every 3 years. The CDC established the DPRP in 2012 and possesses significant experience assessing the quality of program delivery by organizations throughout the United States, applying a comprehensive set of national quality standards. For further information on the DPP model test, the CDC's National DPP, and DPRP Standards, please refer to the CY 2017 [238] and CY 2018 PFS [239] final rules and the following websites: *https://Innovation.cms.gov/initiatives/Health-Care-Innovation-Awards/*; *https://www.cdc.gov/diabetes/prevention/index.html*; and *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf*.

We are proposing to amend § 410.79(b) to remove the definition for the core maintenance session interval while adding definitions for the following terms: Combination delivery, Distance learning, Extended flexibilities, Extended flexibilities period, Full-Plus CDC DPRP recognition, Online delivery, and Virtual sessions. In addition, we propose to amend § 410.79(c)(2)(i)(A) and (B) to update the maximum number of payable sessions during the MDPP core services period. We also propose to amend § 410.79(e)(2) to extend certain flexibilities established through rulemaking as a result of the recent COVID–19 public health emergency (PHE) for a period of 4 years. Furthermore, we propose to amend § 414.84 to streamline the MDPP payment structure by adding service-based attendance payments, while still retaining the diabetes risk reduction performance payments for 5 percent and 9 percent weight loss. We also propose to amend § 424.205(a) and (c) to remove ''MDPP interim preliminary recognition'' and replace it with ''CDC preliminary recognition''.

1. Proposed Changes to § 410.79 by Amending Paragraphs (b), (c)(2)(i) and (e)(2)

The MDPP expanded model was implemented through the rulemaking process in two phases in the CY 2017 PFS final rule [240] and in the CY 2018 PFS final rule.[241] Through this proposed rule, we are proposing to amend the MDPP expanded model to revise certain

[236] *https://www.cdc.gov/diabetes/prevention/resources/curriculum.html*.

[237] Centers for Disease Control & Prevention Diabetes Prevention Recognition Program: Standards and Operating Procedures. May 1, 2021. *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf*.

[238] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements. 81 FR 80471. Accessed March 12, 2023. *https://www.govinfo.gov/content/pkg/FR–2016–11–15/pdf/2016–26668.pdf*.

[239] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. 82 FR 52976. *https://www.govinfo.gov/content/pkg/FR–2018–11–23/pdf/2018–24170.pdf*.

[240] *https://www.govinfo.gov/content/pkg/FR–2016–11–15/pdf/2016–26668.pdf*.

[241] *https://www.govinfo.gov/content/pkg/FR–2017–11–15/pdf/2017–23953.pdf*.

MDPP policies adopted through previous rulemaking. We are proposing to amend § 410.79(b) to remove the definition for the core maintenance session interval while adding definitions for Combination delivery, Distance learning and Online delivery modalities, among other definitions. The core maintenance session interval, as defined in the CY 2018 PFS, means one of the two consecutive 3-month time periods during months 7 through 12 of the MDPP services period, during which an MDPP supplier offers an MDPP beneficiary at least one core maintenance session per month. The core maintenance session interval represents a performance interval for attendance-based payments in the current payment structure. Given that we are proposing that beneficiary attendance be paid on a fee-for-service basis, we propose removing the core maintenance session interval to make the payment structure less confusing.

In prior rulemaking, we did not formally define the MDPP delivery modalities that are considered virtual. In this proposed rule, we propose adding definitions for distance learning and online delivery modalities in § 410.79(b) to better clarify which virtual modalities can be used in the proposed Extended flexibilities period.

We are also proposing to modify the definitions for Make-up session, MDPP services period, and MDPP session as defined in § 410.79(b) to remove most references to ongoing maintenance sessions. In the CY 2022 PFS, we removed eligibility for the Ongoing Maintenance Sessions for those beneficiaries who started the Set of MDPP services on or after January 1, 2022. Given that the 2-year MDPP services period for those beneficiaries who started MDPP on or before December 31, 2022 will end on or before December 30, 2024, eligibility for ongoing maintenance services will end December 31, 2023 for all beneficiaries.

The core services period, as defined in § 410.79(c)(2)(i)(A) and (B), consists of at least 16 core sessions offered at least one week apart during the months 1 through 6 of the MDPP services period, and two 3-month core maintenance session intervals offered during months 7 through 12 of the MDPP services period. In order to conform to the proposed revisions to the payment structure in § 414.84, we are proposing to amend the expanded model regulations to allow for fee-for-service payments for beneficiary attendance during the core services period.

MDPP's performance-based payment structure was established in the CY 2018 PFS to pay for the Set of MDPP services that makes up the periodic performance payments to MDPP suppliers during the MDPP services period. The aggregate of all MDPP performance payments constitutes the total performance-based payment amount for the Set of MDPP services. Although beneficiaries may currently attend at least 16 weekly sessions in months 1–6 and at least 6 monthly sessions in months 7–12, MDPP suppliers are only paid five times for beneficiary attendance: after a beneficiary attends the 1st, 4th and 9th sessions in months 1–6, and after attending the second core maintenance session in months 7–9 and in months 10–12.

Since this payment structure went into effect in 2018, we received feedback from suppliers and interested parties that the MDPP performance-based payment structure is confusing to suppliers, including those new to Medicare and existing Medicare-enrolled suppliers. Confusion with claims submission has been due in part to the MDPP payment structure, which pays for attendance and diabetes risk-reduction performance-based milestones instead of paying for an individual service. Paying for an individual service delivery is typical in Medicare. Public comments in response to the CY 2018 PFS proposed rule have indicated that CMS should modify its payment structure such that it allows for an adequate and predictable payment stream to cover the cost of providing services as long as beneficiaries attend sessions.

After 5 years of testing the current performance-based payment structure, we have determined that the attendance-based performance payments are not working. For example, there are currently five attendance-based performance payments over the 12-month MDPP service period, with a potential 4 to 5-month lag between the third payment and the fourth payment. Our monitoring data show that attendance sharply drops after the first quarter of the expanded model, which is likely after the 9th weekly session has been attended. We believe that our current payment structure does not incentivize beneficiary retention. As a result, we are proposing fee-for-service payments for beneficiary attendance, allowing for up to 22 attendance-based payments versus the five that are currently in place. Thus, we propose allowing beneficiaries to attend a maximum of 22 sessions during the core services period, including up to 16 sessions in months 1–6 and up to 6 sessions in months 7–12.

We are proposing to amend the MDPP expanded model to revise certain MDPP policies finalized in the CY 2021 PFS final rule. We are proposing to extend the flexibilities allowed under the COVID–19 Public Health Emergency for a period of 4 years until December 31, 2027. These Extended flexibilities are described in § 410.79(e)(3)(iii), and (iv) of this paragraph. The MDPP regulations provide for the following flexibilities during the PHE or an applicable 1135 waiver event:

- *Alternatives to the requirement for in-person weight measurement (§ 410.79(e)(3)(iii)).* Section 410.79(e)(3)(iii) permits an MDPP supplier to obtain weight measurements for MDPP beneficiaries for the baseline weight and any weight loss-based performance achievement goals in the following manner: (1) via digital technology, such as scales that transmit weights securely via wireless or cellular transmission; or (2) via self-reported weight measurements from the at-home digital scale of the MDPP beneficiary. We stated that 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. Alternatively, the MDPP beneficiary may self-report their weight by submitting to the MDPP supplier a date-stamped photo or video recording of the beneficiary's weight, with the beneficiary visible in their home. The photo or video must clearly document the weight of the MDPP beneficiary as it appears on the digital scale on the date associated with the billable MDPP session. This flexibility allows suppliers to bill for participants achieving weight loss performance goals.
- *Elimination of the maximum number of virtual services (§ 410.79(e)(3)(iv):* The virtual session limits described in § 410.79 (d)(2), and (d)(3)(i) and (ii) 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. MDPP suppliers were permitted to provide the Set of MDPP services virtually during the COVID–19 PHE, as 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 are proposing that during the Extended flexibilities period, MDPP

suppliers may provide virtual services as long as they are provided in a manner consistent with the CDC DPRP standards for distance learning. The proposed extension of these flexibilities under § 410.79(e)(3)(v) will allow beneficiaries to obtain the Set of MDPP services either in-person, through distance learning, or through a combination of in-person and distance learning for a proposed period of 4 years.

In the May 2, 2023 **Federal Register** (88 FR 27413), we published a notice extending COVID–19 PHE flexibilities for MDPP suppliers, providing them the opportunity to deliver the Set of MDPP services either virtually or in-person (or a combination of both) from May 12, 2023 through December 31, 2023. As a result, MDPP suppliers can continue delivering the Set of MDPP services on a virtual basis during this period to allow MDPP suppliers additional time to resume in-person services. For more information on the **Federal Register** Notice, please see *https://www.federalregister.gov/d/2023–09188*. For more information on the flexibilities that MDPP suppliers were permitted to implement during the PHE, please see *https://www.cms.gov/files/document/participants-medicare-diabetes-prevention-program-cms-flexibilities-fight-covid-19.pdf*.

The CDC's 2021 DPRP Standards allow two types of virtual delivery modalities: ''Distance learning'' and ''online'' delivery. According to CDC, *Distance learning* involves ''a yearlong National DPP lifestyle change program delivered 100 percent by trained Lifestyle Coaches via remote classroom or telehealth. The Lifestyle Coach provides live (synchronous) delivery of session content in one location and participants call-in or video-conference from another location.'' Although ''telehealth'' is included in CDC's definition of distance learning, CMS stated in the CY 2017 PFS final rule (82 FR 52976) that MDPP services delivered via a telecommunications system or other remote technologies do not qualify as telehealth services.[242]

Additionally, CDC defines *online* delivery as a yearlong National DPP lifestyle change program delivered online for all participants. One hundred percent of the program is experienced through the internet via phone, tablet, laptop, in an asynchronous classroom where participants are experiencing the content on their own time without a live Lifestyle Coach teaching the content. However, live Lifestyle Coach interaction should be provided to each participant no less than once per week during the first 6 months and once per month during the second 6 months. Emails and text messages can count toward the requirement for live coach interaction as long as there is bi-directional communication between coach and participant.[243]

In the CY 2021 PFS final rule (85 FR 84472),[244] we established that virtual sessions performed under flexibilities finalized in that rule could only be performed by suppliers who offered in-person services. For the proposed Extended flexibilities period, CMS proposes to limit virtual delivery to the CDC DPRP definition of ''distance learning.'' This proposal is based on the data we have obtained to date from the PHE, including anecdotal, monitoring, evaluation, claims, and CDC DPRP data, suggesting that the majority of the MDPP virtual sessions delivered during the COVID–19 PHE 1135 waiver event were distance learning sessions.

MDPP was certified and established as an in-person service. However, in response to the COVID–19 PHE, we established and implemented policies that allowed MDPP suppliers to provide MDPP services virtually during the PHE, as long as the virtual services: were furnished in a manner that is consistent with the CDC DPRP standards for virtual sessions, the curriculum furnished during the virtual sessions addressed the same curriculum topics as the CDC-approved National DPP curriculum, the supplier had an in-person DPRP organizational code, and other requirements specified at § 410.79(e)(3)(iv) were satisfied. We believe that distance learning allows for a similar live group experience for beneficiaries, but delivered only in a synchronous virtual manner through telephonic or video conference. Through utilizing distance learning, participants may still interact with their Coach and other participants in their cohort in real-time, allowing for relationship building and peer support, unlike online delivery which is delivered asynchronously. Therefore, the proposed Extended flexibilities do not include online delivery (or asynchronous virtual), as defined in the CDC DPRP Standards through the ''online'' modality, including virtual make-up sessions.

We previously stated that the MDPP expanded model was certified for expansion by the Chief Actuary of CMS, based on a model test that used in-person delivery. Given the 3-year duration of the COVID–19 PHE and the feedback received from MDPP suppliers, beneficiaries, MA plans, interested parties, and comments submitted during the CY 2022 rulemaking, there is interest in extending the flexibilities offered during the PHE to reduce the burden of traveling to an in-person class on a weekly basis, as beneficiaries experienced transportation as well as child/elder care challenges with in-person delivery. Additionally, we have heard interest in a hybrid or combination delivery option where participants could attend some in-person classes as well as virtual classes. As a result of this feedback, we are proposing to extend the flexibilities allowed under § 410.79(e)(3)(iii) (regarding use of alternative methods for obtaining weight measurements during virtual services) and § 410.79(e)(3)(iv) (regarding elimination of the maximum number of virtual services) for 4 years, to give us time to test and evaluate the distance learning delivery of MDPP.

Since MDPP was established in the CY 2017 PFS final rule, CMS and interested parties have considered whether fully virtual services could be included as part of the expanded model. For example, in the CY 2017 PFS proposed rule, CMS proposed that MDPP suppliers be allowed to provide MDPP services via remote technologies, even though the majority of CDC DPRP organizations provided in-person

[242] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model. 82 FR 52976, November 15, 2017. *https://www.govinfo.gov/content/pkg/FR–2017–11–15/pdf/2017–23953.pdf*.

[243] Centers for Disease Control & Prevention Diabetes Prevention Recognition Program: Standards and Operating Procedures. May 1, 2021. *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf*.

[244] Centers for Medicare & Medicaid Services. 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. (85 FR 84472), December 28, 2020. *https://www.federalregister.gov/d/2020–26815*.

delivery at that time.[245] However, we also recognized that the virtual delivery of the Set of MDPP services may introduce additional risk of fraud and abuse. CMS stated that if that provision was to be finalized, we would propose specific policies in future rulemaking to mitigate these risks. In the CY 2017 PFS final rule (81 FR 80459), CMS deferred establishing policies related to organizations delivering the Set of MDPP services virtually.

In the subsequent CY 2018 PFS proposed rule, we explained our rationale for proposing not to allow fully virtual delivery of MDPP, but did propose to allow, consistent with CDC DPRP Standards, a limited number of virtual make-up sessions for participants who missed a regularly scheduled session. ''Virtual make-up session'' was defined in § 410.79(d)(2) as a make-up session that is not furnished in-person and that is furnished in a manner consistent with the requirements in paragraph § 410.79(d)(1). In the CY 2018 PFS final rule, we finalized that the Set of MDPP services would be primarily delivered in-person, in a classroom-based setting, and within an established timeline.

We prioritized establishing a service that, when delivered within this framework, would create the least risk of fraud, waste, and abuse, increase the likelihood of success for beneficiaries, and maintain the integrity of data. Furthermore, we believed at that time that in-person administration of beneficiaries' weight measurements was the most reliable and appropriate approach to monitoring beneficiary-level progress toward the 5 percent weight loss programmatic goal.

However, circumstances have changed since the start of the expanded model. We have received comments from interested parties in response to the CY 2018 PFS proposed rule and thereafter regarding increasing the limited virtual delivery of MDPP. Commenters noted that increased virtual options could expand access to MDPP for beneficiaries in rural areas, beneficiaries who are homebound or who lack transportation options, as well as increase beneficiary choice of delivery modality and flexibility of location. Commenters also noted that virtual National DPP delivery has been successful in reaching beneficiaries in certain locations. Ultimately, we finalized our policy that suppliers could offer no more than four virtual makeup sessions during months 1–6 and two virtual makeup sessions during months 7–12.

On March 13, 2020, less than 2 years after MDPP went into effect, COVID–19 was declared a national emergency by Proclamation 9994.[246] By mid-March 2020, MDPP suppliers were largely unable to deliver in-person classes due to national and local restrictions resulting from the national emergency. On April 6, 2020, CMS established MDPP PHE-related flexibilities in the first Interim Final Rule with Comment (IFC–1),[247] to allow for temporary flexibilities that prioritized availability and continuity of services for MDPP suppliers and MDPP beneficiaries impacted by extreme and uncontrollable circumstances during the COVID–19 PHE. These flexibilities allowed an unlimited number of virtual sessions, waived the once-per-lifetime limit for those participating in MDPP when the PHE started, and waived the 5 percent weight loss requirement to continue with ongoing maintenance sessions.

However, we did not waive the requirement for in-person weigh-ins at that time, leaving suppliers unable to obtain the 5 percent weight loss performance payment given the local and State restrictions and stay-at-home orders during the initial months of the PHE. This prevented suppliers from collecting an in-person weight from beneficiaries at each MDPP session as described in § 424.205(g)(2)(v) to document the 5 percent weight loss.

In the CY 2021 PFS final rule, we finalized the MDPP Emergency Policy and updated the PHE flexibilities established in the IFC–1 in the following ways: allowing for virtual weigh-ins and new cohorts to begin virtually; reinstating the 5 percent weight loss requirement during an 1135 waiver event; and reinstating the once-per-lifetime limit during an 1135 waiver event starting with beneficiaries who started the Set of MDPP services in 2021 or thereafter. These changes sought to address interruptions in services caused by CMS not waiving the in-person weigh-in in IFC–1, which prevented MDPP suppliers from starting new cohorts and getting reimbursed for participants who achieved and maintained the 5 percent weight loss goals. Additionally, beneficiaries who began sessions on or before December 31, 2020, were able to re-start MDPP sessions at a later date. Similarly, we allowed suppliers to pause, then resume MDPP sessions at a later date.

During the COVID–19 PHE, we allowed full virtual delivery of MDPP. In making that policy change in the CY 2021 PFS final rule, we stated that ''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 indicated that it is not appropriate to permit virtual-only suppliers, such as suppliers with CDC DPRP recognition in the distance learning, online, or combination only modalities, to furnish MDPP services when the Emergency Policy is in effect. This is due to the requirement that MDPP suppliers remain prepared to resume in-person delivery of the Set of MDPP services to start new cohorts and to serve beneficiaries who wish to return to in-person services when the Emergency Policy is no longer in effect.

As stated earlier, we propose to extend the flexibilities allowed during the COVID–19 PHE under § 410.79(e)(3)(iii), and (iv) for 4 years, or through December 31, 2027. We are proposing that the Extended flexibilities under § 410.79(e)(3)(iii) and (iv) continue to apply only to MDPP suppliers that have and maintain CDC DPRP in-person recognition. We recognize that organizations and interested parties may be disappointed that we are not proposing to allow organizations with CDC recognition in distance learning delivery modalities to participate in MDPP unless they also have and maintain their in-person CDC recognition. In the CY 2021 PFS final rule, we stated that 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.

[245] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model. **Federal Register**, 81(136): July 15, 2016. *https://www.govinfo.gov/content/pkg/FR–2016–07–15/pdf/2016–16097.pdf.*

[246] *https://www.whitehouse.gov/briefing-room/presidential-actions/2023/02/10/notice-on-the-continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic-3/#:~:text=On%20March%2013%2C%202020%2C%20by,(COVID%2D19)%20pandemic.*

[247] Centers for Medicare & Medicaid Services, HHS. Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency. (85 FR 19230, Monday, April 6, 2020) *https://www.federalregister.gov/documents/2020/04/06/2020–06990/medicare-and-medicaid-programs-policy-and-regulatory-revisions-in-response-to-the-covid-19-public.*

MDPP was established as an in-person service since the original DPP test and data used in the certification were based on in-person delivery. During the COVID–19 PHE, we were able to allow greater use of virtual sessions, but the virtual delivery was primarily furnished as a virtual classroom. We are also proposing that suppliers may offer a combination delivery of MDPP, including both in-person and distance learning. We believe that after almost 4 years of having the option to deliver the Set of MDPP services through distance learning, between the COVID–19 PHE and the **Federal Register** Notice to extend the PHE flexibilities through December 31, 2023, allowing MDPP suppliers to have the option to continue delivering the Set of MDPP services in the same manner will be the least disruptive to both suppliers and beneficiaries. We are also proposing that MDPP suppliers may no longer suspend the Set of MDPP services as described in paragraph (e)(3)(v) in this section on or after January 1, 2024. We believe we have given MDPP suppliers ample time, through the **Federal Register** Notice to extend the PHE flexibilities through December 31, 2023, to adequately prepare to resume MDPP services from an operational perspective.

Furthermore, we also believe that our proposal to extend the PHE flexibilities for 4 years, or through December 31, 2027, will make MDPP more equitable and accessible for all eligible beneficiaries by providing both suppliers and beneficiaries more flexibility in how the Set of MDPP services are delivered, including in-person, distance learning, or a combination of in-person and distance learning. For an example, allowing virtual sessions will make MDPP more accessible to beneficiaries who reside in rural communities and who may have transportation and other barriers to attending in-person classes. We anticipate that the combination of a simplified payment structure in addition to more flexibilities regarding how MDPP is delivered will encourage more organizations to engage in and deliver MDPP, making MDPP more accessible to more beneficiaries.

Additionally, extending the COVID–19 PHE flexibilities for 4 years would provide CMS an opportunity to evaluate the impact of the Extended flexibilities over a longer period of time. To better track the use of distance learning through claims, we are proposing the creation of a new HCPCS G-code specific to ''distance learning,'' that will more accurately track sites from which distance learning occurs, the number of MDPP sessions delivered by distance learning, monitor the expanded model for fraud, waste, or abuse, and evaluate the impact of distance learning and in-person delivery modalities of MDPP relative to cost-savings and diabetes risk reduction among participants.

In previous rulemaking, we received comments about how to best monitor the use of virtual make-up sessions, and whether CMS would use an additional HCPCS code or modifier to indicate virtual sessions since there was a limit to the number of virtual make-up sessions a beneficiary can attend.[248] In response, we finalized the use of the virtual make-up sessions in § 410.79(d)(2) and stated that MDPP suppliers must include the virtual modifier (VM) on claims to indicate the use of the virtual make-up session. As part of the MDPP flexibilities established in response to the COVID–19 PHE, we eliminated the maximum number of virtual make-up sessions that could be delivered by MDPP suppliers, described in § 410.79(d)(2) and (d)(3)(i) and (ii), but still required MDPP suppliers to use the VM to indicate when a beneficiary received MDPP virtually.

Given the inconsistent use of the virtual modifier as it was described in the CY 2018 PFS final rule to document the virtual make-up sessions allowed during the PHE as described in § 410.79(e)(2)(iii), we propose to add a HCPCS code for distance learning to better track the synchronous virtual delivery of the Set of MDPP services to be used instead of the VM when submitting MDPP claims, including claims for make-up sessions since we are not permitting online (asynchronous virtual) delivery of the Set of MDPP services. At this time, we are not proposing to remove use of the VM entirely in-case we need it in future rulemaking, for example, should we allow online make-up sessions in future rulemaking.

MDPP supplier locations have traditionally clustered proximate to large metropolitan areas, leaving significant gaps throughout rural communities. Given that the MDPP curriculum consists of no fewer than 16 weekly sessions in months 1–6, and 6 monthly sessions in months 7–12 months, the participation commitment may pose significant challenges to beneficiaries with limited mobility or access to reliable transportation. Based on findings from the 2nd evaluation report of the MDPP expanded model,[249] we believe that in-person requirements have contributed to significant MDPP under-utilization, not only for those who reside in rural communities, but also populations that experience excessive diabetes related disparities, including populations of color, low-income beneficiaries, those living in Tribal and rural communities, and the disabled.

To date, beneficiary uptake of MDPP has been low, with 4,848 beneficiaries participating as of December 31, 2021, and approximately half of those participants were Medicare FFS beneficiaries. White women account for the majority of MDPP participants to date, with the both the National DPP and MDPP having enrolled a similar high proportion of non-Hispanic white women. RTI estimated that 97 percent of participants travel less than 25 miles to attend in-person services, with the average distance to the nearest MDPP supplier location being 5 to 7 miles.

At the time of the second annual evaluation report, which was released in November, 2022 and includes data through December 31, 2021, 39 percent of all Medicare beneficiaries live more than 25 miles from the nearest MDPP location. Extending the PHE flexibilities to allow distance learning will make MDPP more accessible to beneficiaries who live more than 25 miles from the nearest MDPP location or lack transportation.[10]

Additionally, the 2nd evaluation report (p. 32) noted that suppliers tried to make MDPP services accessible to Medicare beneficiaries by scheduling sessions at locations that were most convenient to Medicare beneficiaries. It was also noted that while beneficiary engagement and connection tend to be stronger with in-person cohorts, moving to distance learning delivery reduced participant barriers (p. 34). While some suppliers and beneficiaries experienced initial challenges migrating to fully virtual delivery, the report noted an overwhelming support from MDPP suppliers for the continued opportunity to administer MDPP through distance learning or a combination of in-person and synchronous virtual delivery. Therefore, by proposing the use of synchronous virtual delivery as an acceptable modality for MDPP delivery,

[248] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model. 82 FR 52976, November 15, 2017. *https://www.govinfo.gov/content/pkg/FR–2017–11–15/pdf/2017–23953.pdf.*

[249] RTI International. *Evaluation of the Medicare Diabetes Prevention Program: Second Evaluation Report.* November 2022. *https://innovation.cms.gov/data-and-reports/2022/mdpp-2ndannevalrpt.*

our goal is to use the Extended Flexibilities period to increase beneficiary access to and uptake of MDPP while demonstrating that the beneficiaries receiving the Set of MDPP services through distance learning experience similar or better outcomes compared to in-person delivery concerning attendance, achievement of the 5 percent weight loss goal, and cost savings.

Through the CY 2018 PFS final rule, we established important MDPP payment policies and program integrity safeguards in order to mitigate the risk of fraud, waste, and abuse in MDPP that included the creation of supplier enrollment requirements and compliance standards. MDPP monitoring activities are performed primarily through an independent monitoring contractor, with referrals sent to CMS for further investigation or enforcement action, as appropriate. We will continue to implement, adapt, and scale the current monitoring strategy for indications of fraud, waste, and abuse for both in-person and the proposed distance learning modalities. Should we identify excessive indicators of fraud, waste, and/or abuse of the synchronous virtual delivery of the Set of MDPP services during the extended PHE flexibilities period, we may opt to discontinue these flexibilities through subsequent rulemaking.

With these safeguards in-place, we anticipate the proposed programmatic updates will boost supplier enrollment, with the goal of increasing beneficiary participation and retention due to increased access to the Set of MDPP services. Moreover, we believe that extending the PHE flexibilities will especially increase equitable access to diabetes preventive services among rural and at-risk populations. For example, for beneficiaries with transportation challenges or child/elder care obligations, the ability to participate in MDPP through a live virtual classroom, or distance learning, may encourage uptake and retention among those participants. Also, for beneficiaries living in rural areas or regions with a limited number of MDPP suppliers, the distance learning option will allow beneficiaries to enroll in programs further away from their homes, making MDPP accessible to more beneficiaries. Finally, we believe that increased participation in the Set of MDPP services through distance learning may provide data necessary to conduct an impactful evaluation of the synchronous virtual delivery of MDPP.

We propose to amend § 410.79(b), (c), and (d) to remove most references to, and requirements of, the Ongoing Maintenance phase described in these sections. In the CY 2022 PFS, CMS removed eligibility for the Ongoing Maintenance Sessions for those beneficiaries who started the Set of MDPP services on or after January 1, 2022. Eligibility for these services will end December 31, 2023.

We are proposing to amend § 410.79(b), (c)(2)(i) and (e)(2), and seek comment on these proposals.

2. Proposed Changes to § 414.84

Although MDPP has over 300 suppliers representing over 1,000 locations across the US, based on fee-for-service claims analysis, only one-third of them have submitted claims since MDPP launched in April 2018. We have heard anecdotally from suppliers, CDC, and interested parties that our payment structure is complex, which has created barriers to organizations wanting to participate in MDPP. As a result, the lack of suppliers has contributed to limited beneficiary access to the preventive services offered under this expanded model. Challenges inherent in the current payment structure include irregular flow of operating funds due to the performance-based payment structure, claims denials due to the complicated payment structure, and a lack of incentive to retain participants after the 9th core session due to the potential 4 to 5-month payment lag between the 9th session attended and the 2nd session attended in months 7–9. Consistent with this last challenge, our monitoring data show a sharp drop in claims after the first quarter.

We propose to update the payment structure from a performance-based attendance and weight loss structure to a hybrid structure that pays for attendance on a fee-for-service basis and diabetes risk reduction (that is, weight loss), on a performance basis. MDPP, as defined in § 410.79(b), consists of up to 16 sessions offered during the core sessions phase (Months 1–6) and 6 monthly maintenance sessions offered during the core maintenance sessions phase (Months 7–12), (collectively the ''core sessions phase''). In the current payment structure, suppliers must submit a claim after a participant completes the first, fourth, and ninth sessions during the first 6 months, then following the second core maintenance session in months 7–9 and in months 10–12 in the core maintenance sessions phase. Depending on the timing of the ninth session attended and the second core maintenance session attended by the beneficiary in months 7 to 9, suppliers may have a 4- to 5-month gap between attendance-based performance payments in the current MDPP payment structure.

Given consistent supplier and interested party feedback regarding the complexity of this payment structure and necessary up-front costs incurred by suppliers, we propose to simplify the payment structure and pay for attendance on a fee-for-service basis. We propose creating an Attendance Payment, which we propose to define as a payment that is made to an MDPP supplier for furnishing services to an MDPP beneficiary when the MDPP beneficiary attends an MDPP core or core maintenance session. We also propose that suppliers may receive an Attendance Payment after they submit a claim for each MDPP session, starting with the first core session, using a new HCPCS G-code, *Behavioral counseling for diabetes prevention, in-person, group, 60 minutes,* or *Behavioral counseling for diabetes prevention, distance learning, 60 minutes,* for MDPP dates of service on or after January 1, 2024.

This proposed payment structure aligns closely to that of similar benefits such as the Intensive Behavioral Counseling for Obesity (IBTO) and Diabetes Self-Management Training (DSMT), and also allows suppliers to receive regular payments for service for up to a year during a 12-month MDPP service period. We propose paying for up to 22 sessions, either in-person or distance learning, or a combination of in-person and distance learning, for MDPP dates of services within a 12-month MDPP services period. In months 1 to 6, payments are allowed for one in-person or distance learning session every week up to a maximum of 16 sessions. During months 7 to 12, payments are allowed for one in-person or distance learning session every month up to a maximum 6 sessions.

We proposing to update the performance goal to mean a weight loss goal that an MDPP beneficiary must achieve during the MDPP services period for an MDPP supplier to be paid a performance payment, and removing the performance-based payments for attendance from the performance goal. We are retaining the diabetes risk-reduction performance payments, which include payments for 5 percent and 9 percent weight loss because we want to continue to pay for outcomes, and the MDPP certification includes a diabetes risk-reduction component (that is, achievement of 5 percent weight loss from baseline). Although we are proposing to remove the attendance-based performance goal and pay for attendance on a fee-for-service basis, we want to continue rewarding suppliers

for successful outcomes for beneficiaries (weight loss), and motivating them to not only retain participants, but also deliver a high-quality program that achieves better outcomes.

As part of the performance payments, MDPP suppliers must still submit a claim when 5 percent weight loss from baseline weight is achieved and will receive a one-time payment for this claim (weight loss G-code). We are proposing to create a new HCPCS G-code, ''Maintenance of 5 percent weight loss from baseline, months 7–12'' to be submitted along with the monthly session claim for beneficiaries who have met the 5 percent weight loss performance goal, for whom the one-time claim for 5 percent weight loss has been submitted. This maintenance of 5 percent weight loss code replaces the attendance plus 5 percent weight loss HCPCS G-codes, G9878 and G9879, in months 7–12.

The one-time claim for 5 percent weight loss must be submitted prior to submitting a claim for the enhanced payment in months 7 to 12 for maintaining the 5 percent weight loss. Additionally, suppliers must continue to submit a claim when 9 percent weight loss from baseline weight is achieved per § 414.84(b)(7), so they may receive a one-time payment for this claim.

This proposed payment structure increases the maximum attendance-based payments a supplier may receive in the first 6 months by $56 per MDPP beneficiary, while allowing for similar maximum attendance payments in months 7–12 and maintaining the maximum total payment of $768 per person during the MDPP services period. Also, this proposed payment structure takes into consideration the Extended flexibilities, by adding a distance learning HCPCS G-code. The new structure simplifies the claims submission process because it no longer requires that suppliers submit 11 to 15 G-codes for different attendance-based sessions at irregular intervals.

This proposed payment structure allows suppliers to submit one of two G-codes (depending on whether the MDPP session was delivered in person or via distance learning) for each session. In months 7–12, suppliers may also add the proposed maintenance of the 5 percent weight loss from baseline G-code to their claim once the 5 percent weight loss has been achieved. The proposed payment structure allows suppliers to indicate which sessions were held via distance learning without needing to provide additional information in the claim submission process. The proposed new payment structure reduces complexity by reducing the number of G-codes from 15 to 6.

Table 41 displays the proposed MDPP payment structure and Table 42 indicates the current CY 2023 performance payments.

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TABLE 41: Proposed Changes to MDPP Payment Structure to include Attendance-Based Service Payments and Diabetes Risk Reduction Performance Payments

HCPCS G-Code	Payment Description*	CY 2024
GXXX0	Behavioral counseling for diabetes prevention, in-person, group, 60 minutes	$25
GXXX1	Behavioral counseling for diabetes prevention, distance learning, 60 minutes	$25
G9880	5 percent WL Achieved from baseline weight	$145
GXXX2**	Maintenance 5 percent WL from baseline in months 7-12	$8
G9881	9 percent WL Achieved from baseline weight	$25
G9890	Bridge Payment	$25
Subtotal Maximum Attendance-Based Payment		**$550**
Total Maximum Payment		**$768**

**Medicare pays up to 22 sessions billed with codes GXXX1 and GXXX0, combined, in a 12-month period:*
Months 1-6: 1 in-person or distance learning session every week (max 16 sessions)
Months 7-12: 1 in-person or distance learning session every month (max 6 sessions)
*** Suppliers must submit claim for 5 percent weight loss (G9880) prior to submitting claims for the maintenance 5 percent WL from baseline in months 7-12.*

TABLE 42: CY 2023 MDPP Payment Structure

HCPCS G-Code	Payment Description	CY 2023
	Core Sessions (Months 1-6)	
G9873	Attend 1 Core Session	$38
G9874	Attend 4 Core Sessions	$115
G9875	Attend 9 Core Sessions	$191
	Core Maintenance (CM) Sessions (Months 7-12)	
G9876	Attend 2 Core Maintenance Sessions (No 5% WL) in CM Interval 1 (Months 7-9)	$76
G9877	Attend 2 Core Maintenance Sessions (No 5 percent WL) in CM Interval 2 (Months 10-12)	$76
G9878	Attend 2 Core Maintenance Sessions (5 percent WL) in CM Interval 1 (Months 7-9)	$101
G9879	Attend 2 Core Maintenance Sessions (5 percent WL) in CM Interval 2 (Months 10-12)	$101
G9880	5 percent WL Achieved from baseline weight	$184
G9881	9 percent WL Achieved from baseline weight	$38
G9890	Bridge Payment	$38
G9891	Non-payable session code (This code is for reporting purposes only).	$0
	Core Maintenance Sessions (Months 7-12)**	
G9882	Attend 2 Ongoing Maintenance (OM) Sessions in OM Interval 1 (Months 13-15)	$57
G9883	Attend 2 Ongoing Maintenance Sessions in OM Interval 2 (Months 16-18)	$57
G9884	Attend 2 Ongoing Maintenance Sessions in OM Interval 3 (Months 19-21)	$58
G9885	Attend 2 Ongoing Maintenance Sessions in OM Interval 4 (Months (22-24)	$58
Subtotal Maximum Attendance-Based Payment		**$496**
Total Maximum Payment		**$768**

**In the CY 2022 PFS, CMS removed the Ongoing Maintenance Sessions for those beneficiaries who started MDPP services on or after January 1, 2022. MDPP beneficiaries who were participating in the Set of MDPP Services on or before December 31, 2021 may continue with the ongoing maintenance phase if they maintain 5 percent weight loss and attendance requirements.

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In previous rulemaking, we received comments regarding how to best monitor the use of virtual make-up sessions, and whether we would use an additional HCPCS code or modifier to indicate virtual sessions since there is a limit to the number of virtual make-up sessions a beneficiary can attend. In response, we finalized the use of the virtual make-up sessions in § 410.79(d)(2) and stated in the preamble to the CY 2018 PFS final rule that MDPP suppliers must include the virtual modifier on claims to indicate the use of the virtual make-up session. As part of the flexibilities established in response to the COVID–19 PHE, we eliminated the maximum number of virtual make-up sessions that could be delivered by MDPP suppliers, described in § 410.79(d)(2) and (d)(3)(i) and (ii), but still required MDPP suppliers to use the virtual modifier to indicate when a beneficiary received MDPP virtually.

We are proposing to amend § 414.84(a), (b), (c), and newly redesignated paragraphs (d)(1) and (e). We seek comment on these proposals.

3. Changes to § 424.205 (a), (b)(1), (c), and Newly Designated (c)(1), (d)(14), (f)(2)(i), (g)(1)(i)(C)

The Centers for Disease Control and Prevention (CDC), which administers the Diabetes Prevention Recognition Program (DPRP), is responsible for implementing the quality assurance function of the National DPP at the national level, including for MDPP. The DPRP awards four categories of recognition: Pending, preliminary, full, and full-plus. Organizations may participate in MDPP with preliminary, full, or full-plus CDC recognition. Organizations may advance in CDC DPRP recognition by demonstrating their ability to effectively deliver the behavioral change program (preliminary) and achieve the outcomes shown to prevent or delay type 2 diabetes (full and full-plus). To achieve full CDC recognition, organizations must demonstrate a reduction in risk of developing type 2 diabetes among completers in the evaluation cohort by showing that at least 60 percent of all completers achieved at least one of the following outcomes:

- At least 5 percent weight loss 12 months after the cohort began; or
- At least 4 percent weight loss and at least 150 minutes/week on average of physical activity 12 months after the cohort began; or
- At least a 0.2 percent reduction in HbA1C.

Organizations are granted an additional 2 years of full recognition (full-plus), for a total of 5 years if, at the time full recognition is achieved, organizations meet the following retention criteria:

- A minimum of 50 percent at the beginning of the fourth month since the cohorts held their first sessions;
- A minimum of 40 percent at the beginning of the seventh month since the cohorts held their first sessions; and
- A minimum of 30 percent at the beginning of the tenth month since the cohorts held their first sessions.

In the CY 2017 PFS final rule, we indicated that we would align the CDC's DPRP and MDPP to the greatest extent possible. When the CY 2018 PFS went into effect on January 1, 2018, CDC's 2018 DPRP Standards had neither been publicly released nor gone into effect. For these reasons, we had to establish an interim MDPP preliminary recognition so that eligible organizations could begin enrolling in Medicare to

become MDPP suppliers starting January 1, 2018, and approved suppliers could start serving Medicare beneficiaries on April 1, 2018.

When the CY 2018 PFS final rule was issued, the CDC 2015 DPRP Standards were still in effect, and CDC only recognized organizations with pending or full DPRP recognition. Consequently, CMS and CDC developed an interim solution that would allow organizations that met the MDPP interim preliminary recognition standard, which went into effect on January 1, 2018, to become eligible to enroll in Medicare as an MDPP supplier.

Because CMS and CDC understood that there would be a 2 to 4-month gap between when the CY 2018 PFS went into effect for MDPP (January 1, 2018) and when the CDC 2018 DPRP Standards would be cleared and go into effect, we worked with CDC to establish an interim solution so that eligible organizations with MDPP interim preliminary or CDC DPRP full recognition could apply to Medicare to become MDPP suppliers before the CDC's 2018 Standards went into effect on March 1, 2018. The CY 2018 PFS final rule at § 424.205(c)(2)(ii) established that CDC-recognized organizations with pending CDC DPRP recognition could meet additional criteria for an ''interim preliminary recognition'' standard and enroll as MDPP suppliers. With the MDPP new supplier type going into effect on January 1, 2018, and beneficiary enrollment starting on April 1, 2018, we wanted suppliers to be able to enroll in Medicare to become MDPP suppliers in time for the April 1 MDPP launch.

Now that the CDC DPRP Standards for preliminary recognition are in effect, we propose to remove § 424.205(c) and retire the MDPP ''interim preliminary recognition'' standard. We also propose to amend § 424.59(a)(1) (redesignated § 424.205(b)(1)) to require that, at the time of enrollment, organizations have preliminary, full, or full-plus CDC DPRP recognition. As described in the CY 2018 PFS final rule, MDPP suppliers who received MDPP interim preliminary recognition during the 4-month time period between when the CY 2018 PFS final rule was published and when the CDC 2018 standards went into effect, have achieved at least CDC preliminary recognition.

To maintain compliance with the current CDC DPRP Standards, organizations that enrolled in Medicare as MDPP suppliers based on their MDPP interim preliminary recognition between January 1, 2018 and February 28, 2018 would have had at least two CDC DPRP evaluations given the 5-year time lapse. Per CDC DPRP Standards, organizations are required to submit data to CDC every 6 months, and undergo evaluation every 12 to 18 months, depending upon the timing of new cohorts.

Since the CDC DPRP Standards were updated in 2018 and 2021 and are due to be updated in Spring 2024, suppliers are required to meet the most current CDC DPRP Standards for preliminary, full, or full-plus recognition to maintain their eligibility to enroll and participate in MDPP as MDPP suppliers. Organizations that are interested in enrolling in Medicare as MDPP suppliers should refer to the CDC DPRP's most current standards [1] to understand how to obtain preliminary, full, or full-plus CDC recognition, and consult § 424.205 for all other enrollment conditions that need to be met, in advance of submitting their application to become a MDPP supplier.

We propose to amend § 424.205 newly designated paragraphs (c) and (f) to remove reference to, and requirements of, the Ongoing Maintenance phase described in these sections with the exception of § 424.205 newly designated paragraph (d)(14), which we are retaining for historical recordkeeping and crosswalk purposes. In the CY 2022 PFS, CMS removed eligibility for the Ongoing Maintenance Sessions for those beneficiaries who started the Set of MDPP services on or after January 1, 2022. Eligibility for these services will end December 31, 2023.

We are proposing to amend § 424.205 (a), (b)(1), newly redesignated paragraphs (c)(1) and (g)(1)(i)(C). We seek comment on these proposals.

4. Proposed Changes to § 424.210(b) and (d)

We propose to amend § 424.210(b) and (d) to remove reference to, and requirements of, the Ongoing Maintenance phase described in these sections. In the CY 2022 PFS final rule, CMS removed eligibility for the Ongoing Maintenance Sessions for those beneficiaries who started the Set of MDPP Services on or after January 1, 2022. Eligibility for these services will end December 31, 2023.

We are proposing to amend its regulation at § 424.210 by amending paragraphs (b) and (d). We seek comment on these proposals.

J. Appropriate Use Criteria for Advanced Diagnostic Imaging

Section 1834(q) of the Act, as added by section 218(b) of the Protecting Access to Medicare Act (Pub. L. 113–93, April 1, 2014) (PAMA), directs CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. Since the bill was passed, we have taken steps to implement this program and codified the AUC program in our regulations at 42 CFR 414.94. In CY 2020, we began conducting an educational and operations testing period for the claims-based reporting of AUC consultation information and the program currently operates in this phase.

1. Background

AUC are evidence-based guidelines that assist clinicians in selecting the imaging studies most likely to improve health outcomes for patients based on their individual clinical presentation. AUC present information in a manner that links a specific clinical condition or presentation; one or more services; and an assessment of the appropriateness of the service(s). For purposes of this program, AUC are a set or library of individual AUC. Each individual criterion is an evidence-based guideline for a particular clinical scenario based on a patient presenting symptoms or condition. Under this program, any clinician who orders an advanced diagnostic imaging service must consult AUC for the imaging service ordered. Examples of advanced diagnostic imaging services include computed tomography, positron emission tomography, nuclear medicine and magnetic resonance imaging.

To consult AUC, clinicians use clinical decision support mechanisms (CDSMs). CDSMs are the electronic portals through which clinicians access the AUC during the patient workup. They can be standalone applications that require direct entry of patient information, but may be more effective when they are integrated into electronic health records (EHRs). Ideally, clinicians would interact directly with the CDSM through their primary user interface, thus minimizing interruption to the clinical workflow.

Under the AUC program, clinicians and facilities that furnish the imaging service are responsible for reporting information about the ordering clinician's AUC consultation on the imaging service claim. The furnishing clinician and facility are not paid if the ordering clinician fails to consult and/or if the consultation information is not correctly included on the imaging service claim.

2. Statutory Authority

Section 218(b) of the PAMA added a new section 1834(q) of the Act entitled, ''Recognizing Appropriate Use Criteria

for Certain Imaging Services,'' which directed the Secretary to establish a program to promote the use of AUC. Section 1834(q)(4) of the Act requires ordering professionals to consult with specified applicable AUC through a qualified CDSM for applicable imaging services furnished in an applicable setting and paid for under an applicable payment system; and payment for such service may only be made if the claim for the service includes information about the ordering professional's consultation of specified applicable AUC through a qualified CDSM.

3. Discussion of Statutory Requirements and Implementation

There are four major components of the AUC program under section 1834(q) of the Act, and each component has its own implementation date: (1) establishment of AUC by November 15, 2015 (section 1834(q)(2) of the Act); (2) identification of mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3) of the Act); (3) AUC consultation by ordering professionals, and reporting on AUC consultation by January 1, 2017 (section 1834(q)(4) of the Act); and (4) annual identification of outlier ordering professionals (based on low adherence to AUC) for services furnished after January 1, 2017 (section 1834(q)(5) of the Act). These four components are precursors to the requirement that, beginning for CY 2017, we establish mandatory prior authorization procedures for outlier ordering professionals when ordering advanced diagnostic imaging services (section 1834(q)(6) of the Act).

a. Establishment of AUC

We addressed the first component of the Medicare AUC program under section 1834(q)(2) of the Act, establishment of AUC, in the CY 2016 PFS final rule with comment period (80 FR 70886). With this rule, we began to codify the statutory requirements in our regulations at 42 CFR 414.94. We also defined provider-led entity (PLE) as well as additional definitions under section 1834(q)(1) of the Act in our regulations at § 414.94(b). In § 414.94(c)(1) and (2), respectively, we set forth the requirements and process by which PLEs become qualified by CMS to develop, modify or endorse AUC. We qualified the first group of PLEs under the AUC program and posted them to the CMS website in June 2016 at which time their AUC libraries became specified applicable AUC for purposes of section 1834(q)(2)(A) of the Act.

b. Identification of Mechanisms for Consultation With AUC

We addressed the second component under section 1834(q)(3) of the Act, identification of mechanisms for consultation with AUC, in the CY 2017 PFS final rule (81 FR 80170). In this rule we defined clinical decision support mechanism (CDSM) in § 414.94(b). In § 414.94(g)(1) and (2), respectively, we set forth the requirements CDSMs must meet and established a process by which CDSMs may become qualified by CMS in accordance with the statutory requirements under section 1834(q)(3)(B)(ii). We qualified the first group of CDSMs under the AUC program and posted them to the CMS website in July 2017.

c. AUC Consultation and Reporting

We addressed the third component under section 1834(q)(4) of the Act, AUC consultation by ordering professionals, and reporting on AUC consultation, primarily in the CY 2018 PFS final rule (82 FR 53190). Additionally, in the CY 2017 PFS final rule, we defined terms in § 414.94(b) (81 FR 80405 and 80406) and identified exceptions to the AUC consultation and reporting requirements under section 1834(q)(4) in § 414.94(i) (81 FR 80422 through 80424) which are pertinent to the third component. We also continued to revise the regulation at § 414.94 as needed and in response to comments from interested parties in subsequent rulemaking cycles. These updates, revisions and clarifications, which continued through annual PFS rulemaking for CYs 2018, 2019, and 2020, are discussed throughout this section as they directly relate to the AUC consultation requirement under section 1834(q)(4)(A) of the Act and reporting requirement under section 1834(q)(4)(B) of the Act.

In the CY 2017 PFS final rule we defined applicable payment systems consistent with section 1834(q)(4)(D) of the Act to include the PFS established under section 1848(b) of the Act, the prospective payment system for hospital outpatient department services under section 1833(t) of the Act, and the ambulatory surgical center payment system under section 1833(i) of the Act (81 FR 80406). In the CY 2016 PFS final rule with comment period we defined applicable setting consistent with section 1834(q)(1)(D) of the Act to include a physician's office, a hospital outpatient department (including an emergency department), and an ambulatory surgical center (80 FR 71105). We later added independent diagnostic testing facility (IDTF) to the definition of applicable setting in the CY 2019 PFS final rule (83 FR 59690 and 59691).

Also in the CY 2017 PFS final rule, consistent with section 1834(q)(4)(C) of the Act, we identified exceptions to the AUC consultation and reporting requirements under section 1834(q)(4) of the Act in the case of: a service ordered for an individual with an emergency medical condition, a service ordered for an inpatient and for which payment is made under Medicare Part A, and a service ordered by an ordering professional for whom the Secretary determines that consultation with applicable AUC would result in a significant hardship (81 FR 80422 through 80424). The significant hardship exception criteria and process under § 414.94(i)(3) was later updated in the CY 2019 PFS final rule (83 FR 59697 through 59700).

In the CY 2018 PFS final rule, we established a voluntary period from July 2018 through the end of 2019 during which ordering professionals who were ready to participate in the AUC program could consult specified applicable AUC through qualified CDSMs and communicate the results to furnishing professionals (82 FR 53193 through 53195). Furnishing professionals who were ready to do so could report AUC consultation information on the claim. To incentivize early use of qualified CDSMs for consulting AUC, we established in the CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstances Policy for the Transition Year final rule with comment period and interim final rule a high-weight improvement activity for ordering professionals who consult specified AUC using a qualified CDSM for the Merit-based Incentive Payment System (MIPS) performance period that began January 1, 2018 (82 FR 54193).

In addition, in the CY 2018 PFS final rule, we established the start date of January 1, 2020, for the Medicare AUC program for advanced diagnostic imaging services in § 414.94(j)(1) (82 FR 53189 through 53195). Specifically, for services ordered on and after January 1, 2020, we established that ordering professionals must consult specified applicable AUC using a qualified CDSM when ordering applicable imaging services in § 414.94(j), and furnishing professionals must report AUC consultation information on the Medicare claim in § 414.94(k). In the CY 2019 PFS final rule, we specified under § 414.94(j)(2) that when delegated by the ordering professional, clinical staff under the direction of the ordering professional may perform the AUC

consultation with a qualified CDSM. In the CY 2018 PFS final rule, we further specified that the AUC program, including the claims denial payment penalty phase, would begin on January 1, 2020, with a year-long educational and operations testing period for CY 2019 during which AUC consultation information was expected to be reported on claims, but claims would not be denied for failure to include proper AUC consultation information (82 FR 53193 through 53195). As discussed in further detail below, the educational and operations testing period was subsequently extended multiple times and the program currently operates in the educational and operations testing period.

In the CY 2018 PFS final rule and consistent with section 1834(q)(4)(B) of the Act, we established in § 414.94(k) that the following information must be reported on Medicare claims for advanced diagnostic imaging services: (1) the qualified CDSM consulted by the ordering professional; (2) whether the service ordered would or would not adhere to specified applicable AUC, or whether the specified applicable AUC consulted was not applicable to the service ordered; and (3) the NPI of the ordering professional (if different from the furnishing professional) (82 FR 53190 through 53193). Section 1834(q)(4)(B) of the Act specifies that payment for advanced diagnostic imaging service claims under the AUC program may only be made if the claim submitted by the furnishing professional (of which there can be more than one if the professional component is furnished by a different entity than the technical component) includes this information about the ordering professional's AUC consultation. This statutory requirement establishes a real-time claims-based reporting requirement whereby payment for the imaging service is contingent upon specific information being present on the claim. We worked to operationalize the real-time claims-based reporting requirement by announcing our intention to use G-codes and HCPCS modifiers to report AUC consultation information on the Medicare claims in the CY 2019 PFS final rule.

In the CY 2022 PFS final rule (86 FR 64996), we provided further clarification around the scope of the AUC program specifically pertaining to updates or modifications to orders for advanced diagnostic imaging services (86 FR 65227 through 65229), the extreme and uncontrollable circumstances significant hardship exception (86 FR 65229 and 65230) and specified claims processing solutions, including creation and use of a new HCPCS modifier intended to accurately identify claims that are and are not subject to the AUC program requirements. We also discussed special circumstances related to: services furnished by a critical access hospital (CAH) (86 FR 65231 and 65232), services paid under the Maryland Total Cost of Care Model (86 FR 65232 and 65233), inpatients converted to outpatients (86 FR 65233 and 65234), Medicare as the secondary payer (86 FR 65234 and 65235), and imaging services ordered prior to the start of the claims denial payment penalty phase but furnished on or after the start of the payment penalty phase (86 FR 65235). We addressed where to identify the ordering professional on practitioner claims for imaging services (86 FR 65231) (we addressed where to identify ordering professionals on institutional claims in educational materials following the CY 2019 PFS final rule claims-based reporting discussion (83 FR 59696)) and confirmed that claims that do not properly append AUC consultation information will be returned for correction and resubmission, rather than denied, when the payment penalty phase begins (86 FR 65234). We did not specify how long claims would be returned before the payment penalty phase would shift to claim denials. Finally, we established that the payment penalty phase would begin on the later of January 1, 2023, or the January 1 that follows the declared end of the PHE for COVID–19. Under this specification and with the declared end of the PHE for COVID–19 on May 11, 2023, the payment penalty phase would have been scheduled to begin on January 1, 2024. However, as announced via the AUC website in 2022 and discussed further below in this section of the proposed rule, the educational and operations testing period will continue until further notice. We did not include provisions pertaining to the AUC program in the CY 2023 PFS final rule (87 FR 69404).

d. Identification of Outlier Ordering Professionals

We began to address the fourth component under section 1834(q)(5) of the Act, identification of outlier ordering professionals, in the CY 2017 PFS final rule by finalizing the first list of priority clinical areas (PCAs) in § 414.94(e)(5) (81 FR 80406 through 80412) which were intended to ultimately guide identification of outlier ordering professionals who would eventually be subject to prior authorization when ordering advanced diagnostic imaging services. Section 1834(q)(5) of the Act directs CMS to: (1) determine on an annual basis no more than 5 percent of total ordering professionals who are outlier ordering professionals; and (2) base the determination of an outlier ordering professional on low adherence to AUC which may be based on comparisons to other ordering professionals and include data for ordering professionals for whom prior authorization applies; and (3) use 2 years of data to identify outlier ordering professionals; and (4) consult with physicians, practitioners and other interested parties in developing methods to identify outlier ordering professionals. To date, we have not proposed or codified the methods for identifying outlier ordering professionals as prescribed by section 1834(q)(5) of the Act, and thus, we have not subjected any ordering professionals to prior authorization when ordering advanced diagnostic imaging services as prescribed by section 1834(q)(6) of the Act.

4. Timeline

As evident from the description of our regulatory activities to date, we have not met the statutory implementation time frame for the AUC program components. The educational and operations testing period began January 1, 2020, and the AUC program continues to operate in this phase currently. In this phase, there are no payment penalties for advanced diagnostic imaging service claims that do not append AUC consultation information. The provisions in section 1834(q) of the Act repeatedly stress the importance of engagement with interested parties in developing the Medicare AUC program. Throughout our implementation activities, we have intentionally taken a diligent, stepwise implementation approach to maximize the opportunity for public comment and engagement with interested parties, and allow for adequate advance notice to physicians and practitioners, beneficiaries and other AUC interested parties of any programmatic changes or updates. These efforts to maximize engagement included speaking and answering live questions at multiple CMS Open Door Forums, participating in external meetings sponsored by and at the request of interested parties like medical specialty societies and health care practitioners, and meeting in person and virtually with interested parties upon request to receive feedback and answer questions to the best of our ability and within the context of already publicly available information. All of these interactions were critical to inform our proposals during each round of notice and comment rulemaking. This

approach has allowed us to be comprehensive in our assessment of implementation options and regulatory proposals, responsive to concerns expressed by interested parties, and agile in reacting to unexpected events, like the PHE for COVID–19. Since the CY 2022 PFS final rule was released, we have used the AUC website [250] to publicly announce updates to the AUC program. In July 2022, we updated the AUC website to inform interested parties that the payment penalty phase of the AUC program would not begin on January 1, 2023 even if the PHE for COVID–19 ended in 2022. This update also stated that the educational and operations testing period would continue and that we are not able to forecast when the payment penalty phase will begin. In October 2022, we updated the AUC website again to announce that applications for CDSM and PLE initial qualification and re-qualification would not be accepted for the 2023 application cycle and that all CDSMs and PLEs qualified as of July 2022 would remain qualified through this cycle.

5. Proposal To Pause Program for Reevaluation

Since 2015, we have taken a thoughtful, stepwise approach that maximized engagement and involvement of interested parties to implement the statutory provisions set forth in section 1834(q), as added by section 218(b) of the PAMA, using notice and comment rulemaking. As discussed previously in this section of the proposed rule, we established the first two components of the AUC statutory requirements—establishment of AUC and mechanisms for consultation. We began to build the parameters for the fourth component, outlier identification, leading to prior authorization, by establishing the PCAs. And we began implementing the third component, the AUC consultation and reporting requirement, using the ongoing educational and operations testing period. At this time, however, we have exhausted all reasonable options for fully operationalizing the AUC program consistent with the statutory provisions as prescribed in section 1834(q)(B) of the Act directing CMS to require real-time claims-based reporting to collect information on AUC consultation and imaging patterns for advanced diagnostic imaging services to ultimately inform outlier identification and prior authorization. As a result, we propose to pause implementation of the AUC program for reevaluation, and rescind the current AUC program regulations from § 414.94. We expect this to be a hard pause to facilitate thorough program reevaluation and, as such, we are not proposing a time frame within which implementation efforts may recommence.

a. Real-Time Claims-Based Reporting

Section 1834(q)(4)(A) of the Act requires ordering professionals to consult AUC using a qualified CDSM. Section 1834(q)(4)(B) of the Act requires furnishing professionals to report information about the ordering professional's AUC consultation with a qualified CDSM on the Medicare claim for the advanced diagnostic imaging service the ordering professional ordered. This section dictates that payment to the furnishing professional is contingent on reporting the ordering professional's AUC consultation information, which must include the ordering professional's NPI, the qualified CDSM that was consulted, and whether the service ordered adheres or does not adhere to the AUC consulted, or if there were no AUC applicable to the order available for consultation via the qualified CDSM that was consulted as described above.

While each component of the statutory requirements has presented unique challenges to implement, the greatest challenge has been in fully implementing and operationalizing the real-time claims-based reporting requirement consistent with section 1834(q)(4)(B) of the Act so as to ensure accurate reporting, claims processing and, ultimately, outlier identification and prior authorization. We formally solicited public comment and feedback from interested parties in notice and comment rulemaking in the CY 2017 PFS rulemaking cycle, and have welcomed and encouraged feedback and information from interested parties less formally throughout the duration of our implementation efforts in each successive year. In the CY 2017 PFS final rule, we discussed the importance of developing and operationalizing a meaningful solution for collecting AUC consultation information on Medicare claims. We explained that ''we must diligently evaluate our options taking into account the vast number of claims impacted and the limitations of the legacy claims processing system.'' We further noted that ''[m]oving too quickly to satisfy the reporting requirement could inadvertently result in technical and operational problems that could cause delays in payments'' (81 FR 80420). In addition to consulting with claims processing experts outside of and between rulemaking cycles, we continued to clearly and intentionally solicit feedback and suggestions from interested parties to assist us in developing workable claims processing edits and solutions to operationalize the AUC reporting requirement consistent with section 1834(q)(4)(B) of the Act in rulemaking cycles for the CY 2018, 2019 and 2022 PFS.

Having considered many rounds of input from interested parties, including internal and external experts, and diligent exploration of options, we have come to believe that the real-time claims-based reporting requirement prescribed by section 1834(q)(4)(B) of the Act presents an insurmountable barrier for CMS to fully operationalize the AUC program. To properly apply the statutory provisions of the AUC program, including specifications around settings in which services are furnished and payment systems under which Medicare payments are made, it is critical that claims are accurately identified in the Medicare claims processing system and accurately subjected to system's edits to ensure AUC consultation information is properly reported on the claim. Equally important is ensuring that claims not subject to the AUC program are not inappropriately subjected to claims system's edits. We consider a process where the Medicare claims processing system properly and accurately identifies only claims for services subject to the AUC program requirements, without manual action by practitioners/facilities that submit claims, to be a fully automated process. The existing Medicare claims processing system does not have the capacity to fully automate the process for distinguishing between advanced diagnostic imaging claims that are or are not subject to the AUC program requirement to report AUC consultation information as prescribed by section 1834(q)(4)(B) of the Act. This means that the Medicare claims processing system is not able to ensure that claims for services that are not subject to the AUC consultation information reporting requirement will not be improperly denied for failure to append AUC consultation information. We note here that our intention, as announced in the CY 2022 PFS final rule, was to begin the payment penalty phase of the AUC program by returning, rather than denying, claims for advanced diagnostic imaging services that do not contain AUC consultation information for correction and resubmission; however, section 1834(q)(4)(B) of the Act specifies

[250] *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/appropriate-use-criteria-program.*

that payment for advanced diagnostic imaging services under the AUC program may only be made if the claim for the imaging service includes specific AUC consultation information. Consequently, the payment penalty phase would eventually need to shift from returning claims for correction and resubmission to denying claims. As such, and without the practicable capacity to fully automate the process for editing claims to ensure only appropriate claims are edited for AUC consultation information, there is a significant risk that full implementation of the penalty phase of the AUC program would result in inappropriate claims denials.

To avoid these inappropriate denials, we considered requiring claims to include certain modifiers that would identify them as not being subject to the AUC consultation and reporting requirements under section 1834(q)(4)(A) and (B) of the Act. However, this would add an extra layer of burden on furnishing professionals, including freestanding and hospital-based imaging facilities, requiring them to append information to the claims even for services that are not subject to the AUC consultation and reporting requirement in order to allow us to identify which imaging services are and are not subject to the AUC consultation and reporting requirements under section 1834(q)(4)(A) and (B) of the Act, and allow us to appropriately process claims.

Additionally, the AUC program is designed to target a subset of advanced diagnostic imaging services furnished in specific settings and paid under specific payment systems, as opposed to, for example, all Medicare part B advanced diagnostic imaging service claims, and includes multifaceted criteria for identifying which services are subject to the program. As such, ordering professionals would need to know, at the time of the order, where each imaging service will be furnished and under which payment system the claim will be paid to determine whether AUC consultation, and transmission of AUC consultation information with the order, is required. Furnishing professionals, including freestanding and hospital-based imaging facilities, would need to be able to delineate which orders received without AUC consultation information are not subject to the AUC program from those that are subject to the program and its requirements. If they are able to confirm that a service is not subject to the AUC program, then they would need to identify the appropriate modifier to append to the claim so it can be processed and be paid without AUC consultation information. Alternatively, if they find that the order is subject to the AUC program, they would need to take steps to obtain AUC consultation information from the ordering professional, decline to furnish the service, or risk denial of the claim for a furnished service.

An example that highlights the practical complexity and unwieldiness of the AUC program is the, not uncommon, scenario where an advanced diagnostic imaging service is furnished in two settings—only one of which is an applicable setting. For example, this occurs when the technical component (TC) of an imaging service is furnished in a setting, like a critical access hospital (CAH), that is not an applicable setting. As we discussed in the CY 2022 PFS final rule, because the service was not furnished in an applicable setting, the entirety of the service (both the technical and professional component (PC)), is not subject to the AUC consultation requirement. Therefore, neither of the separate claims for the TC and PC for the service are required to include AUC consultation information. However, there is no way in real-time claims processing for us to identify that the PC claim is for an imaging service that was not furnished in an applicable setting. For the claim to process and be paid when it does not include AUC consultation information, the furnishing professional for the PC would need to append a modifier to the claim to identify it as not being subject to the AUC consultation and reporting requirement.

b. Accuracy of Claims Data

Because, as noted above, the CMS claims processing system is unable to fully automate editing advanced diagnostic imaging claims, risks around reporting accuracy are inherent to the AUC program prescribed by section 1834(q)(4)(B) of the Act. These risks directly impact furnishing professionals, including free-standing and hospital-based facilities, by affecting payment for advanced diagnostic imaging services they furnish, in some cases based on conduct of ordering professionals with whom they have little or no affiliation. Beyond the potential for inappropriate claims denials as discussed above, by manually appending information to their claims as supplied by ordering professionals, furnishing professionals are attesting to the credibility and accuracy of that information and may find themselves subject to audits or post-pay review. Considering that the AUC program ultimately involved the identification of outlier ordering professionals and imposing a prior authorization procedure for them as prescribed in sections 1834(q)(5) and (6) of the Act, reliance on manual reporting by one party of information supplied by another party presents a serious risk to data accuracy and integrity. Since section 1834(q)(5) of the Act directs CMS to use these data from claims-based AUC consultation information collection to identify outlier ordering professionals, and section 1834(q)(6) of the Act directs CMS to require prior authorization for outlier ordering professionals, the quality and accuracy of the data used to make these determinations is critical to ensure the AUC program leads to appropriate application of prior authorization for advanced diagnostic imaging services.

c. Effect on Medicare Beneficiaries

We recognize that a program to promote the use of AUC for advanced diagnostic imaging could improve imaging utilization patterns for Medicare beneficiaries. Ideally, beneficiaries would undergo fewer and more appropriate imaging procedures to inform more efficient treatment plans and address medical conditions more quickly and without unnecessary tests. In the CY 2019 PFS final rule, we estimated how adding AUC consultation to an ordering professional's workload would directly impact a Medicare beneficiary based on the additional office visit time needed for consultation and ordering. We estimated this impact by calculating the cost to beneficiaries associated with the additional consultation time to be $68,001,000 annually (83 FR 60040). In the CY 2022 PFS final rule we updated this estimate based on Medicare claims data and changes in wage estimates to $54,789,518 annually. We estimated that potential savings would offset this cost by $27,394,759 annually based on process efficiencies that may be implemented over time by ordering professionals (86 FR 65626). In the CY 2019 PFS final rule, we estimated other impacts associated with the AUC program including potential savings to the Medicare program. We estimated potential savings of $700,000,000 annually by extrapolating savings from a clinical decision support pilot project performed by the Institute for Clinical Systems Improvement in Bloomington, Minnesota [251] (83 FR 60043). Since this estimate was based on information from previous clinical decision support experiences and not Medicare claims

[251] Miliard, M. Nuance, ICSI aim to prevent unnecessary imaging tests. Healthcare IT News. November 10, 2010.

data or wage estimates, we did not update this estimate in the CY 2022 PFS final rule.

While the incorporation of any new process into workflows can be expected to impart burden that eventually lessens, we have additional concerns about risks for beneficiaries stemming from the real-time claims-based reporting requirement prescribed by section 1834(q)(4)(B) of the Act. Beyond the burden of adding to the workload of the ordering and furnishing professionals for advanced diagnostic imaging services, the AUC consultation program can produce risk to beneficiaries in receiving timely imaging services, and potentially being financially liable for advanced diagnostic imaging service claims denied by the Medicare program, whether properly or due to omissions or errors in conveying AUC consultation information on claims. Beneficiaries may experience delays in scheduling and receiving imaging if AUC information is not properly provided with the order from the ordering professional to furnishing professionals/facilities. This may happen, even if the imaging service is not subject to the AUC program requirements, in any circumstance where the furnishing professional/facility is unclear whether the AUC consultation and reporting requirements apply (for example if Medicare is the secondary payer, or under other circumstances as discussed in the CY 2022 PFS final rule). Section 1834(q) of the Act does not separately establish protections to Medicare beneficiaries from financial liability for advanced diagnostic imaging service claims not paid by Medicare as required under the AUC program. As discussed above, because the Medicare claims processing system cannot fully automate a process to ensure only claims for advanced diagnostic imaging services subject to the AUC program reporting requirement under section 1834(q)(4)(B) of the Act are edited as such, there is a risk of inappropriate claims denials. Additionally, in the event that an ordering professional fails to consult AUC or neglects to communicate AUC consultation information (or relevant exception information) to the furnishing professional/facility and the furnishing professional/facility proceeds with furnishing the imaging service despite the absence of this information, the beneficiary may incur unwarranted financial liability for the imaging service.

d. Summary

Taken together and, in particular, due to the inability of the Medicare claims processing system to automate claims processing edits that ensure only claims subject to the AUC program requirements as prescribed in section 1834(q) of the Act will be processed as such, returned or denied accordingly, we believe the inherent risks in terms of data integrity and accuracy, beneficiary access, and potential beneficiary financial liability for advanced diagnostic imaging services render the AUC program impracticable, and have led us to our proposal to pause efforts to implement the AUC program for reevaluation and rescind current regulations. Working within the parameters prescribed under section 1834(q) of the Act, we have not identified any practical way to move the AUC program forward beyond the educational and operations testing period. Further, without a way forward to fully implement the AUC program, we believe there is no utility in continuing the educational and operations testing period. We will continue efforts to identify a workable implementation approach and will propose to adopt any such approach through subsequent rulemaking. We note, and discuss further below in this section of the proposed rule, that clinical decision support tools can be beneficial in assisting with clinical decision making and we encourage continued use of clinical decision support in a manner that best serves and assists clinicians.

6. Summary of Other Quality Initiatives

As discussed above, section 218(b) of the PAMA of 2014 entitled ''Promoting Evidence-Based Care'' established the Medicare AUC program. The statute was designed to promote the use of AUC for advanced diagnostic imaging services with enforcement through immediate non-payment of claims for which there was no AUC consultation and, eventually, prior authorization for ''outliers'' that more frequently neglect to consult AUC. Promoting the use of AUC in clinical practice is an activity that encourages the use of evidence-based information/guidelines/recommendations to guide patient care thus resulting in improved value and quality. Subsequent to PAMA, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015) established the Quality Payment Program, which is an incentive program to tie Medicare PFS payment to performance by rewarding high-value, high-quality care. After enactment of these laws, CMS worked to implement both programs by successfully establishing and fully operationalizing the Quality Payment Program (both the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs)) and, as discussed above, taking steps to implement each component of the AUC program up to and through the ongoing educational and operations testing period. We have developed outreach and educational materials and made all AUC program-related information available on the CMS AUC website.[252] We believe that many goals of the AUC program have been met by the QPP and other more comprehensive accountable care initiatives such as the Medicare Shared Savings Program, advances in electronic clinical quality measures (eCQMs) and Interoperability requirements of Certified Electronic Health Record Technology (CEHRT), and new Innovation Center models such as ACO REACH and Kidney Care Choices where physicians and other health care providers join together to take responsibility for both the quality of care and total cost of care their patients experience. These quality and value-based care programs are designed to achieve quality of care goals by addressing issues of utilization, cost and quality holistically instead of via claim-by-claim examination and improvement initiatives for specific types of services.

While these initiatives, including the Shared Savings Program, do not specifically target advanced diagnostic imaging, we expect that this more global approach to improving quality and accountable care would broadly affect all services, including advanced diagnostic imaging utilization. Both ACO participation and episode of care payment models promote accountability for beneficiary cost of care as well as improving or maintaining quality of care according to applicable quality measures. Similarly, the MIPS ties together quality and costs by measuring and scoring performance in four performance categories: quality, cost, improvement activities, and promoting interoperability. MIPS uses measures and activities in each of these categories, such as the Total Per Capita Cost (TPCC) specialty measure, which focuses on effective primary care management to support Medicare savings. While also not specific to advanced diagnostic imaging, improvements in primary care management including ordering of diagnostic tests may involve consideration of appropriate imaging orders.

[252] *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/appropriate-use-criteria-program.*

More specific to advanced diagnostic imaging, MIPS includes 10 specific quality measures pertaining to imaging or under the ''Diagnostic Radiology'' Specialty Measure Set. Additionally, the Meaningful Measures 2.0 Framework includes a priority area for safety with the goal of ''Reduced Preventable Harm'' (*https://edit.cms.gov/files/document/cascade-meaningful-measures-framework.xlsx*). An objective under this goal is ''Diagnostic Accuracy/Error'' which includes a cascade measure concept/family of ''Appropriate use of radiology and lab testing.'' An example of an existing measure within this concept is ''Appropriate Follow-up Imaging for Incidental Abdominal Lesions'' (*https://www.cms.gov/files/document/cascade-measures.xlsx*).

While a standalone program specifically requiring AUC consultation when ordering advanced diagnostic imaging services would directly target goals of improving advanced diagnostic imaging ordering patterns, our experience in recent years has demonstrated that the goals of appropriate, evidence based, coordinated care can be achieved more effectively, efficiently and comprehensively through other CMS quality initiatives.

7. Proposal To Rescind § 414.94

To execute this proposal and provide clarity to interested parties, we propose to amend our regulations to rescind the current regulations by removing the text of § 414.94 and reserve it for future use. This section contains the entirety of the regulations we adopted in the course of implementing elements of section 1834(q) of the Act. We believe the removal of these regulations is consistent with our proposal to pause efforts to implement the AUC program for reevaluation, and would avoid the potential confusion that could result if we were merely to retain or amend the regulation text at § 414.94.

We want to acknowledge and emphasize the value of clinical decision support to bolster efforts to improve the quality, safety, efficiency and effectiveness of health care. We welcome and encourage the continued voluntary use of AUC and/or clinical decision support tools in a style and manner that most effectively and efficiently fits the needs and workflow of the clinician user. Across many specialties and services, not just advanced diagnostic imaging, clinical decision support predates the enactment of the PAMA and, given its utility when accessed and used appropriately, we expect it to continue being used to streamline and enhance decision making in clinical practice and improve quality of care. Resources on clinical decision support are available on HHS Agency websites including the following:

- Office of the National Coordinator—*https://www.healthit.gov/topic/safety/clinical-decision-support.*
- Agency for Healthcare Research and Quality—*https://www.ahrq.gov/cpi/about/otherwebsites/clinical-decision-support/index.html.*
- Centers for Disease Control and Prevention—*https://www.cdc.gov/opioids/healthcare-admins/ehr/clinical-decision-support.html.*

8. Summary

In conclusion, we are proposing to pause efforts to implement the AUC program for reevaluation and to rescind the current AUC program regulations at § 414.94. We are not proposing a time frame within which implementation efforts may recommence. We will continue efforts to identify a workable implementation approach and will propose to adopt any such approach through subsequent rulemaking.

K. Medicare and Medicaid Provider and Supplier Enrollment

1. Medicare Enrollment

a. Background

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers into the Medicare program. The overarching purpose of the enrollment process is to help confirm that providers and suppliers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all applicable Federal and State requirements to do so. The process is, to an extent, a ''gatekeeper'' that prevents unqualified and potentially fraudulent individuals and entities from entering and inappropriately billing Medicare. Since 2006, we have undertaken rulemaking efforts to outline our enrollment procedures. These regulations are generally codified in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.575 and hereafter occasionally referenced as subpart P). They address, among other things, requirements that providers and suppliers must meet to obtain and maintain Medicare billing privileges.

As outlined in § 424.510, one such requirement is that the provider or supplier must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) the appropriate enrollment form, typically the Form CMS–855 (OMB Control No. 0938–0685). 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, PECOS), collects important information about the provider or supplier. Such data includes, but is not limited to, general identifying information (for example, legal business name), licensure and/or certification data, and practice locations. The application is used for a variety of provider enrollment transactions, including the following:

- Initial enrollment—The provider or supplier is—(1) enrolling in Medicare for the first time; (2) enrolling in another Medicare contractor's jurisdiction; or (3) seeking to enroll in Medicare after having previously been enrolled.
- Change of ownership—The provider or supplier is reporting a change in its ownership.
- Revalidation—The provider or supplier is revalidating its Medicare enrollment information in accordance with § 424.515. (Suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) must revalidate their enrollment every 3 years; all other providers and suppliers must do so every 5 years.)
- Reactivation—The provider or supplier is seeking to reactivate its Medicare billing privileges after it was deactivated in accordance with § 424.540.
- Change of information—The provider or supplier is reporting a change in its existing enrollment information in accordance with § 424.516.

After receiving the provider's or supplier's initial enrollment application, CMS or the MAC reviews and confirms the information thereon and determines whether the provider or supplier meets all applicable Medicare requirements. We believe this screening process has greatly assisted CMS in executing its responsibility to prevent Medicare fraud, waste, and abuse.

As previously mentioned, over the years we have issued various final rules pertaining to provider enrollment. These rules were intended not only to clarify or strengthen certain components of the enrollment process but also to enable us to take further action against providers and suppliers: (1) engaging (or potentially engaging) in fraudulent or abusive behavior; (2) presenting a risk of harm to Medicare beneficiaries or the Medicare Trust Funds; or (3) that are otherwise unqualified to furnish Medicare services or items. Consistent with this, and as we discuss in this section III.K. of this proposed rule, we

propose several changes to our existing Medicare provider enrollment regulations.

(We note that section III.K.2 of this proposed rule addresses a proposed change to one of our Medicaid provider enrollment provisions.)

b. Legal Authorities

There are two principal categories of legal authorities for our proposed Medicare provider enrollment provisions:

- Section 1866(j) of the Act furnishes specific authority regarding the enrollment process for providers and suppliers.
- Sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

c. Medicare Provider Enrollment Provisions

i. Revocation and Denial Reasons and Revisions to Other Revocation Policies

(A) Revocations

Under § 424.535(a), CMS may revoke a Medicare provider's or supplier's enrollment for any of the reasons specified within that paragraph. (The revocation grounds are currently identified as § 424.535(a)(1) through (22), with paragraphs (a)(15) and (16) designated as reserved.) These reasons include, for instance, the provider's or supplier's: (i) failure to adhere to Medicare enrollment requirements; (ii) exclusion by the HHS Office of Inspector General (OIG); (iii) felony conviction within the previous 10 years; (iv) pattern of improper or abusive billing, prescribing of Part B or Part D drugs, or ordering/referring/certifying of Medicare services or items; and (v) termination by another Federal health care program. A revocation is designed to safeguard the Medicare program, the Trust Funds, and beneficiaries by removing from (and preventing payment to) Medicare providers and suppliers that have engaged in problematic or otherwise non-compliant behavior. When a provider or supplier is revoked, they are generally barred from reenrolling in Medicare for a period of 1 to 10 years. The length of this ''reenrollment bar'' is determined based upon the severity of the basis of the revocation. The maximum reenrollment bar is typically restricted to egregious acts of misconduct.

We have previously finalized a number of regulations adding new revocation reasons to § 424.535(a) to address particular program integrity vulnerabilities and types of provider or supplier behavior. We have also used rulemaking to refine other policies regarding revocations, such as the reenrollment bar and the effective dates of certain revocations. Given our continuing obligation to assess potential vulnerabilities and establish payment safeguard measures, we believe that several additions and revisions to our revocation policies in § 424.535(a) are necessary at this time.

(1) Non-Compliance Revocation Ground (§ 424.535(a)(1))

Existing § 424.535(a)(1), in part, permits revocation if the provider or supplier is determined to not be in compliance with the enrollment requirements described in subpart P or in the enrollment application applicable to its provider or supplier type. We propose to change the language therein that reads ''described in this subpart P or in the enrollment application'' to ''described in this title 42, or in the enrollment application . . .'' This is because there are enrollment requirements located outside of 42 CFR part 424, subpart P; for instance, certain enrollment requirements pertaining to opioid treatment programs are in § 424.67(b). All enrollment requirements, regardless of their placement in title 42, must be adhered to, which is why we believe the scope of § 424.535(a)(1) should be expanded.

(2) Misdemeanor Convictions

As already alluded to, a provider or supplier can be revoked under § 424.535(a)(3)(i) if the provider, supplier, or any owner, managing employee, officer, or director of the provider or supplier was, within the preceding 10 years, convicted of a Federal or State felony that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries. Section 424.535(a)(3)(ii) lists examples of such felonies, though they are not limited in scope and severity to these offenses.

Section 424.535(a)(3) does not include misdemeanor convictions, and there currently is no regulatory authority to revoke a provider or supplier based solely on a misdemeanor. However, we have become aware of and increasingly concerned about providers and suppliers convicted of misdemeanors for conduct that could endanger the Trust Funds' integrity and Medicare beneficiaries' health and safety. One case, for instance, involved a physician who wrote and filled prescriptions in fictitious patients' names to obtain Schedule II controlled substances for personal use. The physician pled guilty to a reduced misdemeanor charge for attempting to obtain controlled substances by fraud. In another situation, an owner of a provider was charged with felony assault with a dangerous weapon; the court reduced it to a misdemeanor as part of a guilty plea and sentenced the defendant to 2 years of probation.

We believe that our responsibility in overseeing the Medicare program requires that we have the ability to take protective action in such instances. To this end, we propose in new § 424.535(a)(16)(i) that CMS may revoke a provider's or supplier's enrollment if they, or any owner, managing employee or organization, officer, or director thereof, have been convicted (as that term is defined in 42 CFR 1001.2) of a misdemeanor under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries. Proposed § 424.535(a)(16)(ii) would state that offenses under § 424.535(a)(16) include, but are not limited in scope or severity to, the following:

- Fraud or other criminal misconduct involving the provider's or supplier's participation in a Federal or State health care program or the delivery of services or items thereunder.
- Assault, battery, neglect, or abuse of a patient (including sexual offenses).
- Any other misdemeanor that places the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct. (This example mirrors that in § 424.535(a)(3)(ii)(C) regarding felonies.)

Our proposal accounts for the fact that some States may classify a particular crime as a misdemeanor while others may deem it a felony; in other words, the misdemeanors included in proposed § 424.535(a)(16) may be treated as felonies in certain States. This reflects our concern about the seriousness of these actions. Indeed, merely because particular State statutes may designate the aforementioned actions as misdemeanors does not, in our view, lessen the risk the latter can pose to Medicare and its beneficiaries. It is, in short, the action itself, rather than its specific classification under State law, that is of principal concern to us.

We are soliciting comments on this proposal. We specifically are seeking feedback on: (1) whether there are any potential unintended consequences of our proposal that we are not considering; or (2) any guardrails we should consider so as not to create unintended consequences for persons with misdemeanor convictions.

(3) False Claims Act Civil Judgments

The False Claims Act (FCA) (31 U.S.C. 3729–3733) is the Federal government's principal civil remedy for addressing false or fraudulent claims for Federal funds. Section 3729(a)(1) of the FCA lists specific actions that can result in an FCA judgment against a defendant. These include the following:

- Knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval.
- Knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim.
- Conspiring to violate any of the provisions in section 3729(a)(1) of the FCA.
- Having possession, custody, or control of property or money used, or to be used, by the government and knowingly delivering, or causing to be delivered, less than all of that money or property.
- Being authorized to make or deliver a document certifying receipt of property used, or to be used, by the government and, intending to defraud the Government, making or delivering the receipt without completely knowing that the information on the receipt is true.
- Knowingly buying, or receiving as a pledge of an obligation or debt, public property from an officer or employee of the government, or a member of the Armed Forces, who lawfully may not sell or pledge property.
- Knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the government.

Under section 3729(a)(1), a party that is liable under the FCA must pay a civil penalty of between $5,000 and $10,000 for each false claim (though these amounts are periodically revised for inflation) and triple the amount of the government's damages.

Although the FCA's scope is not restricted to the health care arena and applies to all types of Federal government programs, the FCA has proven effective in helping to stem Medicare fraud. However, an FCA civil judgment against a provider or supplier does not, in and of itself, impact the latter's Medicare enrollment. Even if, for example, a provider is found to have knowingly submitted fraudulent claims and is liable for $100,000 in damages, we have no ability to revoke the provider's enrollment on this basis. This concerns us, for the actions identified in section 3729(a)(1) of the FCA involve serious misbehavior. We believe we must address this vulnerability to protect the Medicare program and its beneficiaries.

We accordingly propose in § 424.535(a)(15) that CMS could revoke the enrollment of a provider or supplier if the provider or supplier, or any owner, managing employee or organization, officer, or director thereof, has had a civil judgment under the FCA imposed against them within the previous 10 years. (Strictly for purposes of (a)(15), however, the term ''civil judgment'' would not include FCA settlement agreements. The provision would require a judgment against the provider or supplier.) Recognizing that the specific facts and circumstances of each case will differ, we would consider the following factors in our decision:

- The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted).
- The types of provider or supplier actions involved.
- The monetary amount of the judgment.
- When the judgment occurred.
- Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502).
- Any other information that CMS deems relevant to its determination.

We note that we would include FCA civil judgments against owners, managing employees and organizations, and officers and directors (as those terms are defined in § 424.502) of the provider or supplier within the scope of this revocation basis. This is consistent with our approach to several other revocation reasons in § 424.535(a) and reflects our recognition that certain owning and managing parties exercise great influence over the provider or supplier organization and its daily operations. Should such a party have an FCA civil judgment against them, this could present a program integrity risk. We therefore believe that § 424.535(a)(15) should encompass such situations, though we would consider the degree of the owning or managing party's control over the provider or supplier (for example, percentage of ownership, scope of day-to-day operational authority) as a factor in our determination.

(4) Violation of Provider and Supplier Standards

Section 410.33(g) lists detailed enrollment standards that independent diagnostic testing facilities (IDTFs) must meet to enroll and maintain enrollment in Medicare. Likewise, § 424.57(c) identifies 30 enrollment standards that DMEPOS suppliers must meet as conditions of enrollment. These IDTF and DMEPOS standards address matters such as the maintenance of liability coverage, solicitation of patients, and customer service requirements. In addition, §§ 424.67(b) and (e), 424.68(c) and (e), and 424.205(b) and (d) contain enrollment standards and conditions for, respectively, opioid treatment programs (OTPs), home infusion therapy (HIT) suppliers, and Medicare diabetes prevention programs (MDPPs). The standards and conditions in §§ 410.33(g), 424.57(c), 424.67(b) and (e), 424.68(c) and (e), and 424.205(b) and (d) are in addition to, and not in lieu of, the more general enrollment requirements in 42 CFR part 424, subpart P with which IDTFs, DMEPOS suppliers, OTPs, HIT suppliers, MDPPs, and all other provider and supplier types must comply.

We propose to add new paragraph (a)(23) to § 424.535 that would permit CMS to revoke an IDTF's, DMEPOS supplier's, OTP's, HIT supplier's, or MDPP's enrollment based on a violation of any standard or condition in, respectively, §§ 410.33(g), 424.57(c), 424.67(b) or (e), 424.68(c) or (e), or 424.205(b) or (d). No revocation reason in existing § 424.535(a) specifically references these regulatory paragraphs or violations thereof. Although we have sometimes applied a comparatively broad revocation basis in § 424.535(a)(1) to certain non-compliant IDTFs, DMEPOS suppliers, OTPs, HIT suppliers, and MDPPs (for example, an invalid practice location under § 424.535(a)(5)), we believe a narrower approach that allows us to target violations of the aforementioned standards and conditions is preferable. That is, our proposal would more directly tie these regulatory paragraphs to § 424.535(a) by establishing a new revocation reason restricted to non-compliance with any of them.

(5) Scope of § 424.535(a)(17)

Under § 424.535(a)(17), we may revoke enrollment if the provider or supplier has an existing debt that CMS appropriately refers to the United States Department of Treasury. In determining whether a revocation is appropriate, CMS considers the six factors outlined in § 424.535(a)(17)(i) through (vi); these include, for instance, the reason for the provider's or supplier's failure to pay the debt. Section 424.535(a)(17)'s purpose is to spur providers and suppliers to repay their financial obligations to Medicare; in our view,

their failure to do so raises doubts as to whether the provider or supplier can be a reliable partner of the Medicare program.

We have received inquiries from interested parties concerning the scope of this provision, such as whether paragraph (a)(17) applies to debts that are no longer being collected or are being appealed. We propose to revise paragraph (a)(17) to address these issues.

First, and to help accommodate our revisions, existing § 424.535(a)(17)(i) through (vi) would be re-designated as paragraphs (a)(17)(i)(A) through (F).

Second, in new paragraph (a)(17)(ii), we propose to exclude from paragraph (a)(17)(i)'s purview those cases where: (1) the provider's or supplier's Medicare debt has been discharged by a bankruptcy court; or (2) the administrative appeals process concerning the debt has not been exhausted or the timeline for filing such an appeal, at the appropriate appeal level, has not expired. In our view, the debts in these two situations have not been finally and fully adjudicated for purposes of paragraph (a)(17)(i)'s applicability. For this reason, we believe basic fairness to the provider or supplier justifies revised paragraph (a)(17)(ii).

Third, in § 424.535(a)(17)(i) we would change the term ''existing debt'' to ''failure to repay a debt''. This would allow us to potentially use our revocation authority even if collection action has ceased and the debt was ultimately terminated as a result, since the provider or supplier had still failed to repay it. Our central concern is more with the provider's or supplier's inaction in fulfilling its financial obligations to Medicare than with the particular status or result of CMS' collection efforts. In other words, and as with all of our revocation reasons in § 424.535(a), the issue is the provider's or supplier's conduct, which, in the case of § 424.535(a)(17), involves the provider's or supplier's failure to repay monies it owed to the Federal government. Simply because the debt could not be collected and was subsequently ''written off'' does not negate the fact that the provider or supplier did not meet its responsibility to repay it in the first place. Although the financial obligation may no longer constitute a debt because it was ''written off'', the core point is that it was a debt at one time but the provider did not repay it. Again, it is the provider's non-payment of the debt when it was current rather than whether said debt still exists that is critical, hence our proposed move away from ''existing debt'' to a status that better reflects the provider's inaction irrespective of the timing of the debt. In our view, a provider's failure to fulfill its financial obligations to the Medicare program: (1) constitutes a potential vulnerability to the program; and (2) could well increase the likelihood that any of the provider's or supplier's future Medicare debts, too, may not be repaid. Our obligation to safeguard the Trust Funds, we believe, requires us to have authority to take action to help prevent the latter occurrence. For these reasons, we believe our proposed change is warranted.

Nevertheless, we recognize that our proposed revision to § 424.535(a)(17)(i) might cause concern within the provider community, for there could be numerous reasons behind the ''writing off'' of a Medicare debt. For example, a provider may have been unable to repay a particular debt (that was later written off) because of a severe local emergency or natural disaster. While we would retain the authority to revoke under paragraph (a)(17)(i), we emphasize that we would still apply the aforementioned six factors in all potential revocation cases under paragraph (a)(17). Indeed, one of these factors is the ''reason(s) for the failure to fully repay the debt (to the extent this can be determined)'', and we will continue to carefully consider the factual circumstances behind the repayment failure so as to ensure fairness to the provider or supplier.

(B) Reasons for Denial

As already discussed, we are proposing new revocation authorities in § 424.535(a)(15), (16), and (23). We believe the rationales for these revocation reasons are equally applicable to newly enrolling providers and suppliers. Our program integrity concerns are the same regardless of whether the provider or supplier is already enrolled or is attempting to enroll; in either case, we must protect the Trust Funds and beneficiaries from problematic parties. Consequently, we propose to largely duplicate these new revocation reasons and establish concomitant grounds in § 424.530 for denying enrollment as follows.

First, § 424.530(a)(1), like § 424.535(a)(1), addresses the need for compliance with subpart P's enrollment requirements. We propose to change this reference from subpart P to title 42. As already noted, several sections of title 42 contain enrollment requirements outside of those in subpart P and to which the provider or supplier must adhere.

Second, we propose in new § 424.530(a)(16)(i) that CMS may deny a provider's or supplier's enrollment application if they, or any owner, managing employee or organization, officer, or director thereof, has been convicted (as that term is defined in 42 CFR 1001.2) of a misdemeanor under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries. (Section 424.530(a)(16)(ii) would mirror proposed § 424.535(a)(16)(ii).) Our concern is that we currently have no legal authority to deny enrollment based on misdemeanor convictions for behavior that could endanger the Trust Funds or Medicare beneficiaries.

Third, new § 424.530(a)(17) would permit CMS to deny a provider's or supplier's enrollment application if the provider or supplier, or any owner, managing employee or organization, officer, or director thereof, has had a civil judgment under the FCA imposed against them within the previous 10 years. The same factors for consideration in § 424.535(a)(15) would be included in § 424.530(a)(17). Given our previously stated view that the actions identified in section 3729(a)(1) of the FCA involve serious misbehavior, we believe proposed § 424.530(a)(17) would help protect the integrity of the Medicare program.

Fourth, and for the same reasons we are proposing new § 424.535(a)(23), we would duplicate the latter in new denial reason § 424.530(a)(18). We must strive to ensure that enrolling IDTFs, DMEPOS suppliers, OTPs, HIT suppliers, and MDPPs are legitimate providers and suppliers, as evidenced in part by their compliance with the standards and conditions applicable to them.

(C) Effective Date of Revocation

Section 424.535(g) addresses revocation effective dates. It states that a revocation becomes effective 30 days after CMS or the contractor mails notice of its determination to the provider or supplier. Yet there are exceptions. If the revocation is based on a Federal exclusion or debarment, felony conviction, license suspension or revocation, or non-operational practice location, the revocation is effective with the date of exclusion or debarment, felony conviction, license suspension or revocation, or the date that CMS or its contractor determined that the provider or supplier was non-operational. The purpose of these exceptions is to prevent payment to a provider or supplier while it is out of compliance with Medicare enrollment requirements. To illustrate, assume a supplier's license is revoked on June 1. CMS learns of this and mails a revocation notice to the

supplier on June 15. If we applied the aforementioned ''30 days after mailing'' policy, the supplier could bill and be paid for services furnished between June 1 and July 15 while unlicensed. Per existing § 424.535(g), however, the revocation would be effective June 1, meaning all services furnished after that date would be ineligible for payment.

We view § 424.535(g)'s four exceptions as an important program integrity protection against improper payments. We do not believe providers and suppliers should be paid for services furnished during a period of non-compliance. With this principle in mind, we propose a number of policy and organizational changes to § 424.535(g).

First, we would split existing § 424.535(g) into several paragraphs. Paragraph (g)(1) would include the previously mentioned 30-day effective date policy, though with the following language at its beginning, ''Except as described in paragraphs (g)(2) and (g)(3) of this section''. New paragraph (g)(2) would list the four retroactive revocation situations in existing § 424.535(g). Each situation (and its associated revocation effective date) would be incorporated into a separate sub-paragraph to make paragraph (g)(2) clearer and more readable.

Second, paragraph (g)(2) would include the following additional situations where a retroactive effective date would be warranted:

- Revocations under proposed § 424.535(a)(16) (regarding misdemeanor convictions): the effective date would be the date of the misdemeanor conviction.
- Revocations based on a State license surrender in lieu of further disciplinary action: the effective date would be the date of the license surrender.
- Revocations based on termination from a Federal health care program other than Medicare (for example, Medicaid): the effective date would be the date of the termination.
- Revocations based on termination of a provider agreement under 42 CFR part 489: the effective date would be, as applicable to the type of provider involved, the later of the following: (1) the date of the provider agreement termination; or (2) as applicable, the date that CMS establishes under 42 CFR 489.55. (Section 489.55 permits payments beyond the provider agreement termination date in certain instances and for a certain period.)
- Revocations based on proposed § 424.535(a)(23) would be as follows:

++ If the standard or condition violation involved the suspension, revocation, or termination (or surrender in lieu of further disciplinary action) of the provider's or supplier's Federal or State license, certification, accreditation, or MDPP recognition, the revocation effective date would be the date of the license, certification, accreditation, or MDPP recognition suspension, revocation, termination, or surrender.

++ If the standard or condition violation involved a non-operational practice location (for example, an IDTF's failure to maintain a physical facility on an appropriate site per § 410.33(g)(3)), the revocation effective date would be the date the non-operational status began.

++ If the standard violation involved a felony conviction of an individual or entity described in § 424.67(b)(6)(i), the revocation effective date would be the date of the felony conviction.

(For all other standard violations, the effective date in paragraph (g)(1) would apply if the effective date in new paragraph (g)(3) (discussed later in this section of the proposed rule) does not.)

As with our existing four bases for a retroactive revocation, these new grounds would help ensure that providers and suppliers do not receive payment for services rendered while non-compliant with enrollment requirements. For example, a provider's State license surrender would mean that the provider is not appropriately licensed (and can thus be revoked under § 424.535(a)(1)) and, accordingly, should not be paid by Medicare for furnished services while unlicensed. Concerning terminations under another Federal health care program, some such programs are occasionally delayed in reporting their actions to CMS, during which period CMS continues making payments to the affected provider or supplier until CMS receives notice of the termination. Any Federal program termination is of concern to us, which is why we promulgated a revocation reason based on this action. We believe that any such termination that leads to a Medicare revocation should consequently be retroactive to the date of the program termination since the latter stemmed from conduct that, in our view, was serious enough to warrant the subsequent revocation. Likewise, there could be a brief administrative time lapse between when a provider agreement is terminated and a Medicare revocation is effectuated, meaning that a provider without a required provider agreement might still receive payments beyond the provider agreement termination date or the date that CMS establishes under § 489.55. The aforementioned retroactive effective dates involving § 424.535(a)(23), meanwhile, generally mirror those currently in § 424.535(g) (for example, felony conviction).

Third, new § 424.535(g)(3) would state that if the action that triggered the revocation occurred before the provider's or supplier's enrollment effective date, the revocation effective date would be the enrollment effective date that CMS assigned to the provider or supplier. To illustrate, suppose an adverse legal action occurred on February 1 and the provider was enrolled effective April 1. Although CMS was unaware of the action at the time of enrollment, it revoked the provider on April 15 upon learning of it. The revocation effective date would be April 1 rather than February 1. The aim of § 424.535(g)(3) is merely to reiterate that we could not apply a revocation effective date that is earlier than the date the provider or supplier is enrolled. It is a technical, though, we believe, obvious clarification.

(D) Timeframes for Reversing a Revocation Under § 424.535(e)

Section 424.535(e) states that if a revocation was due to adverse activity (sanction, exclusion, felony) by one of the parties listed in § 424.535(e) (for example, owner, managing employee, authorized or delegated official, supervising physician), the revocation can be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that party within 30 days of the revocation notification. We have been concerned about this 30-day period. We do not believe a provider or supplier should be afforded so much time to terminate this business relationship; each day the revoked provider or supplier remains affiliated with the party in question, the more Medicare dollars that could be paid until the 30-day timeframe expires. It is the provider's or supplier's constant responsibility to ensure that its owning and managing personnel present no program integrity risks to the Medicare program. To give the provider or supplier 30 days to terminate a relationship that should have been promptly ended upon the commission of the adverse action (for example, when the owner became excluded) would be inconsistent with our obligation to protect the Trust Funds; it could also convey a false impression that maintaining affiliations with problematic parties is acceptable so long as the relationship ceases within a month of the revocation notice. To this end, we propose to revise § 424.535(e) to reduce the 30-day period therein to 15

days. We are not proposing, for instance, a 5-day period because we recognize that it might be administratively and financially difficult to immediately terminate the business relationship in question, especially an owner's interest in the provider or supplier. Still, the reduction from 30 days to 15 days evidences our concern about making Medicare payments to providers and suppliers that have relationships with parties presenting program integrity risks.

We emphasize that this change would have no impact on a revoked provider's or supplier's ability to appeal a revocation under 42 CFR part 498. It would only affect the provider's or supplier's utilization of § 424.535(e) to reverse the revocation. We are soliciting comments on whether 15 days is an appropriate timeframe.

ii. Stay of Enrollment

CMS may deactivate a provider's or supplier's Medicare billing privileges for any of the reasons specified in § 424.540(a). A deactivation differs from a revocation in that the former: (1) merely involves the stoppage, rather than the termination, of the provider's or supplier's billing privileges; and (2) does not entail any reenrollment bar under § 424.535(c). The latter is a particularly important distinction, for a deactivated provider or supplier can reactivate its billing privileges by following the procedures in § 424.540(b). It need not wait (as a revoked provider or supplier must) for the expiration of the 1 to 10-year bar period referenced in § 424.535(c) before attempting to restore its ability to bill Medicare. Indeed, we sometimes impose a deactivation instead of a revocation when we believe a more modest sanction is warranted.

Nevertheless, a deactivation can still impose a potential burden on a provider or supplier. This is especially true concerning § 424.540(e), which prohibits a provider or supplier from receiving payment for services or items furnished while deactivated. While deactivation is a less severe action than a revocation, it may be too punitive in certain cases. We believe that a middle ground between a deactivation and non-action on our part is warranted. In our view, we need as much flexibility as possible to take appropriate, fair, and reasonable measures that are commensurate with the degree of the provider's or supplier's action, inaction, or non-compliance.

For these reasons, we propose in new § 424.541 a new enrollment status labeled a ''stay of enrollment.'' This would be a preliminary, interim status—prior to any subsequent deactivation or revocation—that would represent, in a sense, a ''pause'' in enrollment, during which the provider or supplier would still remain enrolled in Medicare; in this vein, CMS would neither formally nor informally treat the stay as a sanction or adverse action for purposes of Medicare enrollment. We would also notify the affected provider or supplier in writing of the stay.

There would be two prerequisites for a stay's implementation. First, the provider or supplier must be non-compliant with at least one enrollment requirement in Title 42. Mere suspicion of or information alleging non-adherence is insufficient. Actual non-compliance is required. Second, CMS ascertains that the provider or supplier can remedy the non-compliance via the submission of, as applicable to the situation, a Form CMS–855, Form CMS–20134, or Form CMS–588 change of information or revalidation application (hereafter collectively referenced ''Form CMS–855 change request'' or ''change of information application''). This change request could involve, for instance, reporting a new street number (to illustrate, a provider's address changed from 10 Smith Street to 15 Smith Street) that the provider previously failed to disclose to CMS. We believe that using the aforementioned, comparatively bright-line Form CMS–855 submission standard would furnish clarity as to the types of non-compliance that can be remedied under our proposal and the specific vehicle for said remedial action.

When a ''stay period'' is imposed, the provider or supplier would not receive payment for services or items furnished during this period. These services and items would not be payable because the provider or supplier was non-compliant with enrollment requirements and thus not entitled to payment, even after the stay concludes. To permit payment for these services and items would be contrary to our obligation to safeguard the Trust Funds.

Although we acknowledge that this denial of payment is similar to what occurs with a deactivation under § 424.540, there are critical differences between the two actions. First, § 424.541 would make clear that a stay period lasts no more than 60 days. A deactivation, on the other hand, has no finite timeframe, meaning that services and items might not be payable for a long period of time if the provider or supplier does not submit the required reactivation application. Second, MACs can generally process Form CMS–855 change requests more rapidly than a reactivation application. A provider or supplier subject to a stay could therefore begin receiving payments sooner than would a deactivated provider or supplier. Third, while a reactivation application typically involves the provider's or supplier's completion of the entire Form CMS–855, a change of information application may only involve the submission of a limited amount of data (such as the information that is changing and basic identifying data). Completion of a change of information application is, in sum, considerably less burdensome for providers and suppliers than completion of a reactivation application.

Indeed, the issue of burden is the core consideration behind our proposal. As previously indicated, we do not wish to have to proceed to a deactivation (much less a revocation) in all cases of non-compliance. This is especially true if CMS believes in a particular case that the non-adherence can be fairly quickly corrected via the provider's or supplier's submission of updated enrollment data. Although we again recognize that payments for services and items furnished during the stay would not be covered, we emphasize that this would also be the case if CMS instead imposed a deactivation or revocation, with the important distinction that the period of non-payment would often be significantly shorter with a stay than with a deactivation and certainly a revocation. In all, we believe that our stay provision would ultimately reduce the burden on providers who would otherwise be deactivated or revoked for non-compliance.

Notwithstanding this, we believe the affected provider or supplier should have an opportunity to raise a concern about a stay by submitting a rebuttal. The rebuttal process would generally mirror that for deactivations and payment suspensions (outlined in 42 CFR 424.546 and 405.374, respectively), the two actions most akin to a stay. We recognize that given the comparatively and rather short time period that a stay would typically entail, many stays would have long expired by the time a provider or supplier files a rebuttal and CMS makes its determination thereon. In addition, if the provider or supplier can quickly return to compliance, they may likely pursue this course rather than submit a rebuttal (although the provider or supplier may still do so). Yet merely because some providers and suppliers might forego submitting a rebuttal does not mean the process should be unavailable to them.

Consistent with all of the foregoing, we propose a number of provisions in § 424.541. In paragraph (a)(1), we propose that CMS may stay an enrolled

provider's or supplier's enrollment if the provider or supplier:

- Is non-compliant with at least one enrollment requirement in Title 42; and
- Can remedy the non-compliance via the submission of, as applicable to the situation, a Form CMS–855, Form CMS–20134, or Form CMS–588 change of information or revalidation application.

We emphasize that our authority to impose a stay would be discretionary. CMS would not be required to stay the provider's or supplier's enrollment. We could, for instance, elect to proceed directly to a deactivation or revocation (if grounds exist for either) without applying a stay as a prerequisite thereto. Our decision as to which action is most appropriate would depend upon the facts and circumstances of the case at issue.

In paragraphs (a)(2)(i) and (ii), respectively, we would state that during the period of any stay imposed under § 424.541:

- The provider or supplier remains enrolled in Medicare; and
- Claims submitted by the provider or supplier with dates of service within the stay period will be denied.

In paragraph (a)(3), we propose that a stay of enrollment would last no longer than 60 days from the postmark date of the notification letter. We believe a 60-day period would give the provider or supplier adequate time to submit the required Form CMS–855 change of information application.

In paragraph (a)(4), we propose that CMS must notify the affected provider or supplier in writing of the stay's imposition.

In paragraph (b), we would outline our proposed rebuttal process, which, as stated, would largely align with that for deactivations and payment suspensions.

In paragraph (b)(1), we propose that if a provider or supplier receives written notice from CMS or its contractor that the provider or supplier is subject to a stay under § 424.541, the provider or supplier has 15 calendar days from the date of the written notice to submit a rebuttal to the stay as described in § 424.541.

In paragraph (b)(2), we propose that CMS may, at its discretion, extend the 15-day time-period referenced in paragraph (b)(1).

In paragraphs (b)(3)(i) through (iv), we propose that the rebuttal must:

- Be in writing.
- Specify the facts or issues about which the provider or supplier disagrees with the stay's imposition and/or the effective date, and the reasons for disagreement.
- Submit all documentation the provider or supplier wants CMS to consider in its review of the stay.
- Be submitted in the form of a letter that is signed and dated by the individual supplier (if enrolled as an individual physician or non-physician practitioner), the authorized official or delegated official (as those terms are defined in § 424.502), or a legal representative (as defined in § 498.10). If the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the provider or supplier; this statement is sufficient to constitute notice of such authority. If the legal representative is not an attorney, the provider or supplier must file with CMS written notice of the appointment of a representative; this notice of appointment must be signed and dated by, as applicable, the individual supplier, the authorized official or delegated official, or a legal representative.

In paragraph (b)(4), we propose that the provider's or supplier's failure to submit a rebuttal that is both timely under paragraph (b)(1) of this section and fully compliant with all of the requirements of paragraph (b)(3) of § 424.541 constitutes a waiver of all rebuttal rights under this section.

In paragraph (b)(5), we propose that upon receipt of a timely and compliant stay rebuttal, CMS reviews the rebuttal to determine whether the imposition of the stay and/or the effective date thereof are correct.

In paragraph (b)(6), we propose that a determination made under paragraph (b) is not an initial determination under § 498.3(b), and therefore, not appealable.

In paragraph (b)(7), we propose that nothing in paragraph (b) requires CMS to delay the imposition of a stay pending the completion of the review described in paragraph (b)(5).

We propose in paragraph (b)(8) to clarify the interaction between a stay and a subsequent deactivation or revocation.

In paragraph (b)(8)(i), we propose that nothing in paragraph (b) would require CMS to delay the imposition of a deactivation or revocation pending the completion of the review described in paragraph (b)(5) of this section. We believe we must retain the discretion to apply a subsequent deactivation or revocation should circumstances warrant.

In paragraph (b)(8)(ii)(A), we propose that if CMS deactivates the provider or supplier during the stay, any rebuttal to the stay the provider or supplier submits that meets the requirements of § 424.541 would be combined and considered with the provider's or supplier's rebuttal to the deactivation under § 424.546 if CMS has not yet made a determination on the stay rebuttal. (This is meant to facilitate efficiency and simplicity in the review process of both rebuttals.) In paragraph (b)(8)(ii)(B), however, we propose that in all cases other than that described in paragraph (b)(8)(ii)(A), a stay rebuttal that was submitted in compliance with § 424.541 would be considered separately and independently of any review of any other rebuttal or, for revocations, appeal.

Finally, existing § 424.555(b) states that payment may not be made for Medicare services and items furnished to a Medicare beneficiary by a deactivated, denied, or revoked provider or supplier. The paragraph further states that the beneficiary has no financial liability for such services and items provided by these providers and suppliers. To clarify the issues of payment and beneficiary liability for purposes of § 424.541, we propose to add providers and suppliers currently under a stay of enrollment to the categories of providers and suppliers falling within the scope of § 424.555(b).

iii. Reporting Changes in Practice Location

Consistent with §§ 424.57(c)(2), 410.33(g)(2), and 424.516(d)(1)(iii), respectively, the following provider and supplier types must report a change in practice location within 30 days of the change: (1) DMEPOS suppliers; (2) IDTFs; and (3) physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations. All other provider and supplier types are required per § 424.516(e)(2) to report practice location changes within 90 days of the change. As explained below, we propose two sets of regulatory revisions regarding practice location changes. First, we propose to revise § 424.516(e)(1) to require therein such location changes involving providers and suppliers other than the categories previously described to be reported within 30 days of the change. Second, we would clarify in §§ 410.33(g)(2), 424.516(d)(1)(iii), and 424.516(e)(1) that a change of practice location includes adding a new location or deleting an existing one.

We have recently discovered instances where certain provider and supplier types not addressed in §§ 424.57(c)(2), 410.33(g)(2), or 424.516(d)(1)(iii), have moved their practice location without notifying CMS. This is problematic for two reasons. One is that Medicare payments are often based on the provider's or

supplier's specific geographic location. If we are not timely informed of the change in location, CMS could be making incorrect payments to the provider or supplier for an extended period (for instance, 90 days); this would be inconsistent with CMS's obligation to protect the Trust Funds. The other reason is that we would be unable to promptly determine whether the new site is compliant with Medicare provider enrollment requirements (for example, via a site visit) because we would not yet know of the change. The provider or supplier might be furnishing services from an invalid location, hence resulting in improper payments. CMS needs to ensure the accuracy of its payments, and being more rapidly advised of critical data like a practice location change would help facilitate this. It would also facilitate consistency with the aforementioned 30-day requirement in §§ 424.57(c)(2), 410.33(g)(2), and 424.516(d)(1)(iii).

For purposes of reporting practice location changes, we have traditionally included additions and deletions of locations within the scope of such changes. There is as much payment safeguard risk with belatedly reported additions and deletions as with changes. Paying a provider or supplier for services it furnishes at an unreported newly-established location could involve improper payments because, again, CMS does not even know whether the site meets all provider enrollment requirements; likewise, CMS could be paying a provider or supplier for services related to a location that was deleted and no longer exists. To make certain we are more promptly notified of practice location additions and deletions, we propose to revise §§ 410.33(g)(2), 424.516(d)(1)(iii), and 424.516(e)(1) to reiterate that these two transactions must be reported within 30 days of the addition or deletion. (A similar revision to § 424.57(c)(2) is unnecessary because all changes to enrollment data (including practice location additions, deletion, and changes) must already be reported within 30 days.)

iv. Definitions

We are also proposing several new and clarified definitions to help explain the meaning of certain provider enrollment concepts.

(A) ''Pattern or Practice''

Several of our existing Medicare enrollment revocation reasons are based upon the provider or supplier engaging in a pattern or practice of conduct. These reasons include all of the following:

- Section 424.535(a)(8)(ii): The provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements.
- Section 424.535(a)(14): The physician or eligible professional has a pattern or practice of prescribing Part B or D drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or fails to meet Medicare requirements.
- Section 424.535(a)(21): The physician or eligible professional has a pattern or practice of ordering, certifying, referring, or prescribing Medicare Part A or B services, items, or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements.

In determining whether such a pattern or practice exists and if a revocation under any of these authorities is warranted, CMS considers the factors specified in § 424.535(a)(8)(ii), (14), and (21), respectively.

We have received questions from interested parties over the years as to what constitutes a pattern or practice under these provisions. We have always made these determinations on a case-by-case basis, using the above-referenced factors. We do not propose to change this general procedure, for it gives us the flexibility we need to address each situation on its own facts and circumstances. Every case is different, and our factors are designed to account for this. Nonetheless, and to furnish elucidation to the provider community, we believe that certain minimum regulatory parameters are appropriate. This would be based on our past experience in applying § 424.535(a)(8)(ii), (14), and (21), our review of the factors therein, and the factual circumstances we have encountered in these cases.

To this end, we propose to establish a definition of ''pattern or practice'' in § 424.502. It would mean:

- For purposes of § 424.535(a)(8)(ii), at least three submitted non-compliant claims.
- For purposes of § 424.535(a)(14), at least three prescriptions of Part B or Part D drugs that are abusive, represent a threat to the health and safety of Medicare beneficiaries, or otherwise fail to meet Medicare requirements.
- For purposes of § 424.535(a)(21), at least three orders, certifications, referrals, or prescriptions of Medicare Part A or B services, items, or drugs that are abusive, represent a threat to the health and safety of Medicare beneficiaries, or otherwise fail to meet Medicare requirements.

We recognize that our minimum threshold of three might appear small upon first impression. Yet interested parties should not assume that three non-compliant claims, orders, etc. would always trigger a revocation. To the contrary, it would often take more than three (and, on occasion, considerably more) to warrant revocation action. In only the rarest of circumstances would we revoke based on three claims, referrals, etc., and these would typically involve egregious non-compliance by the provider or supplier; we specifically chose three as our threshold to account for these isolated instances. We assure the provider community that, in every case, we would continue to diligently consider the factors outlined in § 424.535(a)(8)(ii), (14), and (21) and would treat the provider or supplier fairly given the facts presented. Our proposed definition in no way negates the validity or importance of these factors; its sole purpose is to furnish greater clarity to the provider community.

To accommodate our definition, we also propose to make several technical changes to § 424.535(a)(8)(ii), (14), and (21).

The introductory paragraph of § 424.535(a)(8)(ii) reads: ''CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements. In making this determination, CMS considers, as appropriate or applicable, the following:''. We are concerned that this language could be construed as meaning that so long as the ''pattern or practice'' definition in § 424.502 is met—that is, at least three non-compliant claims, orders, etc., were involved—a § 424.535(a)(8)(ii) revocation must automatically follow. As previously discussed, this is untrue. Even if the definition's threshold is met, we would then consider the entirely separate question of whether a revocation is warranted. In other words, the first step in our analysis would be to ascertain whether the activity involved qualifies as a ''pattern or practice.'' If (and only if) it does, the second step would be to determine, using the specified factors, whether the provider or supplier should be revoked. To clarify this approach, we propose to change § 424.535(a)(8)(ii)'s opening paragraph to state: ''CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements and that a revocation on this basis is warranted. In determining whether a revocation is warranted, CMS

considers, as appropriate or applicable, the following:''.

Language similar to that in existing § 424.535(a)(8)(ii) is present in § 424.535(a)(14)(i) and (ii). For the reasons outlined in the previous paragraph, we propose to revise the opening of § 424.535(a)(14)(i) to state: ''The pattern or practice is abusive or represents a threat to the health and safety of Medicare beneficiaries, or both, and CMS determines that a revocation on this basis is warranted. In determining whether a revocation is warranted, CMS considers the following factors:''. The revised opening of § 424.535(a)(14)(ii) would read: ''The pattern or practice of prescribing fails to meet Medicare requirements and CMS determines that a revocation on this basis is warranted. In determining whether a revocation is warranted, CMS considers the following factors:''.

With respect to § 424.535(a)(21), the closing language of the first sentence and the entirety of the second sentence reads: ''. . . or otherwise fails to meet Medicare requirements. In making its determination as to whether such a pattern or practice exists, CMS considers the following factors:''. We propose to change this to state: ''. . . or otherwise fails to meet Medicare requirements, and CMS determines that a revocation on this basis is warranted. In determining whether a revocation is warranted, CMS considers the following factors:''.

(B) Indirect Ownership

We propose to define ''indirect ownership interest'' in § 424.502. Some interested parties have expressed uncertainty about what indirect ownership is. An understanding of indirect ownership is important for providers and suppliers because they are required to report on their enrollment application all of their 5 percent or greater indirect owners. Section 420.201 defines an ''indirect ownership interest'' as ''any ownership interest in an entity that has an ownership interest in the disclosing entity. The term includes an ownership interest in any entity that has an indirect ownership interest in the disclosing entity.'' We believe this definition (albeit with certain modifications for purposes of clarity and to conform to the terminology of part 424, subpart P) would provide the desired elucidation. Accordingly, our proposed definition of ''indirect ownership interest'' would state:

- Any ownership interest in an entity that has an ownership interest in the enrolling or enrolled provider or supplier. (For example, Provider A is owned by Entity B. Entity B is owned by Entity C. Entity C would have an indirect ownership interest in (and be an indirect owner of) Provider A.)
- Any ownership interest in an indirect owner of the enrolling or enrolled provider or supplier. (Using the preceding example, if Entity D had an ownership interest in Entity C, Entity D would have an indirect ownership interest in Provider A.)

We would designate this portion of our definition as paragraphs (1)(i) and (ii). To further clarify the concept of indirect ownership, we propose in paragraph (2) to mirror an example contained in § 420.202(a). Paragraph (2) would state: ''The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation that owns 80 percent of the provider or supplier, A's interest equates to an 8 percent indirect ownership interest in the provider or supplier and must be reported on the enrollment application. Conversely, if B owns 80 percent of the stock of a corporation that owns 5 percent of the stock of the provider or supplier, B's interest equates to a 4 percent indirect ownership entity in the provider or supplier and need not be reported.''

(C) PTs and OTs in Private Practice and Speech-Language Pathologists

Physical therapists in private practice (PTPPs), occupational therapists in private practice (OTPPs), and speech-language pathologists (SLPs) are permitted under the Act to receive payment for furnished Medicare services. However, they do not fall within the regulatory definition of ''supplier'' under § 400.202. The reason is that while the services they provide are payable under Medicare (thus allowing these individuals to enroll in the program), PTPPs, OTPPs, and SLPs are not formally recognized in either the Act or the CFR as types of ''suppliers.'' Nevertheless, we have applied the provisions of subpart P of part 424 to PTPPs, OTPPs, and SLPs via current guidance. We have also afforded PTPPs, OTPPs, and SLPs the same appeal rights (for example, appeals of enrollment denials and revocations) as all other enrolling or enrolled individuals and entities. To codify these practices in the CFR, we propose several regulatory provisions.

First, we propose to define ''supplier'' in § 424.502 as follows: ''Supplier means, for purposes of this subpart, all of the following: (1) the individuals and entities that qualify as suppliers under § 400.202; (2) physical therapists in private practice; (3) occupational therapists in private practice; and (4) speech-language pathologists.'' Second, we would include within new § 405.800(d) the same definition of ''supplier'' we are proposing in § 424.502. This is because subpart H of part 405 addresses various types of provider enrollment appeals under Medicare Part B. Third, 42 CFR part 498, too, contains various provisions concerning provider enrollment appeals. Section 498.2 defines ''supplier'' for purposes of part 498 by outlining several categories of suppliers. One such category, codified in paragraph (6) of this definition, reads, ''Physical therapist in independent practice.'' We propose to revise paragraph (6) to state: ''For purposes of this part, physical therapist in private practice, occupational therapist in private practice, or speech-language pathologist.''

(D) Authorized Officials

Under § 424.510(d)(3), an authorized official or delegated official must sign the Medicare enrollment application (for example, Form CMS–855A) on behalf of the provider or supplier if the latter is a corporation, partnership, group, limited liability company, or other organization. The terms authorized official and delegated official are defined in § 424.502. The former is ''an appointed official (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program.'' A delegated official is defined as an individual ''who is delegated by the 'Authorized Official' the authority to report changes and updates to the enrollment record. The delegated official must be an individual with ownership or control interest in, or be a W–2 managing employee of, the provider or supplier.''

With respect to the authorized official definition, interested parties have questioned CMS on whether the term ''organization'' as used therein means: (1) the entity listed in Section 2 of the Form CMS–855 as identified by its legal business name (LBN) and tax identification number (TIN); or (2) the provider or supplier type that is enrolling. To illustrate, suppose Entity A (with its unique LBN and TIN) submits three separate Form CMS–855A

initial enrollment applications to enroll an HHA, a hospice, and a skilled nursing facility (SNF), all of which have Entity A's LBN and TIN. In this type of situation, the question is whether ''organization'' refers to Entity A or instead to three separate ones—that is, the HHA, hospice, and the SNF.

We propose to add a sentence to the conclusion of the ''authorized official'' definition clarifying that the term ''organization'' therein—and exclusively for purposes of applying the ''authorized official'' definition—means the enrolling entity as identified by its LBN and TIN and not the provider or supplier type(s) that the entity is enrolling as. Using our previous illustration, this is because the HHA, hospice, and the SNF are not legal entities (such as corporations) separate and distinct from Entity A but are, in effect, part of Entity A itself; Entity A, in other words, is enrolling as an HHA, hospice, and SNF. In practical terms, this means an authorized official serves in that role on behalf of the enrolling entity (Entity A). Per our example, therefore, the individual could sign CMS provider enrollment applications concerning the HHA, hospice, and the SNF. We welcome comments on our proposed clarification.

2. Medicaid and CHIP Enrollment

a. Background

The Medicaid program (title XIX of the Act) is a joint Federal and State health care program that (as of December 2022) covers more than 85 million low-income individuals. States have considerable flexibility when administering their Medicaid programs within a broad Federal framework, and programs vary from State to State. The Children's Health Insurance Program (CHIP) (title XXI of the Act) is a joint Federal and State health care program that (as of December 2022) provides health care coverage to over 7 million children in families with incomes too high to qualify for Medicaid, but too low to afford private coverage.

In operating Medicaid and CHIP, and as required by sections 1902(a)(78) and 2107(e)(1)(D) of the Act, respectively, each State requires providers to enroll if the providers wish to furnish, order, prescribe, refer, or certify eligibility for Medicaid or CHIP items or services in that State.[253] States may also establish their own provider enrollment requirements which must be met in addition to the applicable Federal provider enrollment requirements. Similar to Medicare provider enrollment, the purpose of the Medicaid and CHIP provider enrollment processes is to ensure that providers: (1) meet all Medicaid or CHIP requirements (and any other State-specific or Federal requirements); (2) are qualified to furnish, order, prescribe, refer, or certify Medicaid and CHIP services, items, and drugs; and (3) are eligible to receive payment, where applicable.

Different States may have different provider enrollment processes in operating their Medicaid and CHIP programs. However, all States must comply with Federal Medicaid and CHIP provider enrollment requirements, including those in part 455, subparts B and E.[254] For example, under subpart B, providers must disclose information regarding, among other things, ownership and control of the provider entity, certain business transactions, and criminal convictions related to Federal health care programs. Under subpart E, States must implement various Medicaid provider screening requirements. (In addition, State enrollment requirements must be consistent with section 1902(a)(23) of the Act and implementing regulations at § 431.51, under which States may set reasonable standards relating to the qualifications of providers; however, States may not restrict the right of beneficiaries to obtain services from any person or entity that is both qualified and willing to furnish such services.)

Another such provision in part 455 to which states must adhere involves denial or termination of enrollment. Under § 455.416, the State must deny or terminate a provider's Medicaid or CHIP enrollment for reasons specified therein, which include the following:

- Any person with a 5 percent or greater direct or indirect ownership interest in the provider fails to: (1) submit timely and accurate information; and (2) cooperate with any screening methods required under part 455, subpart E.
- Any person with a 5 percent or greater direct or indirect ownership interest in the provider has been convicted of a criminal offense related to that person's involvement with Medicare, Medicaid, or CHIP in the last 10 years.
- The provider, or a person with an ownership or control interest in or who is an agent or managing employee of the provider, fails to submit timely or accurate information as required.
- The provider, or any person with a 5 percent or greater direct or indirect ownership interest in the provider, fails to submit sets of fingerprints in a form and manner to be determined by the State Medicaid agency within 30 days of a CMS or a State Medicaid agency request.
- The provider fails to permit access to provider locations for any site visits under § 455.432.

Of particular importance, as will be discussed in more detail in this section III.K. of this proposed rule is that, under section 1902(a)(39) of the Act and § 455.416(c), the State must deny or terminate the provider's enrollment if the provider is terminated under the Medicare program, or the Medicaid program or CHIP of any other State.

These termination reasons require States to take action against providers that have, for instance, demonstrated an unwillingness or inability to meet certain Medicaid or CHIP requirements, or engaged in improper conduct. The possibility of being terminated also encourages providers to abide by Medicaid and CHIP enrollment rules, thus protecting Medicaid and CHIP against improper provider activity. Recognizing, however, that special circumstances may exist concerning a particular provider (and given the importance of leaving the States with as much discretion in their enrollment processes as possible), several of the otherwise mandatory termination reasons in § 455.416 permit the State to forgo termination if the State: (1) determines that such an action would not be in the Medicaid program's best interests; and (2) documents this decision in writing. Furthermore, States may develop additional State-specific reasons for terminating a Medicaid or CHIP provider, so long as such reasons (and the enforcement thereof) are not inconsistent with the requirements of §§ 455.416 and 431.51.

b. The 21st Century Cures Act's Medicaid and CHIP Provider Enrollment Requirements

The 21st Century Cures Act (Pub. L. 114–255; hereafter referred to as the Cures Act) was signed into law on December 13, 2016. The Cures Act addresses a variety of nationwide health care issues. Among the topics outlined in section 5005 of the Cures Act is Medicaid and CHIP provider enrollment and, in particular, Medicaid and CHIP provider terminations. For purposes of our proposals in this section III.K., the most pertinent provisions in section 5005 of the Cures Act are as follows:

- Section 5005(a)(1) of the Cures Act added a new paragraph (8) to section

[253] Section 1902(kk)(7) also requires physicians and other eligible professionals who order or refer Medicaid services and items to be enrolled in Medicaid. This requirement is made applicable to CHIP via section 2107(e)(1)(G) of the Act.

[254] All of subpart E, and 42 CFR 455.107 in Subpart B, are applicable to CHIP under § 457.990.

1902(kk) of the Act requiring the State to report the termination of a provider under Medicaid or CHIP to the Secretary within 30 days after the effective date of the termination. Section 5005(a)(1) of the Cures Act also outlines information that must be included in the termination notification that the State sends to CMS. However, paragraph (8)(A) limits this reporting requirement to terminations for reasons specified in § 455.101 as in effect on November 1, 2015, which are limited to terminations ''for cause'' (including, but not limited to, terminations for reasons relating to fraud, integrity, or quality). Paragraph (8)(B) provides that, for purposes of the reporting requirement, the effective date of a termination is the later of: (1) the effective date specified in the notice of termination; or (2) the date on which applicable appeal rights have been exhausted or the timeline for appeal has expired.

- Section 5005(a)(3) of the Cures Act added a new paragraph (ll) to section 1902 of the Act stating that within 30 days of receiving notification of a Medicaid or CHIP provider termination, the Secretary shall review such termination and, if the Secretary determines appropriate, include such termination in any database or similar system developed under section 6401(b)(2) of the Affordable Care Act.
- Section 5005(a)(4)(A) of the Cures Act added a new paragraph (D) to section 1903(i)(2) of the Act providing that, except for emergency items or services (but not including items or services furnished in a hospital emergency department), no Federal financial participation (FFP) funds may be paid for items and services furnished by a provider terminated under Medicaid or CHIP (as described in section 1902(kk)(8)) beginning 60 days after the date the termination is included in the termination database.

We have issued extensive sub-regulatory guidance to assist States in implementing Medicaid and CHIP screening and enrollment provisions outlined in 42 CFR part 455. This guidance is compiled in a document titled ''Medicaid Provider Enrollment Compendium'' (MPEC) (*https://www.medicaid.gov/sites/default/files/2021-05/mpec-3222021.pdf*), originally issued in May 2016 and subsequently updated several times. After the enactment of the Cures Act, CMS again updated the MPEC to clarify the operational details concerning several of the statutory provisions amended by section 5005.

Under CMS' existing process (under the statute and MPEC guidance), when a State reports a ''for cause'' termination, CMS determines whether: (1) the State submitted the required termination data in accordance with section 1902(kk)(8) of the Act; and (2) the termination is, indeed, ''for cause.'' If CMS concludes that the reported termination is ''for cause'' and is thus appropriate to be included in the database referenced in section 1902(ll) of the Act, the information is uploaded into a CMS-managed database. This database contains information on Medicaid and CHIP terminations and Medicare revocations, the latter of which is updated at least monthly. The database enables a State to review Medicaid and CHIP terminations in other States, as well as Medicare revocations, and, under § 455.416(c), to deny enrollment or take its own termination action against a provider if the latter is also enrolled in the State. Moreover, the database gives CMS access to information on Medicaid and CHIP provider terminations nationwide, which permits us to take a Medicare revocation action against the provider under § 424.535(a)(12)(i), if appropriate, based on the Medicaid or CHIP termination.

c. Proposed Provisions

i. Termination Lengths—Background

There are two termination database-related matters that have generated uncertainty during our implementation of the § 455.416(c) termination requirement. They involve: (1) the length of time for which a termination remains active in the termination database; and (2) the interaction of different termination periods imposed by the States and/or the Medicare program.

Under § 424.535(c), if a Medicare provider or supplier is revoked from Medicare, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the reenrollment bar, which, under existing § 424.535(c), is generally for a period of 1 to 10 years. This 1- to 10-year period typically constitutes: (1) the time period for which the provider or supplier is revoked from Medicare; and (2) the amount of time that the Medicare revocation will remain in the termination database.

Many States have similar reenrollment bars for terminated Medicaid and CHIP providers. (Hereafter, and for purposes of consistency, the terms ''termination period'' and ''reenrollment bar'' as used in this section III.K. refer to a Medicaid or CHIP reenrollment bar, unless otherwise noted.) Yet these termination periods often differ among the States. For instance, State A may terminate a provider for 3 years for a particular transgression while State B might do so for 10 years for the same conduct. We recognize the traditional deference given to States regarding the establishment of reenrollment bars. However, the interplay between varying termination period lengths (especially as they relate to the termination database and the previously-mentioned termination requirement in § 455.416(c)) has caused confusion among the States, provider communities, and other interested parties. Accordingly, we propose to specify in regulation the length of time for which for cause provider terminations will remain in the database and, by extension, the period for which other States must deny or terminate the provider under to § 455.416(c).

ii. Revision to § 455.416(c)

As previously indicated, under § 455.416(c) the State Medicaid agency must deny or terminate the enrollment of any provider that is terminated on or after January 1, 2011, under title XVIII of the Act, or under the Medicaid program or CHIP of any other State. We propose to add the following clause to the end of § 455.416(c): ''and is currently included in the termination database under § 455.417.'' This revision would clarify that the denial and termination requirement under § 455.416(c) is predicated on the provider's inclusion in the termination database.

iii. Length of Inclusion in Database (§ 455.417)

For the reasons outlined above, we propose several provisions in new § 455.417 as follows:

- In paragraph (a)(1), we propose that a provider would remain in the termination database referenced in section 1902(ll) of the Act for a period that is the lesser of:

++ The length of the termination period imposed by the initially terminating State Medicaid program or CHIP, or the reenrollment bar imposed by the Medicare program; or

++ 10 years (for those Medicaid or CHIP terminations that are greater than 10 years).

- Under proposed paragraph (a)(2) all other State Medicaid programs or CHIPs in which the provider is enrolled or seeking to enroll would be required to terminate or deny the provider's enrollment from their respective programs (under § 455.416(c)) for at least the same length of time as the termination database period).

• In paragraphs (b)(1)(i) and (ii), respectively, we propose that nothing in paragraph (a) would prohibit:

++ The initially terminating State from imposing a termination period of greater than 10 years consistent with that State's laws, or

++ Another State from terminating the provider, based on the original State's termination, for a period: (A) of greater than 10 years; or (B) that is otherwise longer than that imposed by the initially terminating State.

In paragraph (b)(2), however, we would make clear that the period established under paragraph (b)(1)(ii) must be no shorter than the period in which the provider is to be included in the termination database under paragraph (a).

To illustrate how paragraphs (a) through (b) would work in practice, consider the following examples:

++ Example 1: State A, the initially terminating State, terminates a provider for a period of 5 years. Under paragraph (a)(1), the provider would remain in the termination database for 5 years. Under paragraph (b), when State B terminates the provider based on the State A termination (under § 455.416(c)), it may impose any termination period so long as (under proposed paragraph (b)(2)) it is no shorter than the 5-year period in which the provider remains in the termination database. (This is because all States must adhere, at a minimum, to the termination database period.) However, whatever period State B imposes would have no effect on the length of time the provider is to remain in the termination database, which is 5 years under the original State's (State A's) termination period. If, therefore, State B imposes an 8-year termination period, the provider would still only remain in the termination database for 5 years, but State B could (under its State law) prohibit the provider from enrolling in its State B Medicaid program or CHIP for another 3 years beyond that period.

++ Example 2: State A, the initially terminating State, terminates a provider for 15 years. Under paragraph (a)(1), the provider would remain in the termination database for only 10 years. Under paragraph (b), however, State A may enforce its original 15-year termination period imposed on the provider notwithstanding that the provider would only remain in the database for 10 years. When State B terminates the provider based on the State A termination (under § 455.416(c)), it may impose any termination period permitted under its State law so long as it is at least the length of the 10-year termination database period in this Example 2.

As indicated in Examples 1 and 2, there is a critical distinction between a State-imposed termination period (or a Medicare reenrollment bar) and the length of time in which a provider remains in the termination database. The former generally involves the period for which the provider is prohibited from reenrolling in the initially terminating State program or Medicare (in the case of a revocation); the latter involves the minimum period in which other States must also terminate the provider under § 455.416(c). (Hereafter, the former will be referred to as the ''termination period'' or ''reenrollment bar'' and the latter the ''termination database period.'')

Aside from the aforementioned need for clarity, there are several other important reasons for proposed § 455.417(a) and (b).

First, despite our aforementioned concerns about inconsistencies in State-imposed termination periods, we are committed to ensuring that States have as much discretion as possible in administering their respective Medicaid programs. We believe proposed § 455.417(a) and (b), taken together, would clarify the duration of the requirement to terminate under § 455.416(c) while preserving each State's ability to impose whatever termination period it deems appropriate (subject to proposed paragraph (b)(2), which designates the termination database period as a minimum).

Second, establishment of a maximum 10-year termination database period would address situations where a State imposes an extremely lengthy, or even a lifetime, termination period that is far longer than: (1) that imposed by other States for the same conduct; or (2) the maximum Medicare 10-year reenrollment bar under § 424.535(c), but other States wish to permit a provider to reenroll before the initially terminating State's reenrollment bar has expired. Moreover, a finite termination database period is needed to address instances where the initially terminating State establishes an indefinite termination period; if the termination remained in the database until that State permitted the provider to reenroll, this would essentially cause the provider to be barred from the Medicaid program in all States indefinitely, regardless of the underlying cause of the termination and the circumstances associated therewith. This could be very problematic for the provider and perhaps lead to access to care issues in some States. Indeed, providers may experience undue burden in these cases because even if they can prove that the underlying cause for the termination has been resolved, they might remain unable to enroll in other States while an indefinite termination remains in the termination database. We believe that a maximum 10-year period in the database (if the State imposes a termination period of 10 years or longer) would give the broadest possible deference to the initially terminating State while still providing a consistent and finite period during which other States are required to terminate (and continue the termination) or deny the provider's enrollment under § 455.416(c).

In paragraph (c)(1), we propose that if the initially terminating State agency or the Medicare program reinstates the provider prior to the end of the termination period originally imposed by the initially terminating State program or Medicare, CMS would remove the provider from the termination database after the reinstatement has been reported to CMS. This proposal is intended to clarify the impact of a reinstatement, including those occurring prior to the expiration of the original termination period. Such instances of early reinstatement might include: (1) resolution of the underlying basis for the original termination; or (2) access to care concerns of the originally terminating State agency. However, we also propose in § 455.417(c)(2) that if the provider is removed from the database due to reinstatement by the originally terminating State agency, nothing prohibits CMS from immediately re-including the provider in the database if a separate basis for doing so exists under 42 CFR part 455 or 424. This is to emphasize that CMS is not required to afford the provider any sort of ''waiting period'' between the expiration of the original termination period and the commencement of a new one should grounds exist for the imposition of the latter; the new termination database period can become effective immediately upon the expiration of the prior one.

Consider the following example of proposed § 455.417(c)(2)'s potential applicability. State A initially terminates a provider for 2 years. Under proposed § 455.417(a), the provider would be included in the termination database for 2 years. Under proposed § 455.417(b), all other States must terminate the provider from their Medicaid programs for at least that same time period. Yet Medicare is not required to (and elects not to) revoke the provider's Medicare enrollment notwithstanding the State A

termination. Now assume that State A reinstates the provider after 1 year. Two days before the reinstatement takes effect, though, the provider is revoked from Medicare with a 3-year enrollment bar for a reason unrelated to the grounds behind the State A termination. Since § 455.416(c) requires State A (and all other States) to terminate the provider based on the Medicare revocation, CMS may place the provider in the termination database for a 3-year period effective immediately upon the expiration of the original termination database period. This is to ensure that the initial 1-year period runs its full course before the beginning of the 3-year termination database. If we commenced the 3-year period 2 days before the 1-year period expired, the 1-year period would, in effect, have lasted 2 days less than 1 year; likewise, the 3-year period would essentially be 3 years minus 2 days. This is due to the 2-day overlap between the two timeframes.

Aside from clarifying that Medicaid termination periods can run consecutively without any break between them, we believe that proposed § 455.417(c) would help ensure a seamless transition between the two periods and, in the process, prevent problematic Medicaid providers from using any gap in periods to bill Medicaid.

We indicated earlier that, per the statute and MPEC guidance, States must report ''for cause'' terminations to CMS for purposes of the termination database. We propose in new § 455.417(d) that, for purposes of § 455.417 only, terminations under § 455.416(c) (which, as previously discussed, are based on another State's termination of the provider) are not themselves considered ''for cause'' terminations, and therefore, need not be separately reported to CMS for inclusion in the termination database. Using Examples 1 and 2 as previously discussed, this would mean that State B would not have to report the terminations in those examples to CMS for termination database purposes, although State B would still be required to: (i) terminate the provider under § 455.416(c), based on the State A termination; and (ii) apply a termination period no shorter than the termination database period established under § 455.417(a). The goal of proposed § 455.417(d) is to eliminate repetitiveness in reporting the same data to CMS so as to ease the burden on States. In our view, and under the foregoing example, there is no reason for State B (and, for that matter, other States) to expend resources in reporting a termination that was already reported by the originally terminating State. Furthermore, this would avoid the potential for additional confusion regarding the termination database period, in that it would ensure that such period is based only on the initial State's termination and not on subsequent derivative terminations.

L. Expand Diabetes Screening and Diabetes Definitions

For CY 2024, we propose to: (1) expand coverage of diabetes screening tests to include the Hemoglobin A1C test (HbA1c) test; (2) expand and simplify the frequency limitations for diabetes screening; and (3) simplify the regulatory definition of ''diabetes'' for diabetes screening (§ 410.18(a)), Medical Nutrition Therapy (MNT) (§ 410.130) and Diabetes Outpatient Self-Management Training Services (DSMT) (§ 410.140).

Medicare coverage for diabetes screening tests under Part B are described in statute (sections 1861(s)(2)(Y), 1861(ww)(2)(K), 1861(yy), and 1862(a)(1)(M) of the Act) and in regulation at 42 CFR 410.18. The statute and regulations allow for diabetes screening tests:

- The Fasting Plasma Glucose (FPG) test (section 1861(yy)(1)(A) of the Act and § 410.18(c)(1));
- The Post Glucose Challenge Test, also called the Glucose Tolerance Test (GTT) (§ 410.18(c)(2)); and
- Such other tests, and modifications to tests, as the Secretary determines appropriate, in consultation with appropriate organizations (section 1861(yy)(1)(B) of the Act) and that may be determined through a national coverage determination (§ 410.18(c)(3)).[255]

We propose to exercise our authority in section 1861(yy)(1) of the Act to add the HbA1c test to the types of diabetes screening tests covered under § 410.18(c), in consultation with recommendations by appropriate organizations.

Section 1861(yy)(3) of the Act limits the frequency of diabetes screening tests to not more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual. Our regulations allow two screening tests per calendar year if the patient was previously diagnosed with pre-diabetes and one screening test per year for patients who were previously tested who were not diagnosed with pre-diabetes, or who were never tested before (§ 410.18(d)). We propose to exercise our authority in section 1861(yy)(1)(3) of the Act to simplify our frequency limitations for diabetes screening by aligning to the statutory limitation of not more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual.

We also propose to simplify the regulatory definitions of ''diabetes'' for the purpose of diabetes screening at § 410.18(a) to remove the codified clinical test requirements from the definition of ''diabetes.'' We also propose to remove the definition of ''pre-diabetes'' at § 410.18(a). The diabetes and prediabetes definitions at § 410.18(a) supported existing regulatory frequency limitations in § 410.18(d), which describe separate frequency limitations between individuals previously diagnosed, and those terms would no longer be needed under our proposed updates. We recognize that it is unnecessary to codify clinically specific test criteria into the regulatory definition of diabetes, which reduces flexibility for the agency and health care system to adapt to evolving clinical standards without potentially producing programmatic benefit. The proposed revised definition of diabetes for screening purposes would be shortened to describe diabetes as diabetes mellitus, a condition of abnormal glucose metabolism.

Medicare coverage for MNT under Part B is described in statute (primarily sections 1861(s)(2)(V), 1861(vv), and 1861(ww)(2)(I) of the Act, in regulations at 42 CFR part 410, subpart G, and in National Coverage Determination (NCD) (Section 180.1 of the Medicare National Coverage Determinations Manual (NCD Manual)). Section 410.130 currently describes a number of definitions for purposes of the MNT benefit, including ''diabetes.'' The regulatory definition of diabetes for MNT purposes at § 410.130 is identical to the existing regulatory definition of diabetes for screening purposes at § 410.18(a). We propose to simplify the regulatory definitions of ''diabetes'' for the purpose of MNT at § 410.130 to remove the codified clinical test requirements. The proposed revised definition of diabetes for MNT purposes would be shortened to simply describe diabetes as diabetes mellitus, a condition of abnormal glucose metabolism. NCD 180.1 refers to the regulatory definition of diabetes at § 410.130, so no modifications would be required to the NCD.

Medicare coverage for DSMT under Part B is described in statute (sections

[255] The Secretary, as of the date of this proposed rule, has not approved additional diabetes screening tests by through a national coverage determination.

1861(s)(2)(S), 1861(qq), 1861(ww)(2)(F) of the Act) and in regulation at part 410 subpart H. Section 410.140 describes a number of definitions for the purposes of the DSMT benefit, including ''diabetes''. The regulatory definition of diabetes for DSMT purposes at § 410.140 is identical to the existing regulatory definition of diabetes for MNT purposes at § 410.130 and the existing regulatory definition of diabetes for screening purposes at § 410.18(a). We propose to exercise our authority to simplify the regulatory definitions of ''diabetes'' for the purpose of DSMT at § 410.140 to remove the codified clinical test requirements. The proposed revised definition of diabetes for DSMT purposes would be shortened to simply define diabetes as diabetes mellitus, a condition of abnormal glucose metabolism.

1. Background

Diabetes is a chronic disease that affects how the body turns food into energy and includes three main types: Type 1, Type 2 and gestational diabetes. The Centers for Disease Control and Prevention (CDC) reports that approximately 37.3 million Americans are living with diabetes and an additional 96 million Americans are living with prediabetes.[256] CDC reports that 326,000 persons age 65 years and older are newly diagnosed with diabetes each year. CDC also estimates that among persons age 65 years and older, 21 percent have been diagnosed with diabetes while 5 percent have undiagnosed diabetes.[257] Diabetes is the leading cause of kidney failure and new cases of blindness among adults, and the sixth leading cause of death among adults age 65 years and older in the U.S.[258] Screening is performed on persons who may not exhibit symptoms to identify persons with either prediabetes or diabetes, who can then be referred for appropriate prevention or treatment, with the intention of improving health outcomes.

In October 2015, the United States Preventive Services Task Force (USPSTF) issued a revised final recommendation statement, with a grade of B, for screening for abnormal blood glucose as part of cardiovascular risk assessment in adults aged 40 to 70 years who are overweight or obese and again identified the FPG, GTT and HbA1c tests as appropriate for diabetes screening.[259] In August 2021, the USPSTF issued a revised final recommendation statement, with a grade of B, that expanded recommended screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity, and that clinicians should offer or refer patients with prediabetes to effective preventive interventions, which are discussed in their report. The USPSTF again recommended the FPG, GTT and HbA1c tests as appropriate for diabetes screening and noted, ''Because HbA1c measurements do not require fasting, they are more convenient than using a fasting plasma glucose level (FPG) or an oral glucose tolerance test (GTT).'' [260] The grade of B is indicated when the USPSTF has high certainty that the net benefit is moderate or moderate certainty that the net benefit is moderate to substantial.

We recognize that both the USPSTF and specialty societies have identified the HbA1c test as clinically appropriate for diabetes screening. In addition, the HbA1c test has certain unique advantages and disadvantages compared to the FPG and GTT tests that should be considered by the practitioner and patient when choosing a diabetes screening test. The American Diabetes Association (ADA) Standards of Care in Diabetes—2023 reads, ''Generally, FPG, 2-h PG during 75-g OGTT (aka GTT), and A1C (aka HbA1c) are equally appropriate for diagnostic screening . . . The same tests may be used to screen for and diagnose diabetes and to detect individuals with prediabetes . . . A1C (aka HbA1c) has several advantages compared with FPG and OGTT (aka GTT), including greater convenience (fasting not required), greater preanalytical stability, and fewer day-to-day perturbations during stress, changes in nutrition, or illness. However, these advantages may be offset by the lower sensitivity of A1C (aka HbA1c) at the designated cut point, greater cost, limited availability of A1C (aka HbA1c) testing in certain regions of the developing world, and the imperfect correlation between A1C (aka HbA1c) and average glucose in certain individuals . . . Despite these limitations with A1C (aka HbA1c), in 2009, the International Expert Committee added A1C (aka HbA1c) to the diagnostic criteria with the goal of increased screening.'' [261] The American Association of Clinical Endocrinology (AACE) also recommends screening for diabetes and prediabetes with similar tests, including HbA1c.[262]

The regulatory texts for diabetes screening, MNT, and DSMT include a clinically specific test-based definition for ''diabetes'' that has since been overtaken by evolving clinical standards. Since 2020, the ADA has revised and expanded its criteria for the diagnosis of diabetes to also include the HbA1c test and a random plasma glucose test for a patient appearing to have hyperglycemia or hyperglycemic crisis.[263]

2. Statutory Authority

Section 613 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) added section 1861(yy) to the Act and mandated coverage of diabetes screening tests in the Medicare Part B program. Section 1861(yy)(1) of the Act describes diabetes screening tests as testing furnished to an individual at risk for diabetes for the purpose of early detection of diabetes, including the FPG test and such other tests, and modifications to tests, as the Secretary determines appropriate, in consultation with appropriate organizations. Section 1861(yy)(2) of the Act describes ''individual at risk for diabetes'' as an individual who has any of a number of listed risk factors, including obesity, defined as a body mass index greater than or equal to 30 kg/m^2 as an independent qualifying factor and overweight, defined as a body mass index greater than 25 kg/m^2, but less than 30, kg/m^2 (when present with a second qualifying factor including a family history of diabetes, a history of gestational diabetes and an age of 65 years or older. Section 1861(yy)(3) of the Act mandates that the Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency of diabetes screening tests, except that such frequency may not be

[256] CDC website on diabetes at *https://www.cdc.gov/diabetes/basics/index.html*.

[257] Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2020. Accessed March 9, 2023. *https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf*.

[258] Heron M. Deaths: Leading causes for 2019. National Vital Statistics Reports; vol 70 no 9. Hyattsville, MD: National Center for Health Statistics. 2021. DOI: *https://dx.doi.org/10.15620/cdc:107021*.

[259] USPSTF website: *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-abnormal-blood-glucose-and-type-2-diabetes-october-2015*.

[260] USPSTF website: *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes*.

[261] Diabetes Care 2023;46(Suppl. 1):S19–S40: *https://doi.org/10.2337/dc23-S002*.

[262] Lawrence Blonde, Guillermo E. Umpierrez, S. Sethu Reddy, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan—2022 Update. Endocrine Practice, 2023; 28: 923–1049, *https://doi.org/10.1016/j.eprac.2022.08.002*.

[263] Diabetes Care 2020;43(Supplement_1):S14–S31, *https://diabetesjournals.org/care/article/43/Supplement_1/S14/30640/2-Classification-and-Diagnosis-of-Diabetes*.

more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual. Section 1861(yy) of the Act does not include a definition of diabetes.

Section 105 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554) added section 1861(vv) to the Act and mandated coverage of MNT under Part B. Section 1861(s)(2)(V) of the Act limits coverage of MNT to patients with diabetes or a renal disease. Section 1861(vv)(1) of the Act describes MNT, in pertinent part, as nutritional diagnostic, therapy, and counseling services for the purpose of disease management. Sections 1861(s)(2)(V) and (vv) of the Act do not include a codified definition of diabetes.

Section 4105(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) added section 1861(qq) to the Act and mandated coverage of DSMT. Section 1861(qq) of the Act describes DSMT, in part, as educational and training services furnished to an individual with diabetes by a certified provider in an outpatient setting by an individual or entity, but only if the physician who is managing the individual's diabetic condition certifies that such services are needed under a comprehensive plan of care related to the individual's diabetic condition to ensure therapy compliance or to provide the individual with necessary skills and knowledge to participate in the management of the individual's condition. Section 1861(qq) of the Act does not establish a definition of diabetes.

3. Regulatory Authority and National Coverage Determinations

Our implementing regulations for diabetes screening tests are codified at § 410.18. The regulatory definition of diabetes and prediabetes for the purposes of diabetes screening were created, in part, to distinguish separate frequency limitations for each. Section 410.18(d) allows two diabetes screening tests per calendar year for individuals diagnosed with pre-diabetes and one diabetes screening test per calendar year for individuals previously tested who were not diagnosed with pre-diabetes, or who were never tested before. Section 410.18(e) limit diabetes screening to ''individual at risk for diabetes'' with a list of qualifying eligibility factors, including obesity, defined as a body mass index greater than or equal to 30 kg/m^2 as an independent qualifying factor (§ 410.18(e)(3)) and overweight, defined as a body mass index greater than 25 kg/m^2, but less than 30, kg/m^2 (when present with a second qualifying factor including a family history of diabetes, a history of gestational diabetes and an age of 65 years or older) (§ 410.18(e)(5)).

Our implementing regulations for MNT are codified at part 410 subpart G. Section 410.130 described a number of definitions for purposes of the MNT benefit, including ''diabetes.'' MNT is also described as a covered service at section 180.1 of the NCD Manual. NCD 180.1 does not include a codified definition of diabetes but does refer to ''diabetes, as defined at § 410.130.'' Our implementing regulations for DSMT are codified at part 410 subpart H. Section 410.140 describes a number of definitions for the purposes of the DSMT benefit, including ''diabetes.''

NCD 190.20, Blood Glucose Testing, describes the indications and limitations of blood glucose testing generally but refers to § 410.18 and the Claims Processing Manual for specific policies on diabetes screening. NCD 190.21, Glycated Hemoglobin/Glycated Protein, authorizes coverage of the HbA1c test for the management of diabetes but does not address screening for diabetes.

In the CY 2004 PFS final rule (68 FR 63195), we finalized proposals to adopt regulatory definitions of diabetes for the purposes of MNT and DSMT. We codified in regulatory text at §§ 410.130 and 410.140 that diabetes is defined as ''diabetes mellitus, a condition of abnormal glucose metabolism diagnosed using the following criteria: A fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2 hour post-glucose challenge greater than or equal to 200 mg/dL on 2 different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes.'' The definition of diabetes was based, in part on a clinical recommendation submitted by the American Association of Clinical Endocrinologists. In the CY 2005 PFS final rule (69 FR 66235), we finalized proposals to adopt implementing regulations for diabetes screening, which was recently added as a Medicare covered benefit in the Section 613 of the MMA. We adopted a new regulatory definition of prediabetes as condition of abnormal glucose metabolism diagnosed using the following criteria: a fasting glucose level of 100–125 mg/dL, or a 2-hour post-glucose challenge of 140–199 mg/dL, as well as including the conditions of impaired fasting glucose and impaired glucose tolerance. We also adopted the regulatory definition of diabetes finalized in the CY 2004 PFS for MNT and DSMT. Neither the statutes nor the regulatory text for diabetes screening, MNT and DSMT distinguish between different types of diabetes.

4. Proposed Revisions

We propose to exercise our authority in section 1861(yy)(1)(B) of the Act to add the HbA1c test to the types of diabetes screening tests covered under § 410.18(c), consistent with a recently revised recommendation by the USPSTF. As described earlier in our proposal, the USPSTF recommended the HbA1C test for diabetes screening in their October 2015 and August 2021 revised final recommendation statements. We have engaged in meetings with appropriate organizations while developing our proposal to expand diabetes screening coverage, including the ADA, the Association of Diabetes Care & Education Specialists (ADCES), the National Clinical Care Commission (NCCC) and the Diabetes Advocacy Alliance (DAA). In addition, we consulted the published clinical recommendations from the USPSTF (described earlier), the ADA [264] and the AACE [265] in developing our proposal. We look forward to further consultation with organizations through the public notice and comment rulemaking process and invite public comment on our proposal.

We propose to exercise our authority in section 1861(yy)(1)(3) of the Act to expand and simplify our frequency limitations for diabetes screening by aligning to the statutory limitation of not more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual. We also propose to remove the regulatory definition of pre-diabetes for the purposes of diabetes screening at § 410.18(a), which functionally served, in part, to distinguish the separate frequency limitations of diabetes screening at two diabetes screening tests per calendar year for individuals diagnosed with pre-diabetes and one diabetes screening test per calendar year for individuals previously tested who were not diagnosed with pre-diabetes, or who were never tested before (§ 410.18(d)). Our proposal to remove the regulatory definition of pre-diabetes is intended to simplify and expand diabetes screening while reducing unnecessary regulatory complexity. We recognize that pre-diabetes and diabetes exist on a continuum and both are screened and identified through common diabetes screening tests. Our proposal to remove

[264] *https://diabetesjournals.org/care/article/45/Supplement_1/S17/138925/2-Classification-and-Diagnosis-of-Diabetes.*

[265] *https://www.endocrinepractice.org/article/S1530-891X(22)00576-6/fulltext.*

the regulatory definition of pre-diabetes does not reflect a change in our position on pre-diabetes screening and treatment as a Medicare benefit. In making this proposal we recognize that the FPG, GTT and HbA1c tests include different levels of burden for the patient and also measure different aspects of diabetes pathology. The August 2021 USPSTF revised final recommendation statement states ''HbA1c is a measure of long-term blood glucose concentration and is not affected by acute changes in glucose levels caused by stress or illness. Because HbA1c measurements do not require fasting, they are more convenient than using a fasting plasma glucose level or an oral glucose tolerance test. Both fasting plasma glucose and HbA1c levels are simpler to measure than performing an oral glucose tolerance test. The oral glucose tolerance test is done in the morning in a fasting state; blood glucose concentration is measured 2 hours after ingestion of a 75-g oral glucose load. The diagnosis of prediabetes or type 2 diabetes should be confirmed with repeat testing before starting interventions.'' [266] We have engaged in meetings with appropriate organizations while developing our proposal to expand diabetes screening coverage, including the ADA, the ADCES, the NCCC, and the DAA. We also consulted with the written recommendations of a number of specialty societies and the USPSTF in developing our proposal. We acknowledge that the USPSTF, ADA and AACE recommend diabetes screening frequency screening of once every 3 years.[267] [268] [269] We propose expanding the frequency limitations for diabetes screening to twice in a 12-month period under the theory that additional flexibility in screening frequency will remove barriers and empower clinicians to apply screening test by multiple types of tests or with increased frequency where the circumstances of the patient demonstrate a medical necessity. We look forward to further consultation with organizations through the public notice and comment rulemaking process and invite public comment on our proposal.

We propose to simplify the regulatory definitions of ''diabetes'' for the purpose of diabetes screening at § 410.18(a), MNT at § 410.130 and DSMT at § 410.140. In all three instances, we propose to remove the codified clinical test requirements from the definition of ''diabetes'' and keep a shorted version of the existing definition that would define diabetes as diabetes mellitus, a condition of abnormal glucose metabolism. We now recognize that regulatorily codifying clinically specific test criteria into the regulatory definition of diabetes for screening, MNT and DSMT benefit reduces flexibility for the agency and health care system to adapt to evolving clinical standards without potentially producing programmatic benefit. We believe that our proposal will empower practitioners to apply clinically accurate and appropriate criteria and that we can ensure certain safeguards through medical coding and claims processing instructions. By analogy, we consider that end stage renal disease (ESRD) is not described with specific clinical test criteria in section 226A and 1881 of the Act, nor in regulations at § 406.13. We generally believe that scientific advancements in understanding and measuring disease pathology outpace the lengthy and formal notice and comment rulemaking process. In the instance of diabetes screening, MNT and DSMT, the regulatory codification of clinical test criteria into disease definitions may not be necessary nor ideal. We note that even without clinical test criteria codified in the regulatory definitions of diabetes and pre-diabetes, a Medicare claim that includes a diagnosis of diabetes or pre-diabetes would still need to include appropriate coding, substantiation in the medical record and compliance with claims processing instructions from CMS and Medicare Administrative Contractors (MACs).

In the alternative, we considered not removing the clinical test criteria for the regulatory definitions of diabetes or removing the regulatory definition of pre-diabetes. We considered adding the HbA1c test criteria result of 6.5% or greater into the regulatory definition of diabetes for screening, MNT and DSMT and the HbA1c test criteria result of 5.7 percent to 6.4 percent to the regulatory definition of pre-diabetes for screening. The alternative would be consistent with our proposal to expand coverage of diabetes screening by adding the HbA1c test, and would also be consistent with clinical recommendations by the USPSTF [270] and the ADA.[271] However, we did not propose this alternative because, while currently clinically appropriate, we believed it would further, unnecessarily complicate the regulatory definition of diabetes and pre-diabetes. As noted earlier, we now recognize that regulatorily codifying clinically specific test criteria into the regulatory definition of ''diabetes'' and ''pre-diabetes'' for screening, and ''diabetes'' for the MNT and DSMT benefits reduces flexibility for the agency and health care system to adapt to evolving clinical standards without potentially producing programmatic benefit. We invite public comment on our proposal and alternative considered.

We believe that our proposal to expand and simplify coverage for diabetes screening aligns with the administration's strategic pillar to advance health equity by addressing the health disparities that underlie our health system. The August 2021 updated USPSTF final recommendation statement reads, ''The prevalence of diabetes is higher among American Indian/Alaska Native (14.7 percent), Asian (9.2 percent), Hispanic/Latino (12.5 percent), and non-Hispanic Black (11.7 percent) persons than among non-Hispanic White (7.5 percent) persons. Disparities in diabetes prevalence are the result of a variety of factors. A large body of evidence demonstrates strong associations between prevalence of diabetes and social factors such as socioeconomic status, food environment, and physical environment. The higher prevalence of diabetes in Asian persons may be related to differences in body composition. A difference in body fat composition in Asian persons results in underestimation of risk based on BMI thresholds used to define overweight in the US.'' [272] The HbA1c test does not require fasting or drinking an unappetizing glucose solution. Expanding coverage for diabetes screening to include the HbA1c test will reduce screening burdens for a disease that disproportionally impacts minority and disadvantaged populations. In addition, earlier identification of diabetes and prediabetes among minorities and disadvantaged persons may lead to improved diabetes control

[266] USPSTF website: *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes.*

[267] *https://diabetesjournals.org/care/article/43/Supplement_1/S14/30640/2-Classification-and-Diagnosis-of-Diabetes.*

[268] *https://www.endocrinepractice.org/article/S1530-891X(22)00576-6/fulltext.*

[269] *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes#bootstrap-panel--10.*

[270] *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes#bootstrap-panel--6.*

[271] *https://diabetesjournals.org/care/article/43/Supplement_1/S14/30640/2-Classification-and-Diagnosis-of-Diabetes.*

[272] USPSTF website: *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes.*

and reduce its complications, which currently occur disproportionately in those groups.

5. Summary

In summary, we propose to exercise our authority in sections 1861(yy) of the Act to: (1) expand coverage of diabetes screening tests to include the HbA1c test; (2) expand and simplify the frequency limitations for diabetes screening; and (3) simplify the regulatory definition of ''diabetes'' for diabetes screening, MNT and DSMT. We believe our proposals will expand access to quality care and improve health outcomes for patients through prevention, early detection, and more effective treatment. We recognize that expanded access and appropriate utilization of diabetes screening is critical to mitigating and avoiding downstream health complications that significantly impact beneficiary wellbeing, as well as being costly and burdensome to the healthcare system. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) website states, ''diabetes can cause serious health problems, such as heart disease, stroke, and eye and foot problems. Prediabetes also can cause health problems. The good news is that type 2 diabetes can be delayed or even prevented. The longer you have diabetes, the more likely you are to develop health problems, so delaying diabetes by even a few years will benefit your health.'' [273] The U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation recently published a Report to Congress on the Affordability of Insulin that included a number of generalized findings on downstream impacts of serious diabetes related complications on health care use.[274] Their findings include:

- In 2019, there were 8.7 million hospitalizations related to diabetes overall. About 71 percent were a result of the patient going to the emergency department. Ten percent of the 8.7 million hospitalizations had a principal diagnosis of diabetes.
- About 83 percent of hospitalizations occurred among patients living in communities in the bottom 50 percent of U.S. income, measured using median household income of the patient's zip code, underscoring the need for affordable access to treatment for diabetes.
- We also examined potentially avoidable hospitalization costs for Medicare and Medicaid beneficiaries with diabetes, specifically examining the costs for patients with amputations and ketoacidosis. For Medicare in 2020, total costs were $3.8 billion for amputations, $5.6 billion for ketoacidosis, and another $1.0 billion for patients with both. Medicare paid more than 90 percent of overall costs, covering $3.5 billion for amputations, $5.2 billion for ketoacidosis, and $936 million for hospitalizations involving both.

M. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

1. Previous Regulatory Action

In the CY 2021, CY 2022, and CY 2023 PFS final rules, we finalized policies for the CMS EPCS Program requirements specified in section 2003 of the SUPPORT Act (Pub. L. 115–271, October 24, 2018). We refer readers to 85 FR 84802 through 84807, 86 FR 65361 through 65370, and 87 FR 70008 through 70014 for the details of the statutory requirements and those finalized policies. Specifically, in the CY 2022 PFS final rule, we extended the date of compliance actions to no earlier than January 1, 2023 and, for prescribers writing Part D controlled substances prescriptions for beneficiaries in long-term care (LTC) facilities, January 1, 2025 (86 FR 65364 and 65365). We also finalized a proposal requiring prescribers to electronically prescribe at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs, except in cases where an exception or waiver applies (86 FR 65366); finalized multiple proposals related to the classes of exceptions specified by section 2003 of the SUPPORT Act (86 FR 65366 through 65369); and finalized our proposal to limit compliance actions with respect to compliance through December 31, 2023 to a non-compliance notice (86 FR 65370).

In the CY 2023 PFS final rule (87 FR 70012 through 70013), we extended the existing non-compliance action of sending notices to non-compliant prescribers, which we had finalized for the CY 2023 CMS EPCS Program implementation year (January 1, 2023 through December 31, 2023), to the CY 2024 Program implementation year (January 1, 2024 through December 31, 2024). We also finalized a change to the data sources used to identify the geographic location of prescribers for purposes of the recognized emergency exception at § 423.160(a)(5)(iii) (87 FR 70011 through 70012) and finalized our proposal to use the Prescription Drug Event (PDE) data from the current evaluated year instead of the preceding year when CMS determines whether a prescriber qualifies for an exception based on issuing 100 or fewer Part D controlled substance prescriptions per calendar year (87 FR 70009 through 70011).

2. CMS EPCS Program Terminology

In the CY 2021, CY 2022, and CY 2023 PFS final rules (85 FR 84802 through 84807, 86 FR 65361 through 65370, and 87 FR 70008 through 70013), we used various terminology to describe aspects of the requirements for EPCS. In order to provide consistency and clarity throughout the CMS EPCS Program and future rules, we will use the following terms going forward.

- *CMS EPCS Program.* We will refer to the program requirements for EPCS at § 423.160(a)(5) as the ''CMS EPCS Program.'' We believe this provides an appropriate distinction from the prescriber's act of electronically submitting individual prescriptions for controlled substances, which is also referred to as EPCS.
- *Non-compliance action or action for non-compliance.* We will use ''non-compliance action'' or ''action for non-compliance'' to refer to a consequence for not meeting the CMS EPCS Program compliance threshold, as described at § 423.160(a)(5), after exceptions have been applied.
- *Measurement year.* When we refer to ''measurement year,'' we mean the time period (beginning on January 1 and ending on December 31 of each calendar year) during which data is collected to calculate outcomes for the CMS EPCS Program. In prior rules, we have used the term ''current year'' or ''evaluated year,'' but moving forward we will use the term ''measurement year.''
- *Compliance threshold.* For the CMS EPCS Program, ''compliance threshold'' is the requirement at § 423.160(a)(5) that prescribers must conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically, after exceptions, each measurement year.
- *Compliance analysis period.* The ''compliance analysis period'' is the time period after the measurement year where data is analyzed to determine whether prescribers have met the compliance threshold for the CMS EPCS Program.

[273] National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), part of the National Institutes of Health, website: *https://www.niddk.nih.gov/health-information/diabetes/overview/preventing-type-2-diabetes.*

[274] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Report on the Affordability of Insulin. December 16, 2022. *https://aspe.hhs.gov/reports/insulin-affordability-rtc.*

• *Notification period.* The ''notification period'' is the time period during which we notify a prescriber of the prescriber's initial compliance status and any associated review or waiver process that may be available prior to CMS determining the prescriber's final compliance status.

• *Measurement cycle.* The ''measurement cycle'' is generally a period of 24 months, consisting of a measurement year, the compliance analysis period, and the notification period.

3. Standard for CMS EPCS Program

a. Updates to the NCPDP Standards

In the CY 2021 PFS final rule (85 FR 84804), we finalized a requirement for Part D prescribers to use the NCPDP SCRIPT standard version 2017071 standard for electronic prescribing of Schedule II, III, IV, and V controlled substances covered under Medicare Part D. In the CY 2021 PFS proposed rule, we had stated our belief that because prescribers were already required to use this standard when e-prescribing for covered Part D drugs for Part D eligible individuals, prescribers should use this same standard when e-prescribing controlled substances (85 FR 50261).

On December 27, 2022, as part of the Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications proposed rule (herein referred to as the ''CY 2024 Medicare Advantage and Part D Policy and Technical Changes proposed rule'') (87 FR 79550), we proposed to update provisions related to e-prescribing standards at § 423.160(b), including, after a transition period, requiring the NCPDP SCRIPT standard version 2022011 proposed for adoption at 45 CFR 170.205(b), and retiring the current NCPDP SCRIPT standard version 2017071, as the e-prescribing standard for covered Part D drugs for Part D eligible individuals. The CY 2024 Medicare Advantage and Part D Policy and Technical Changes final rule appeared in the April 12, 2023 **Federal Register** (88 FR 22120). In the final rule, we did not address comments received on the provisions of the proposed rule related to e-prescribing standards as these provisions were not finalized in the final rule. Rather, we will address provisions of the proposed rule that we did not finalize at a later time, such as in possible future rulemaking, as appropriate.

As stated in the CY 2021 PFS proposed rule (85 FR 50261), our intent with the CMS EPCS Program is for prescribers to use the same version of the NCPDP SCRIPT standard for their electronic prescribing of Schedule II–V controlled substances that are Part D drugs as for other electronic prescribing for Part D eligible individuals. Although we finalized the NCPDP SCRIPT standard version 2017071 as the standard in the CY 2021 PFS final rule, we want to clarify that, based on the existing regulatory text at § 423.160(a)(5), the CMS EPCS Program will automatically adopt the electronic prescribing standards at § 423.160(b) as they are updated. This is based on the requirement at § 423.160(a)(5) that prescribers conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically using the applicable standards in paragraph (b) of § 423.160. Therefore, any proposals from the CY 2024 Medicare Advantage and Part D Policy and Technical Changes proposed rule to standards at § 423.160(b) that are finalized will apply to electronic prescribing for the CMS EPCS program as well.

b. Standards for Same Legal Entity

In the CY 2022 PFS final rule (86 FR 65366), we finalized an exception at § 423.160(a)(5)(i) for prescriptions issued where the prescriber and dispensing pharmacy are the same entity (hereafter called the same entity exception). We stated our belief that a requirement to use the NCPDP SCRIPT standard version 2017071 within a closed system could increase costs and the rate of performance errors, such as data corruption and patient matching errors, which we understand often happens when a unified database is split into a transaction system that relays information to and from the same entity.

As we have implemented the same entity exception, our experience has been that the Prescription Drug Event (PDE) data, which we use for CMS EPCS Program compliance calculations, does not have a field that consistently and accurately identifies prescribers and dispensing pharmacies that are part of the same entity, making it impossible to exclude these prescriptions from the compliance calculations using PDE data. Additionally, we realized that we can include prescriptions where the prescriber and dispensing pharmacy are the same entity without triggering the concerns that led us to us to finalize the same entity exception, if we remove the requirement to use the NCPDP SCRIPT standard listed in § 423.160(b), as described below.

Medicare Part D has an existing electronic prescribing regulation that permits the use of either HL7 messages or the NCPDP SCRIPT Standard to transmit prescriptions or prescription-related information internally when the sender and the beneficiary are part of the same legal entity while still maintaining the requirement for e-prescribing. The Medicare Program; E-Prescribing and Prescription Drug Program final rule (70 FR 67581), which appeared in the November 7, 2005 **Federal Register**, codified at § 423.160(a)(3)(ii), that either HL7 messages or the NCPDP SCRIPT Standard could be used when all parties to a transaction are, for example, employed by and part of the same legal entity. We subsequently finalized a proposal to move the provision to § 423.160(a)(3)(iii) in the CY 2008 PFS final rule (72 FR 66405).

We propose to integrate this regulation into the CMS EPCS Program, as it provides alignment across electronic prescribing policies for prescriptions prescribed and dispensed within the same legal entity without forcing these entities to adopt the NCPDP SCRIPT standard for such transmittals. With this proposal, prescribers in the same legal entities as the dispensing pharmacy would have multiple methods to conduct internal electronic transmittals for Schedule II, III, IV, and V controlled substances that are Part D drugs, as permitted in § 423.160(a)(3)(iii). Therefore, we believe that these prescribers' prescriptions can be included in the CMS EPCS Program compliance calculation so long as prescribers' electronic prescriptions are transmitted consistent with the exemption in § 423.160(a)(3)(iii).

With this proposal, we would no longer need to separately identify and apply different methodologies based on whether the prescriber and dispensing pharmacy are the same entity. We would identify electronic prescriptions for Schedule II–V controlled substances that are Part D drugs using the Prescription Origin Code data element in the PDE record, where a value of three indicates electronic transmission. Additionally, this proposal would expand the available standards for prescribers that are within the same legal entities as the dispensing pharmacy under the CMS EPCS Program, as defined by the Medicare Program; E-Prescribing and Prescription Drug Program final rule (70 FR 67581),

by cross-referencing the standards at § 423.160(a)(3)(iii), which broadens the requirements of the e-prescribing standard that can be used to meet CMS EPCS Program requirements. We believe that by aligning with the regulation at § 423.160(a)(3)(iii), we are advancing e-prescribing standardization and addressing potential concerns about burdening prescribers within the same legal entity, including workflow and data errors.

Therefore, to address our data limitations and also to provide flexibility where prescriptions are transmitted within the same legal entity, we are proposing to remove the same entity exception at § 423.160(a)(5)(i) from the CMS EPCS Program requirements and to redesignate paragraphs (a)(5)(ii) through (iv) as paragraphs (a)(5)(i) through (iii), respectively. We also propose to add ''subject to the exemption in paragraph (a)(3)(iii) of this section'' to § 423.160(a)(5). Under this proposed change, prescriptions that are prescribed and dispensed within the same legal entity would be included in CMS EPCS Program compliance calculations as part of the 70 percent compliance threshold at § 423.160(a)(5), and prescribers will not be exempt from the requirement to prescribe electronically at least 70 percent of their Schedule II–V controlled substances that are Part D drugs—but such prescriptions would only have to meet the applicable standards in § 423.160(b) subject to the exemption in § 423.160(a)(3)(iii).

We seek comment on the proposals to remove the same entity exception and expand the available standards for same legal entities within the CMS EPCS Program.

4. Definition of Prescriptions for Compliance Calculation

In the CY 2022 PFS final rule, we finalized the compliance threshold requirement for the CMS EPCS Program such that prescribers are required to prescribe at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically, except in cases where an exception or waiver applies (86 FR 65366). Additionally, we indicated that the compliance threshold for each prescriber would be calculated by examining PDE data at the end of the measurement year and dividing the number of Part D controlled substances that were e-prescribed by the total number of Part D controlled substance prescriptions (excluding from both the numerator and denominator any prescriptions issued while a prescriber falls within an exception or is subject to a waiver) (86 FR 65365). Previously, we did not define how prescriptions with multiple fills would affect the compliance threshold calculation. We are now proposing to specify how the compliance threshold is affected by multiple fills within the same year.

For purposes of CMS EPCS Program, we will count unique prescriptions in the measurement year using the prescription number assigned by the pharmacy and included in the Part D claims data. All prescriptions, regardless of how they are transmitted, may include a number of refills so that the pharmacy may provide additional fills of the prescribed medication without the need for a new prescription from, or visit to, a prescriber. Refills are not separately transmitted prescriptions; they are documented as part of the original prescription transmittal, which includes any refills issued against the original prescription (by the pharmacy). However, renewals of prescriptions (such as those for maintenance medications) require prescribers to generate a new prescription along with a new set of refills. Because of this distinction, we will count renewals as an additional prescription in the CMS EPCS Program compliance threshold calculation, and we will not count refills as an additional prescription in the CMS EPCS Program compliance threshold calculation unless the refill is the first occurrence of the unique prescription in the measurement year.

We believe, if we were to include every fill in the compliance threshold calculation, an increased burden could be placed on small prescribers, as they would potentially no longer qualify for the small prescriber exception at § 423.160(a)(5)(ii) (which we propose to be redesignated to § 423.160(a)(5)(i), as described in section III.M.3.b. of this rule). If we were to count every single fill, preliminary analysis of 2021 Part D data shows that approximately 23,000 prescribers would no longer qualify for the small prescriber exception and that approximately 6,900 additional prescribers would be considered non-compliant. For this reason, we would count only the unique prescriptions in the measurement year for the purposes of CMS EPCS Program compliance threshold calculations.

5. Updates to CMS EPCS Program Exceptions for Cases of Recognized Emergencies and Extraordinary Circumstances

a. Background

In the CY 2022 PFS final rule (86 FR 65367 through 65368), we finalized two exceptions related to exceptional circumstances that may prevent prescribers from being able to conduct EPCS. The first exception, codified at § 423.160(a)(5)(iii), is for prescribers who are prescribing during a recognized emergency, such as a natural disaster, a pandemic, or a similar situation where there is an environmental hazard. Prescribers in a geographic area of an emergency or disaster declared by a Federal, State, or local government entity are excluded from the CMS EPCS Program requirements. In the CY 2023 PFS final rule (87 FR 70012), we modified the exception to use the prescriber's PECOS address or, in situations where a prescriber does not have a PECOS address, the prescriber's address in the National Plan and Provider Enumeration System (NPPES) data, to determine whether the exception at § 423.160(a)(5)(iii) is applicable.

The second exception, codified at § 423.160(a)(5)(iv), is for prescribers who request and receive from CMS a waiver, which we grant to prescribers who are facing extraordinary circumstances that prevent them from electronically prescribing a controlled substance to a Part D beneficiary, but who are not in an emergency or disaster area. We defined ''extraordinary circumstance'' for purposes of this exception to mean a situation, other than an emergency or disaster, outside of the control of a prescriber that prevents the prescriber from electronically prescribing a controlled substance to a Part D beneficiary (86 FR 65367).

In this rule, we are proposing to further modify the recognized emergency exception and extraordinary circumstances waiver (which we propose to be codified at § 423.160(a)(5)(ii) and (iii), respectively, as described in section III.M.3.b. of this rule). We are proposing to modify the rules for when these exceptions apply by enabling prescribers to apply for waivers in times of an emergency and disaster and by limiting the emergencies or disasters that would trigger the recognized emergency exception. Additionally, we are proposing to modify the duration of both exceptions and proposing timing requirements for submitting a waiver application.

b. Updating the Circumstances Applicable for the Recognized Emergency and Extraordinary Circumstances Waiver Exceptions

Our current exception for recognized emergencies applies to all prescribers with an address in PECOS, or alternatively in NPPES, in the geographic area of an emergency or

disaster declared by a Federal, State, or local government entity. As we have implemented this exception, we realize there may be unintended consequences to our existing policy. First, while we can identify emergencies recognized by the Federal Emergency Management Agency (FEMA) or pandemics recognized by the Department of Health and Human Services (HHS), we may not be able to identify every local or state emergency. Because we excluded emergencies and disasters from our extraordinary circumstances waiver policy, some prescribers may not be able to receive an exception for an emergency or disaster we did not identify. Second, we realize that not every emergency may impact the ability of prescribers to conduct EPCS, and thus it may not be appropriate to automatically apply the exclusion to all prescribers in the affected geographic area of some emergencies. Third, we realized that some of our policies do not align with other emergency policies of CMS programs for quality reporting and performance. Therefore, in order to address these concerns, we looked to the Quality Payment Program Merit-based Incentive Payment System (MIPS) automatic policy for extreme and uncontrollable circumstances and to the extraordinary circumstances exceptions (ECE) for many of our quality reporting and value-based purchasing programs for hospitals and other types of facilities to see other examples of when we apply automatic exceptions versus when we ask clinicians or facilities to apply for a waiver.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38410) and CY 2018 OPPS/ASC final rule (82 FR 52584), we worked to align common processes for our ECE policies across many of our quality programs including the Hospital IQR Program, Hospital OQR Program, IPFQR Program, ASCQR Program, and PCHQR Program, as well as the Hospital VBP Program, HAC Reduction Program, and the Hospital Readmissions Reduction Program. Using the Hospital IQR Program as an example, generally, CMS may grant an exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the hospital (42 CFR 412.140(c)(2)). A hospital may submit such a request in the form and manner described on *QualityNet.org.* CMS may also grant an exception to one or more hospitals that have not requested an exception if: CMS determines that a systemic problem with CMS data collection systems directly affected the ability of the hospital to submit data; or if CMS determines that an extraordinary circumstance, such as an act of nature (for example, hurricane), has affected an entire region or locale (*see* § 412.140(c)(2)(ii) and 76 FR 51651). We stated that if we make the determination to grant an ECE to hospitals in a region or locale, we would communicate this decision through routine communication channels (76 FR 51652).

Separately, in the context of clinicians participating in MIPS, CMS established another ECE policy. In the Medicare Program; CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstance Policy for the Transition Year (CY 2018 Quality Payment Program final rule), we adopted in an interim final rule with comment period an automatic extreme and uncontrollable circumstances policy for one performance period due to several hurricanes (82 FR 53895 through 53900). In discussing the triggering events for this policy (82 FR 53897), we stated that we have discretion not to require MIPS eligible clinicians to submit an application for reweighting the performance categories in cases where an extreme and uncontrollable circumstance, such as an act of nature (for example, hurricane), affects an entire region or locale. We noted that we anticipate the types of events that could trigger this policy would be events designated by the Federal Emergency Management Agency (FEMA) as major disasters or a public health emergency declared by the Secretary, although we will review each situation on a case-by-case basis. We also noted our intention to align the automatic extreme and uncontrollable circumstance policy with the ECE policies for other Medicare programs such that events that trigger ECE policies would also trigger the automatic extreme and uncontrollable circumstance policy (82 FR 53897). In the CY 2019 PFS final rule (83 FR 59875), we finalized a similar policy for all future years, which we codified at § 414.1380(c)(2)(i)(A)(*8*) and (C)(3).

We believe that it would be beneficial to interested parties for the CMS EPCS Program to have a similar policy as it relates to applying for an exception versus having an automatic exception for all prescribers in an affected region. This would streamline communications across CMS programs, as well as ensure that CMS can, where appropriate, except all prescribers for an appropriate circumstance beyond their control, including disasters or emergencies. In order to facilitate this transition, for the waiver exception at § 423.160(a)(5)(iv) (which we propose to codify at § 423.160(a)(5)(iii), as described in section III.M.3.b. of this rule), we are proposing to modify the definition of ''extraordinary circumstance'' to mean a situation outside of the control of a prescriber that prevents the prescriber from electronically prescribing a Schedule II–V controlled substance that is a Part D drug. This updated definition would drop the restriction ''other than an emergency or disaster,'' that we previously included when discussing this exception. This modification would allow prescribers the ability to request a waiver regardless of whether we trigger the recognized emergency exception.

Additionally, we are proposing to modify the recognized emergency exception at § 423.160(a)(5)(iii) (which we propose to codify at § 423.160(a)(5)(ii), as described in section III.M.3.b. of this rule) so that CMS will identify which events trigger the recognized emergency exception. We believe the ability to identify triggering events will allow us to ensure that the emergency affects widespread EPCS functionality. In applying this determination of which emergencies or disasters would trigger this exception, we would review each emergency situation on a case-by-case basis but would generally look to events designated as a FEMA major disaster or a public health emergency declared by the Secretary. We also intend to align the determination of the emergency exception with the MIPS automatic extreme and uncontrollable circumstances policy, such that events that would trigger this policy, in most instances, would also qualify under the CMS EPCS Program exception for recognized emergencies. We expect any deviation from MIPS automatic extreme and uncontrollable circumstances policies would be rare and only in circumstances which may cause disruption for MIPS performance but should not affect a prescriber's ability to electronically prescribe Schedule II–V controlled substances that are Part D drugs, or vice versa.

We would inform prescribers of which emergencies or disasters qualify for the exception, as determined by CMS, using normal communication channels such as listservs and the CMS EPCS Program website.

We invite public comment on the proposals related to circumstances applicable for the recognized emergency and extraordinary circumstances waiver exceptions.

c. Duration of Recognized Emergency Exceptions

In the CY 2022 PFS final rule (86 FR 65367), we clarified that the recognized emergency exception would be applicable only if the dispensing date of the medication occurs during the time period that the declared disaster is occurring. In an effort to continue aligning the CMS EPCS Program with the Quality Payment Program, we propose that, as a default, prescribers impacted by the CMS EPCS Program recognized emergency exception at § 423.160(a)(5)(iii) (which we propose to codify at § 423.160(a)(5)(ii), as described in section III.M.3.b. of this rule) would be excepted for the entire measurement year, and not just for the duration of the emergency. We believe this would protect prescribers who may not be able to monitor their compliance status over multiple periods of time.

We seek comment on the proposed duration for exceptions due to recognized emergencies.

d. Duration and Timing of Extraordinary Circumstances Waiver Exception

In the CY 2022 PFS final rule (86 FR 65367 through 65368), we finalized an attestation process for prescribers to request a waiver.[275] In this rule, we are not proposing any modifications on the information needed to request a waiver, but we are proposing the timeframe that would be covered by a waiver that is authorized under the CMS EPCS Program and the timing of waiver requests.

Section 1860D–4(e)(7)(B)(iii) of the Act, as added by section 2003 of the SUPPORT Act, refers to a waiver or a renewal thereof for a period of time, not to exceed one year, as determined by the Secretary. We propose that approved waivers for the CMS EPCS Program would apply to the entire measurement year. Prescribers who receive a waiver and continue to experience exceptional circumstances that extend beyond December 31 of a measurement year would be required to complete a new waiver application for the subsequent measurement year.

In the CY 2022 PFS proposed rule (86 FR 39332), we signaled that we would include more information about the waiver process in subsequent rulemaking. One issue that was not clearly defined is the timing of when a prescriber can request a waiver. In the CY 2022 PFS final rule (86 FR 65370), we finalized that we would notify prescribers that they are violating the EPCS requirement with information about how they can come into compliance, the benefits of EPCS, an information solicitation as to why they are not conducting EPCS, and a link to the CMS portal to request a waiver. We are now proposing that a prescriber has a period of 60 days from the date of the notice of non-compliance to request a waiver. Approved waivers would apply to prescriptions written by a prescriber for the entire measurement year, and the waiver would expire on December 31 of the applicable measurement year.

We seek comment on the proposed waiver duration and the proposal for the timing and process of applying for waiver in cases of extraordinary circumstances.

6. Actions for Non-Compliance

In the CY 2022 PFS final rule (86 FR 65370), we limited compliance actions with respect to compliance from January 1, 2023 through December 31, 2023, to a non-compliance notice sent to prescribers who are violating the CMS EPCS Program requirement. In the CY 2023 PFS final rule (87 FR 70013), we extended the existing compliance action of sending notices to non-compliant prescribers from the CY 2023 CMS EPCS Program implementation year (January 1, 2023 through December 31, 2023) to the CY 2024 EPCS Program implementation year (January 1, 2024 through December 31, 2024). The content of the notices will remain unchanged and continue to consist of a notice to prescribers that they are violating the CMS EPCS Program requirements, information about how they can come into compliance, the benefits of EPCS, and a link to the CMS EPCS Program dashboard where the prescriber may request a waiver and provide information as to why they are not conducting EPCS.

We propose to continue the practice of issuing a prescriber notice of non-compliance as a non-compliance action for subsequent measurement years. As stated in the CY 2023 PFS final rule (87 FR 70013), we believe prescriber use of EPCS encourages the use of interoperable technology, produces a verifiable and traceable history, prevents fraud and abuse, and reduces burden. We believe that continuing to send non-compliance notices would support increased EPCS adherence and encourage increased EPCS adoption rates, which could be more effective than imposing more restrictive non-compliance actions or penalties that may increase burden on prescribers.

In the CY 2023 PFS proposed rule (87 FR 46240 through 46241), we solicited ideas of possible non-compliance actions with the goal of identifying one that would be operationally feasible (for example, can be accomplished without requiring modifications to the data available through the PDE file) and support the nation's ongoing fight against drug abuse and diversion without adding administrative burden to prescribers or hindering beneficiary access to needed medications. We did not receive a large number of comments. However, we did receive one comment noting that non-compliance alone is not a definitive indicator of fraud, waste, or abuse. We agree with the commenter that non-compliance alone is not a definitive indicator of fraud, waste, or abuse; however, we maintain that one risk to public safety is potential fraud, waste, and abuse and intend that a prescriber's non-compliance under the CMS EPCS program may be considered in our processes for assessing potential fraud, waste, and abuse.

We may use this information in our processes for assessing potential fraud, waste, and abuse, which, in some instances, could result in a referral to law enforcement or revocation of billing privileges, in the event that evidence of fraud, waste, or abuse is present. At this time, we believe the risk of fraud, waste, or abuse can be mitigated without the need for further penalties for CMS EPCS program non-compliance. Literature suggests a correlation between use of EPCS and reduction in fraud, waste, and abuse related to opioid prescriptions.[276] [277] Prescriber use of EPCS is directly related to improving prescription security, decreasing prescription forgery, and reducing the overall chance of fraud and alteration associated with paper prescribing.[2] Also notable are studies demonstrating reductions in opioid overdoses when EPCS use is increased and general findings that e-prescribing can improve coordination of care, reduce fraud and abuse, and contribute to public health safety.

Although we are not proposing further non-compliance actions beyond the extension of sending notices at this time, we will continue to evaluate compliance and prescriber performance

[275] The waiver application is currently going through the Paperwork Reduction Act approval process under the document identifier CMS–10834, and the proposed collection comment request appeared in the March 10, 2023 **Federal Register** (88 FR 15037).

[276] Achar, Suraj, et al. ''Adoption and Increased Use of Electronic Prescribing of Controlled Substances.'' *Journal of Medical Regulation,* Federation of State Medical Boards, 27 Aug. 2021, *https://doi.org/10.30770/2572-1852-107.2.8.*

[277] Abuok, Rahi, and David Powell. ''Can Electronic Prescribing Mandates Reduce Opioid-Related Overdoses?'' Science Direct, JOURNAL of ECONOMICS & HUMAN BIOLOGY, Elsevier B.V., 14 Apr. 2021, *https://doi.org/10.1016/j.ehb.2021.101000.*

under the CMS EPCS Program and will consider whether to propose changes in future years. We seek public comment on our proposal to continue the action of sending notice to prescribers who are identified as non-compliant.

N. Proposed Changes to the Regulations Associated With the Ambulance Fee Schedule and the Medicare Ground Ambulance Data Collection System (GADCS)

1. Background on Ambulance Services

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Since April 1, 2002, payment for ambulance services has been made under the ambulance fee schedule (AFS), which the Secretary established, as required by section 1834(l) of the Act, in 42 CFR part 414 subpart H. Payment for an ambulance service is made at the lesser of the actual billed amount or the AFS amount, which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a geographic adjustment factor (GAF), and other applicable adjustment factors as set forth at section 1834(l) of the Act and § 414.610 of the regulations. In accordance with section 1834(l)(3) of the Act and § 414.610(f), the AFS rates are adjusted annually based on an inflation factor. The AFS also incorporates two permanent add-on payments in § 414.610(c)(5)(i) and three temporary add-on payments to the base rate and/or mileage rate, which are discussed in the next section of this proposed rule.

Our regulations relating to coverage of and payment for ambulance services are set forth at 42 CFR part 410, subpart B, and 42 CFR part 414, subpart H.

2. Ambulance Extender Provisions

a. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275, enacted July 15, 2009) (MIPPA), amended section 1834(l)(13) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008, and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

- For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.
- For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

The payment add-ons under section 1834(l)(13) of the Act have been extended several times. Most recently, division FF, section 4103 of the CAA, 2023 (Pub. L. 117–328, December 29, 2022) amended section 1834(l)(13) of the Act to extend the payment add-ons through December 31, 2024. Thus, these payment add-ons apply to covered ground ambulance transports furnished before January 1, 2025. We are proposing to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(13) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74438 through 74439), the CY 2015 PFS final rule with comment period (79 FR 67743), the CY 2016 PFS final rule with comment period (80 FR 71071 through 71072) and the CY 2019 PFS final rule with comment period (83 FR 59681 through 59682)).

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase, and does not require any substantive exercise of discretion on the part of the Secretary.

b. Amendment to Section 1834(l)(12) of the Act

Section 414(c) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173, December 8, 2003) added section 1834(l)(12) to the Act, which specified that, in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations. Using the methodology specified in the July 1, 2004 interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment increase was applied to ground ambulance transports that originated in a ''qualified rural area,'' that is, to transports that originated in a rural area comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of rural census tract). This rural bonus is sometimes referred to as the ''Super Rural Bonus'' and the qualified rural areas (also known as ''super rural'' areas) are identified during the claims process via the use of a data field included in the CMS-supplied ZIP code file.

The Super Rural Bonus under section 1834(l)(12) of the Act has been extended several times. Most recently, division FF, section 4103 of the CAA, 2023 amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2024. Therefore, we are continuing to apply the 22.6 percent rural bonus described in this section (in the same manner as in previous years) to ground ambulance services with dates of service before January 1, 2025 where transportation originates in a qualified rural area. Accordingly, we are proposing to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(12) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74439 through 74440), CY 2015 PFS final rule with comment period (79 FR 67743 through 67744), the CY 2016 PFS final rule with comment period (80 FR 71072) and the CY 2019 PFS final rule with comment period (83 FR 59682)).

This statutory provision is self-implementing. It requires an extension of this rural bonus (which was previously established by the Secretary) through December 31, 2024, and does not require any substantive exercise of discretion on the part of the Secretary.

3. Medicare Ground Ambulance Data Collection System

a. Background

Section 50203(b) of the BBA of 2018 added paragraph (17) to section 1834(l) of the Act, which requires ground ambulance providers of services and suppliers (ground ambulance organizations) to submit cost and other information. Specifically, section 1834(l)(17)(A) of the Act requires the Secretary to develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary for providers and suppliers of ground

ambulance services. Section 1834(l)(17)(B)(i) of the Act required the Secretary to specify the data collection system by December 31, 2019, and to identify the ground ambulance providers and suppliers that would be required to submit information under the data collection system. Section 1834(l)(17)(D) of the Act required that beginning January 1, 2022, the Secretary apply a 10 percent payment reduction to payments made under section 1834(l) of the Act for the applicable period to a ground ambulance provider or supplier that is required to submit information under the data collection system and does not sufficiently submit such information. The term ''applicable period'' is defined under section 1834(l)(17)(D)(ii) of the Act to mean, for a ground ambulance provider or supplier, a year specified by the Secretary not more than 2 years after the end of the period for which the Secretary has made a determination that the ground ambulance provider or supplier has failed to sufficiently submit information under the data collection system. Division P, section 311 of the CAA, 2022 (Pub. L. 117–103) amended section 1834(l)(17)(F)(i) of the Act to delay the deadline for MedPAC to submit its report to Congress on the ground ambulance data collection system study until the second June 15th following the date the Secretary transmits data for the first representative sample of ground ambulance organizations. Section 1834(l)(17)(I) of the Act states that the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.) does not apply to the collection of information required under section 1834(l)(17) of the Act.

In the CY 2020 PFS final rule (84 FR 62864 through 62897), we implemented section 1834(l)(17) of the Act and codified regulations governing data reporting by ground ambulance organizations at §§ 414.601, 414.605, 414.610(c)(9), and 414.626. We also finalized a data collection system that collects detailed information on ground ambulance provider and supplier characteristics including service areas, service volume, costs, and revenue through a data collection instrument, commonly referred to as the Medicare Ground Ambulance Data Collection Instrument, via a web-based system. We refer the reader to our CY 2020 PFS final rule (84 FR 62864 through 62897) for more specifics on the establishment of the Medicare Ground Ambulance Data Collection System.

In the CY 2022 PFS final rule (86 FR 65306 through 65317), we finalized a number of updates to the Medicare Ground Ambulance Data Collection System, including: (1) a new data collection period beginning between January 1, 2023, and December 31, 2023, and a new data reporting period beginning between January 1, 2024, and December 31, 2024, for selected ground ambulance organizations in Year 3; (2) aligning the timelines for the application of penalties for not reporting data with our new timelines for data collection and reporting and a notice that the data collected will be publicly available beginning in 2024; and (3) revisions to the Medicare Ground Ambulance Data Collection Instrument that include better accounting for labor hours across different categories of personnel and better distinguishing between accrual and cost basis accounting methodologies. We refer the reader to our CY 2022 PFS final rule (86 FR 65306 through 65317) for more specifics on the revisions to the Medicare Ground Ambulance Data Collection System.

In the CY 2023 PFS final rule (87 FR 70014) we finalized a series of changes to the Medicare Ground Ambulance Data Collection System. First, we finalized our proposal to update our regulations at § 414.626(d)(1) and (e)(2) to provide the necessary flexibility to specify how ground ambulance organizations should submit hardship exemption requests and informal review requests, including to our web-based portal once that portal is operational. Second, we finalized our proposed changes and clarifications to the Medicare Ground Ambulance Data Collection Instrument to reduce burden on respondents, improve data quality, or both. We refer the reader to our CY 2023 PFS final rule (87 FR 70014) for more specifics on the revisions to the Medicare Ground Ambulance Data Collection System.

b. Proposed Revisions to the Medicare Ground Ambulance Data Collection Instrument

As described in the CY 2022 PFS final rule (86 FR 65307) and the CY 2023 PFS Final Rule (87 FR 70014), we made several changes to the instrument instructions and questions to improve clarity and reduce burden for respondents. A printable version of the current instrument instructions and questions is available in English and Spanish on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/Ground-Ambulance-Services-Data-Collection-System.*

We continue to receive ad hoc questions and feedback related to the Medicare Ground Ambulance Data Collection System and the Medicare Ground Ambulance Data Collection Instrument via four primary channels. First, we receive email and other written communication from ground ambulance organizations via the CMS Ambulance Data Collection email inbox (*AmbulanceDataCollection@cms.hhs.gov*) and through other channels (for example, inquiries sent by organizations to Medicare Administrative Contractors (MACs) and then forwarded to CMS). These emails and other communications often include questions seeking clarification of instrument questions and their applicability to specific ground ambulance organization scenarios and context. We continue to update a Medicare Ground Ambulance Data Collection System Frequently Asked Questions (FAQ) document with answers and the GADCS User Guide to commonly asked questions. These documents are available on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/ambulancefeeschedule/ground-ambulance-services-data-collection-system.* Through review of questions and feedback, we identified some instances where a clarification to the instrument language itself will likely be more useful and less burdensome to respondents than having to respond with reference to the FAQ document, the GADCS User Guide, or to other resources. Second, we answer questions live from interested parties during webinars, dedicated question and answer sessions, and other educational sessions. As with the emailed questions described above, live question and answer exchanges sometimes identify opportunities for clarifying instrument language. Third, we have begun analyzing initial data responses submitted via the GADCS portal by selected organizations in Year 1 and Year 2. Findings from this initial analysis, including inconsistent response patterns, unusual combinations of responses across questions, and investigation of outlier results were helpful to identify some additional opportunities for clarification. Fourth, we continue to identify opportunities to clarify instructions and correct a small number of typos through the final development and launch of the web-based GADCS.

Based on information that we received via the four sources described above, we are proposing the following further changes and clarifications to the Medicare Ground Ambulance Data Collection Instrument. The changes and clarifications aim to reduce burden on

respondents, improve data quality, or both.

1. Addressing Partial-Year Responses

Ground ambulance organizations selected to participate in the GADCS that are in operation for only part of their continuous, 12-month data collection period are, following the GADCS instructions, still required to collect and report data. However, there is not a field for these organizations to report that they were in operation, and therefore collecting data, for less than a full 12-month period via the GADCS. In these cases, we would not know that the costs, revenue, and utilization reported by these partial-year organizations are comparatively smaller than those reported by similar organizations in operation for an entire 12-month period. As a result, some statistics from analyses of GADCS data, for example total annual expenditures per ground ambulance organization, would be biased downward.

To address this limitation, we are proposing to add a response option to Section 2 (Organizational Characteristics), Question 1 which asks whether the selected national provider identifier (NPI) linked to the organization was used to bill Medicare for ground ambulance services during its data collection period. The current response options are ''Yes (1)'' and ''No (0)''. We propose to split the existing ''Yes (1)'' response into two separate responses, one reading ''Yes, throughout the organization's continuous, 12-month data collection period (1)'' and ''Yes, but for only part of the organization's continuous, 12-month data collection period (2).'' The ''No (0)'' response would not change. Respondents from organizations that billed for ground ambulance services during part of, but not all of, its continuous, 12-month data collection period, would select ''Yes, but for only part of the organization's continuous, 12-month data collection period (2)''. Those that did so would be prompted to enter the date they started and/or stopped operations during the continuous, 12-month data collection period in a pop-up box, followed by an instruction to proceed through the remainder of the GADCS reporting process.

Organizations selecting ''Yes, throughout the organization's continuous, 12-month data collection period (1)'' would proceed through the rest of the GADCS reporting process as do respondents answering ''Yes (1)'' to this question currently. Organizations selecting ''No (0)'' would, as is currently the case, be prompted with several follow-up questions which result in either outreach to the GADCS helpdesk for assistance if the listed NPI does not match their organization, or if they answer that none of the scenarios in the follow-up questions apply, or the completion of the organization's data reporting requirement.

This approach allows CMS to understand when reported costs, revenue, and utilization are measured over a period of time less than a full 12 months and, if necessary, to adjust partial-year responses so that they are more comparable to most responses that will cover a continuous full 12-month data collection period. Furthermore, we believe this approach will reduce confusion and burden for organizations in operation for only part of their 12-month data collection periods.

We invite comments on this proposal to address partial-year responses.

2. Programming Logic for Hospitals and Other Medicare Providers of Services

Section 2 of the GADCS printable instrument includes a programming note after Question 9 reading: ''For the remainder of the data collection instrument, instructions and items related to fire, police, or other public safety department-based ground ambulance organizations are shown to organizations that answer Section 2, Question 7 = ''a'' or ''b'' OR Question 8 = Yes (1) OR answer Question 9 = Yes (1) to one or both of a and b.'' The intent of this programming note is to ensure questions in Section 7 (Labor Costs) present instructions and response fields appropriate to organizations with staff having both ground ambulance and fire, police, or other public safety responsibilities. In other words, a for-profit, ground ambulance-only organization should not be asked whether they have ground ambulance staff with fire, police, or other public safety responsibilities, while a fire department-based ground ambulance organization should.

Section 2, Question 8 asks whether organizations reporting to be fire department-based (response ''a'' in Section 2, Question 7), police or other public safety department-based (response ''b'' in Section 2, Question 7), or hospital or other Medicare provider of services-based (response ''d'' in Section 2, Question 7) share operational costs between ground ambulance and the respective other reported function. A programming note for Section 2, Question 8 states that the question should be asked of organizations responding a, b, or d to Section 2, Question 7. As a result, hospitals and other Medicare provider of services-based organizations responding ''d'' in Section 2, Question 7 are presented with Section 2, Question 8, and many may respond ''Yes'' to Section 2, Question 8. As discussed above, answering ''Yes'' to Section 2, Question 8 triggers the appearance of table columns in Section 7, Question 1 related to fire, police, and other public safety staff (''Section 2, Question 7 = ''a'' or ''b'' OR Question 8 = Yes (1) OR answer Question 9 = Yes (1) to one or both of a and b.)

As a result of these programming notes, many hospital-based organizations answering ''d'' to Section 2, Question 7 and ''Yes'' to Section 2, Question 8, and any options other than ''a'' or ''b'' in Section 2, Question 9 will see columns for fire, police, and other public safety staff in Section 7, Question 1, which was not intended. We believe that no ground ambulance organizations with this response pattern will have fire, police, or other public safety staff to report via the GADCS. Furthermore, we are concerned that this will result in confusion for hospital-based organizations.

We are proposing to change the programming note after Section 2, Question 9 to read as follows: ''. . . instructions and items related to fire, police, or other public safety department-based ground ambulance organizations are shown to organizations that: (A) answer Section 2, Question 7 = ''a'' or ''b'' AND answering Question 8 = Yes (1); OR, (B) answer Question 9 = Yes (1) to one or both of ''a'' or ''b''.'' This change to the programming logic will result in provider-based ground ambulance organizations seeing only two columns in Section 7, Question 1, one for paid and the other, if applicable, for volunteer staff, and not columns specific to staff with fire, police, or other public safety responsibilities.

We invite comments on this proposal to change the programming note after Section 2, Question 9 in the GADCS printable instrument.

3. Typos and Technical Corrections

We are proposing to make four corrections to the GADCS printable instrument.

- Section 2, Question 1a.ii is missing the word ''period'' after ''data collection'' in the text. Therefore, we are proposing the question to read as: ''The NPI was in operation during the data collection period but was not used during the data collection to bill Medicare for ground ambulance services.''
- Section 2, Question 3 in the printable instrument questions ''What is the name of your organization? For the remainder of the instrument, the term

''organization'' refers to the NPI for which we are requesting data. (enter name)'' while the web-based GADCS asks ''Is [ORGANIZATION NAME] the name of your organization? For the remainder of the instrument, the term 'organization' refers to the NPI for which we are requesting data. Yes (1)/ No (0).'' The web-based GADCS asks the question in this way because organization name is pre-populated in the system and not entered directly. We are proposing to change the language in the printable instrument to match the text in the web-based GADCS for consistency.

- Section 9.1 (Ground Ambulance Vehicle Costs), Question 5 current wording states ''Do not report ground ambulance acquisition costs related to an annual depreciation expense for the same ambulance'' which does not make sense. We are proposing Question 5 to read as: ''Do not report an acquisition cost and an annual depreciation expense for the same ground ambulance.''
- Section 9.2 (Other Vehicle Costs (Non Ambulance)), Question 5 current wording includes the same error as noted above for Section 9.1, Question 5, and also mistakenly refers to ground ambulances rather than non-ambulance vehicles: ''Do not report non-ambulance vehicle acquisition costs related to an annual depreciation expense for the same ground ambulance.'' We are proposing to change the question to read as: ''Do not report an acquisition cost and an annual depreciation expense for the same ground non-ambulance vehicle.''

We invite comments on these proposals related to GADCS typos and technical corrections.

O. Hospice: Changes to the Hospice Conditions of Participation

1. Background and Statutory Authority

We have broad statutory authority for most provider and supplier types to establish health and safety regulations, which includes the authority to establish health and safety requirements that advance health equity for underserved communities. Certain status explicitly gives CMS the authority to enact regulations that the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in an institution, while others give CMS the authority to prescribe regulations as may be necessary to carry out the administration of the program. Section 122 of the Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97–248) (TEFRA), added section 1861(dd) to the Act to provide coverage for hospice care to terminally ill Medicare beneficiaries who elect to receive care from a Medicare-participating hospice. Under the authority of section 1861(dd)(2)(G) of the Act, the Secretary has established the Conditions of Participation (CoPs) that a hospice must meet to participate in Medicare and/or Medicaid, and these conditions are set forth at 42 CFR part 418. The CoPs apply to the hospice as an entity, as well as to the services furnished to each individual under hospice care. Under section 1861(dd), the Secretary is responsible for ensuring that the CoPs and their enforcement, are adequate to protect the health and safety of the individuals under hospice care. To implement this requirement, State survey agencies conduct surveys of hospices to assess their compliance with the CoPs.

The Consolidated Appropriations Act of 2023 (Pub. L. 117–328) (CAA 2023), was signed into law on December 29, 2022. Division FF, section 4121 of the CAA 2023 establishes a new Medicare benefit category for marriage and family therapist (MFT) services and mental health counselor (MHC) services furnished by and directly billed by MFTs and MHCs, respectively. Section 4121(b)(2) of CAA 2023 specifically adds these services to covered hospice care services under section 1861(dd)(2)(B)(i)(III) of the Act. In order to implement division FF, section 4121 of the CAA 2023, we are proposing to modify the requirements for the hospice CoPs at § 418.56 ''Interdisciplinary group, care planning and coordination of service'' and § 418.114 ''Personnel qualifications.'' This statutorily-required modification allows MHCs or MFTs to serve as members of the interdisciplinary group (IDG). Specifically, the CAA 2023 revised section 1861(dd) of the Act to state that the hospice interdisciplinary group is required to include at least one social worker, MFT, or MHC. In addition, we are proposing to modify the hospice personnel qualification at § 418.114(c) to also include qualifications for an MFT and an MHC.

2. Provisions of the Proposed Regulations

a. Updates to the Hospice CoPs To Permit Mental Health Counselors or Marriage and Family Therapists To Serve as Members of the Hospice Interdisciplinary Group (§§ 418.56 and 418.114)

The CAA 2023 established the new Medicare benefit category for MFT services and MHC services furnished by and directly billed by MFTs and MHCs.

In accordance with the statute, we propose to revise § 418.56(a)(1)(iii) to specify that the IDG must include a social worker (SW), an MFT, or an MHC. In addition, we believe that with the introduction of MHC and MFT into the hospice CoPs, it is important to also include these new disciplines into the personnel qualifications at § 418.114. Currently the requirement at § 418.114 establishes the requirements for several disciplines that work in hospices including but not limited to social worker, nurse and the therapist. In this rule, we are proposing to add both MHC and MFT to the provider requirements under 42 CFR subpart B, Medical and Other Health Services at §§ 410.54 and 410.53. Therefore, to avoid duplication and confusion between the CoP and the Medical and Other Health Services requirements, we are proposing to add both MHC and MFT to the requirements as new standards at § 418.114(c)(3) and (4) and reference the new requirements at §§ 410.54 and 410.53, respectively.

We note that the CAA 2023 specifically modified the statute to require the hospice interdisciplinary team to include at least one SW, MFT or MHC. However, we emphasize that each hospice patient and family are different in their needs and goals. Therefore, it is important for the hospice to assess and determine, along with the input from the patient and family, which care and services best align with the preferences and needs of the patient.

Furthermore, while we believe the role of the SW in hospice is unique and paramount to quality hospice care and services as the patient and their family approach the end of life, we also understand that some patients may benefit from the care and services of an MFT or MHC. However, the role and training of the SW, MFT and MHC vary greatly. As part of the SW role they offer unique support and services to the patient and family such as explaining what hospice care is and the role of the hospice team, assisting the patient and family in navigating the healthcare system, assisting patients and their family in understanding care options as they relate to patient goals and life circumstances, and identifying and working with the patient and their family to connect the patient to other services that may improve the patients quality of life. For example, a SW can make a referral for Meals on Wheels or link the patient to the Veteran's Administration (VA) and other benefits. The hospice SW can also guide the patient and family in applying for financial assistance or resources, such

as Medicaid, temporary assistance programs for energy or utilities, or county assistance programs. In addition, hospice SW are educated to assist patients in completing a living will and other advance directives, as well as educating patients about health care choices and assisting the patient and family in understanding the differences between wills and powers of attorney. They assist patients and family in deciding what environment is best for the patient to receive care and coordinate the many requirements for transferring the patient to the most appropriate care setting. For example, the SW will assist the patient as they transition from a hospital, assisted living facility or nursing home back to their home, or vice versa.

SW, MFTs and MHCs have some similar roles and responsibilities as they relate to counseling. All three of these providers can assist the patient and family with issues related to family dynamics, assessing situations, strengths, and the patient's support network. They can also assist patients and families with navigating the changes and challenges at the end of life including grief counseling and coping strategies to ease day to day emotions. The SW, MFT, or MHC can also provide age-appropriate education and emotional support for children and grandchildren. Some examples of this include providing activities that allow them to express their feelings appropriately, leading support groups, and providing individual, couples, and family counseling. The addition of the MFT and MHC may also be particularly beneficial for individuals living in rural areas who were previously not able to access these types of services.

We acknowledge that there are clear similarities and differences between SWs, MFTs and MHCs, ranging from offered services to experience to scope of practice. While the services SWs, MFTs, and MHCs provide are not interchangeable, each offers unique supports that may be valuable to the patient and family based on the situation. Therefore, the individual hospice patient's needs, preferences, and goals, should guide the determination of which member of the team (SW, MFT or MHC) serves as the member of the IDG for that patient. For example, if the patient's assessed needs relate to VA benefits, the SW may be the most appropriate provider to meet those needs. However, if the patient's assessed needs are related to unresolved issues with their spouse, it may be appropriate to have MHC or MFT provide services to the patient. We believe the ability for hospice patients to receive additional mental health services and supports as part of their hospice care may empower patients and their families in decision making, thus improving the overall health and safety of the patient.

b. Personnel Qualifications (§ 418.114)

As noted above, Division FF, section 4121 of the CAA 2023 requires CMS to permit an MHC or MFT to serve as members of the IDG. As discussed previously, we are proposing to modify the language at § 418.56 regarding the composition of the IDG to include MHCs and MFTs.

P. Request for Information: Histopathology, Cytology, and Clinical Cytogenetics Regulations Under the Clinical Laboratory Improvement Amendments (CLIA) of 1988

1. Background

The Clinical Laboratory Improvement Advisory Committee (CLIAC), CMS, interested parties, and State Agency (SA) surveyors have identified areas in the CLIA requirements that may need updating.

a. Histopathology

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578, October 31, 1988) regulations related to histopathology have not been updated since 1992. The current Histopathology requirements may not represent new innovations and technology performed in laboratories.

(1) Slide Preparation and Staining

Facilities only collecting or preparing specimens (or both) or only serving as a mailing service but not performing testing are not considered laboratories.[278] Slide staining and tissue processing have not been subject to the CLIA regulations. However, we received inquiries from interested parties stating that slide staining and tissue processing are an essential part of the testing process for histopathology. Absent these steps, the tissue cannot be prepared, mounted onto a slide, or accurately evaluated by a pathologist to make an assessment for diagnosis.

Slide staining in histopathology includes routine Hematoxylin and Eosin (H&E) staining, special stains, and immunohistochemical (IHC) stains. Routine slide staining in histopathology provides simple cellular identification and requires minimal steps with solutions, dyes, and clearing reagents (for example, Hematoxylin & Eosin stains, Giemsa stain). An individual trained under the supervision of a qualified technical supervisor can perform these staining techniques. An independent facility (for example, a processing center, that performs slide staining) is not required to hold a CLIA certificate. IHC stains are complex stains designed to identify specific antigens and targets within the cells. These targets can include ribonucleic acid (RNA) and deoxyribonucleic acid (DNA) specific reactivity. The U.S. Food and Drug Administration (FDA) has categorized instruments that perform automated IHC staining as high complexity. Therefore, individuals that perform IHC staining in a CLIA certified laboratory (for example, histotechnicians, histotechnologists, and pathology assistants) must meet the personnel requirements for facilities carrying out high complexity testing. The facility must also hold a CLIA certificate in the subspecialty of testing performed.

(2) Gross Tissue Examination Review

Testing in histopathology includes both gross tissue examination (macroscopic) and the microscopic evaluation of the stained slide(s) with evaluation and diagnostic interpretations, and the reporting of diagnostic findings by qualified personnel. Gross examination means the manipulation, orientation, and selection of the desired representative pieces of excised tissue from the total specimen received. This includes the physical examination and description, color, weight, measurements, and other characteristics of the tissue. Selected portions of the tissue are placed into a tissue cassette, subjected to a fixative, processed and infiltrated with paraffin wax, placed onto a slide(s), and stained before being reviewed and evaluated by a technical supervisor.

The CLIA State Operations Manual (SOM), Appendix C (''Interpretive Guidelines'') [279] for 42 CFR 493.1489(b)(7) state that gross examinations may be performed by individuals qualified under § 493.1489 as delegated by the technical supervisor. The technical supervisor is not required to provide on-site supervision, but is responsible for the review, accuracy, and confirmation of the macroscopic gross examination in the patient report. The documentation of the review of the results of the macroscopic gross examination by the technical supervisor must be included in the signed microscopic examination report, as

[278] See definition of ''laboratory'', *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#493.2*.

[279] CLIA Interpretive Guidelines: *https://www.cms.gov/regulations-and-guidance/legislation/clia/interpretive_guidelines_for_laboratories*.

required at § 493.1273(d). The CLIA regulations do not cover the acceptable timeframe in which the review of the gross tissue examination must be completed. The discussion surrounding the review of the gross tissue examination includes CLIA's oversight at this phase of the histopathology testing process. CLIA supports an acceptable timeframe to permit a pathologist to review the tissue specimen prepared during the gross examination by a qualified technical supervisor. This review can be delegated by the technical supervisor to a qualified individual. Gross examination is a critical part of the tissue analysis process to ensure subsequent pathology tests are accurate and reliable. The review of the gross tissue is important to protect the patient's specimen identification during the testing process.

b. Cytology

(1) CLIA Statute and Regulations

CLIA revised section 353 of the Public Health Service Act (42 U.S.C 263a) to authorize the regulation of all clinical laboratories. Section 353(4)(B)(vi) of the Public Health Service Act requires that all cytological screening be done on the premises of a laboratory that is certified under this section.

The CLIA regulations for cytology state that cytology slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology at § 493.1274(a).

(2) Clinical Laboratory Improvement Amendments (CLIA) Guidance for Temporary Testing Sites Under the Multiple Site Exception,[280] CMS Policy Memo (QSO–22–13–CLIA)

The intent of the CLIA program is to ensure that test results provided to individuals and their healthcare providers are accurate, timely, and reliable. During the COVID–19 public health emergency (PHE), we issued memo QSO–22–13–CLIA that informed interested parties that we exercised enforcement discretion to allow pathologists the ability to examine histopathology and cytology slides/images remotely, under the following conditions:

- The primary laboratory's CLIA certificate must include the specialty of pathology with the subspecialties of histopathology and cytology, as appropriate.
- The remote location complies with other applicable Federal laws, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA).
- The primary laboratory's written procedure manuals for tests, assays, and examinations are available to the pathologists at the remote location.
- Retention time for histopathology slides (10 years), specimen blocks (2 years), preserved tissue remnants (until a diagnosis was made), and cytology slides (5 years) were maintained.
- The use of equipment, supplies and reagents, and similar items needed at the remote location are not allowed to be permanently stored on site.

Under the memorandum, QSO–22–13–CLIA, the remote location could allow pathologists the opportunity to examine histopathology and cytology slides for specified intervals of time to include a PHE, medical condition, or a situation where a pathologist has to examine slides away from the primary location.

Pathologists that currently hold a CLIA certificate are exempt from this enforcement discretion. The pathology community has expressed their desire to make this enforcement discretion a permanent provision after the end of the PHE for COVID–19.

c. Clinical Cytogenetics

We require any testing facility that meets the CLIA regulatory definition of a ''laboratory'' (per § 493.2, *Definitions*[281]) to have a CLIA certificate. A laboratory may choose to outsource a test or a portion of their test procedure because it lacks the equipment, personnel with the expertise in the subject, or is considered more cost-efficient. The CLIA regulations at § 493.1242(c) require the laboratory to only refer a test (for example, reflex, confirmatory, or distributive testing) to another laboratory that is CLIA certified or a laboratory meeting equivalent requirements as determined by CMS. Therefore, each laboratory or testing facility that performs clinical testing must have its own CLIA certificate and comply with the regulations for the complexity of the testing it performs.

Clinical cytogenetics testing is generally categorized as a CLIA high complexity test. A cytogenetics test may be conducted at one facility, or involve a testing workflow model in which one facility performs the analytical bench testing activities (for example, sample processing, extraction, chemical reaction, slide preparation, imaging) and another facility conducts the non-bench testing activities (for example, review of images, analysis, interpretation or reporting of the results). When any part of a test is performed by more than one facility, this testing model is considered distributive testing. CLIA defines distributive testing under § 493.2, *Definitions,* as ''laboratory testing performed on the same specimen, or an aliquot of it, that requires sharing it between two or more laboratories to obtain all data required to complete an interpretation or calculation necessary to provide a final reportable result for the originally ordered test. When such testing occurs at multiple locations with different CLIA certificates, it is considered distributive testing.'' Therefore, any facility performing clinical cytogenetics testing activities must be CLIA certified and meet high complexity testing requirements.

During the PHE for COVID–19, we exercised enforcement discretion regarding clinical cytogenetics distributive testing models. Under the enforcement discretion, we allowed clinical cytogenetics personnel the opportunity to examine clinical cytogenetics digital images (that is, non-bench testing activities) at a remote testing location without obtaining a separate CLIA certificate for the remote site under certain conditions. Some interested parties have requested we make this enforcement discretion permanent. Changes to the current CLIA regulations would be necessary to allow the examination of clinical cytogenetics images at a different, remote location from the primary CLIA-certified site without a separate CLIA certificate. Please note that a remote location not associated with or covered by a primary CLIA-certified laboratory would be required to obtain its own CLIA certificate. The primary site laboratory director would be responsible for the overall operation and administration of the laboratory including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately, and proficiently; for assuring compliance with applicable regulations in their primary laboratory; and for the supervision of the personnel reviewing digital laboratory data, digital results, and digital images remotely.

2. Solicitation of Public Comments

We are soliciting public input and comment on the following areas of CLIA: Histopathology; Cytology; and Clinical cytogenetics. The topics listed in this RFI are areas that CMS, CDC,

[280] QSO–22–13–CLIA: *https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/clinical-laboratory-improvement-amendments-clia-guidance-temporary-testing-sites-under-multiple-site.*

[281] See definition of ''laboratory'', *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#493.2.*

interested parties, and SA surveyors have identified that may potentially be used by CMS for future rulemaking.

a. Histopathology

We are seeking public comments on the following:

- Whether, and how, CLIA should provide oversight of histopathology preparation and processing of tissue samples for slide staining, specifically related to guidance for routine histopathology slide staining and complex IHC staining.
- What criteria (for example, training programs, on-the-job training, experience, or academic degree) would interested parties recommend for personnel performing high complexity automated IHC staining?
- How does the categorization of automated staining systems impact personnel who are currently performing this task but do not meet the qualifications for performing high complexity testing?
- What is an acceptable timeframe between the review of the macroscopic gross tissue examination, and the review and confirmation of these tissue findings by a pathologist prior to the microscopic review of slides to protect the integrity of the macroscopic tissue?
- What education and experience or training requirements should be required for individuals to qualify as a general supervisor (GS) for histopathology? If qualified, what is an acceptable timeframe for the GS to review and evaluate gross examinations under the specialty of histopathology?
- What education and professional experience, or training requirements should be required for individuals performing gross tissue examination that have an associate degree from a histotechnician program or a PA who has training from an accredited program and is certified as a PA?

b. Histopathology and Cytology Testing at Remote Locations

We are seeking public comments on the following:

- How should ''remote testing location'' be defined?
- How should the CLIA regulations be revised to allow pathologists to examine histopathology and cytology slides/images at a remote testing location?
- What conditions (including, location(s)) should apply for a pathologist to examine histopathology or cytology slides/images remotely without obtaining a separate CLIA certification?
- Under what conditions should a primary location cease permitting testing at the remote location?
- How should the remote location be included on the final patient report?
- How should CMS, SAs, or Accreditation Organizations perform onsite surveys at remote locations?

c. Clinical Cytogenetics

We are seeking public comments on the following:

- Under what circumstances should CLIA allow remote locations or testing facilities to examine clinical cytogenetics images without obtaining a separate CLIA certification?
- Under what circumstances would the examination of clinical cytogenetics images be unacceptable for the remote location scenario?
- What clinical cytogenetics testing processes should the primary laboratory have in place to ensure the remote site complies with the CLIA requirements?
- What ''conditions'' or ''criteria'' would be necessary for the remote location to ensure quality testing for the examination of clinical cytogenetics images?

Q. Changes to the Basic Health Program Regulations

Section 1331 of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted March 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010) (collectively referred to as the Affordable Care Act or ACA), provides States with the option to operate a Basic Health Program (BHP). In the States that elect to operate a BHP, the State's BHP makes affordable health benefits coverage available for lawfully present individuals under age 65 with household incomes between 133 and 200 percent of the Federal poverty level (or in the case of a lawfully present non-citizen, ineligible for Medicaid or the Children's Health Insurance Program (CHIP) due to immigration status, whose household income is between zero and 200 percent of the FPL) who are not eligible for Medicaid, CHIP, or other minimum essential coverage. As of the date of this proposed rule, only New York and Minnesota have implemented a BHP.

Federal funding for BHP is based on 95 percent of the value of the premium tax credits (PTC) and cost sharing reduction (CSR) subsidies that BHP enrollees would have received had they instead enrolled in Qualified Health Plans (QHPs) through the Exchange in accordance with section 1331(d)(3)(A)(i) of the ACA. These funds are paid to trusts established by the States and dedicated to the BHP, and the States then administer the payments to BHP standard health plans within the BHP. Under section 1331(d)(2) of the ACA, Federal funding for the BHP can only be used to reduce the premiums and cost-sharing of, or to provide additional benefits for, eligible individuals enrolled in standard health plans within the State.

1. Allowing States To Suspend a BHP

Current regulations require States to operate a BHP under a certified Blueprint approved by CMS, and to operate the BHP as long as their approved certified Blueprint is in place. Under 42 CFR 600.140, a State may terminate its BHP, which requires that the BHP trust fund balance must be refunded to the Federal government. A State has inquired about whether it could ''suspend'' its program for a portion of time, so that it could shift BHP enrollees to other coverage with comparable benefits and cost sharing, while maintaining its BHP trust fund, which it could use if the State were to resume the BHP.

We see the value in allowing a State currently operating a BHP to experiment with other ways of providing coverage that may increase the number of people covered while not increasing Federal costs. We propose to give a State the option of temporarily ''suspending'' its BHP program, while retaining accrued funds in the BHP trust fund for a limited period of time. Should the State decide to resume operating its BHP, the suspension would allow the State to leverage accrued funds and avoid the processes of terminating the program and refunding trust funds, and then later having to submit a new BHP application for approval. For that reason, under the authority of section 1331(c)(4) of the ACA, which requires coordination with other State health programs, we are proposing to amend § 600.140 to add an option at paragraph (b) for a State to suspend its BHP.

We propose at § 600.140(b)(1) that States wishing to suspend their BHP must submit an application to HHS. Under proposed § 600.140(b)(1), States could also seek approval to extend a BHP suspension previously approved by HHS. In § 600.140(b)(1)(vi), we propose that the application must be submitted at least 9 months in advance of the proposed effective date of the suspension or extension. In § 600.140(c), we propose that the State cannot implement the suspension or extension without prior approval by the Secretary. However, for States seeking to suspend a BHP in the first plan year that begins

following publication of a final rule adopting this proposal, States must submit an application within 30 days of the publication of such a final rule. HHS will approve or deny such application as expeditiously as possible. We propose in § 600.140(b)(2) that a suspension application would need to be approved prior to the effective date of suspension, except in the case of a State seeking to suspend a BHP in the first plan year that begins following publication of a final rule adopting this proposal.

The proposed substantive requirements for the suspension application are described in § 600.140(b)(1)(i) through (v). During the period of suspension, BHP enrollees should receive comparable coverage that is as comprehensive and affordable as, or more comprehensive and affordable than, BHP coverage during the period of suspension. Therefore, in § 600.140(b)(1)(i) through (iii), we propose to require that the suspension and extension application demonstrates that the benefits that will be provided to individuals that meet the BHP eligibility criteria are at least equivalent to the benefits offered in the State's BHP. We propose that the cost sharing and premiums that will be charged to such individuals under the new coverage option do not exceed the amounts charged under the BHP to reduce the risk that these individuals are harmed by the transition to other coverage.

We propose at § 600.140(b)(1)(i) to require that benefits provided under the new coverage option must be at least equal to the BHP benefits in the certified Blueprint in effect on the effective day of suspension. This is the same standard that is used in the Medicaid regulations at § 440.330 to determine if a State's alternative benefit package is equivalent to the benchmark benefit package. Additionally, it is similar to the standard that is used by CHIP at § 457.420 to determine if a State's CHIP benefit package is equivalent to the benchmark benefit package, although the CHIP standard allows for some variation if the State is adding additional benefits as required by Title XXI. We note that it would be acceptable to provide additional benefits under the new coverage option, such that individuals receive more or greater benefits under the new coverage option. We considered whether there should be a look back period, such that benefits under the new coverage option would be compared to the BHP benefits provided under the certified Blueprint in effect for a period of time prior to the effective date of the suspension and seek comments on this alternative approach.

In order to determine that the cost sharing required of individuals under the new coverage option does not exceed the BHP cost sharing levels, we propose at § 600.140(b)(1)(ii) to require that the actuarial value of the new coverage option must meet or exceed the actuarial value of the BHP standard health plans in effect immediately prior to the suspension period. This may result in cost sharing for individual benefits differing between the BHP and the new coverage program, provided the actuarial value of the new coverage options meets or exceeds the actuarial value of the BHP standard health plans. If there are multiple health plans being offered under the new coverage option and/or multiple standard health plans in effect in the State, we propose that the median actuarial value of the health plans offered under the new coverage option must meet or exceed the median actuarial value of the BHP standard health plans. We considered whether to require that cost sharing under the new coverage option instead meet the cost sharing requirements under current regulations at § 600.520(c) and seek comment on whether this alternative approach should be adopted in the final rule.

Similarly, we propose at § 600.140(b)(1)(iii) to require that the premiums charged to individuals under the new coverage option must be comparable to BHP standard health plan premiums in effect immediately prior to the suspension period, beyond reasonable increases due to inflation as measured by the Consumer Price Index (CPI). We considered alternative methods for measuring equivalency in premiums. First, we considered whether to require that premiums under the new coverage option instead meet the premium requirements under § 600.505(a). Second, we considered whether premiums charged to individuals under the new coverage option should instead not exceed the premiums in effect on December 31, 2020, as these premiums levels do not account for any additional premium tax credit subsidies offered under the American Rescue Plan Act or the Inflation Reduction Act. Third, we considered whether premium and cost sharing levels, considered together, under the new coverage option would be considered sufficient, if those levels meet the requirements under a section 1115 demonstration or section 1332 waiver. We also seek comment on whether these alternative approaches should be adopted in the final rule.

We also considered alternatives to the timing of the comparison of benefits and cost sharing in BHP to the new coverage option. Specifically, we considered whether benefits and cost sharing under the new coverage option should be compared to the benefits and cost sharing under the BHP on the date the suspension application is submitted to HHS, or some other date. We also seek comment on the potential adoption of these alternatives in the final rule.

Finally, we believe that the suspension period should not result in individuals losing coverage, solely due to a change in eligibility criteria for the program. Therefore, we are proposing in § 600.140(b)(1)(iv) that a state must demonstrate in its application that the eligibility criteria for coverage during the suspension is not more restrictive than the criteria described in § 600.305.

We believe that the suspension period should be long enough to allow the State to evaluate the alternative coverage provided to BHP eligible individuals, but should not be indefinite. Therefore, we are proposing in § 600.140(b)(1)(v) that a State could request a suspension of up to 5 years in an initial suspension application, after which a State could request an extension of up to 5 additional years. Additional extension periods would not be allowed. When the suspension period, including any extension period, ends, we propose that the State would need to transition the BHP eligible population back to the BHP, or terminate the BHP. We propose at § 600.140(b)(7) that at least 9 months before the end of the suspension period, a State must submit a transition plan to HHS that explains how the State will reinstate its BHP, or terminate the program under § 600.140(a) of the current regulations. The state must also notify the public of this change. Under proposed § 600.140(b)(7), a State also could elect to end a BHP suspension before the end of the initial or extended suspension period by following the same process.

We chose 5 years for the initial approval period because this aligns with the duration of initial waivers and demonstration projects approved under section 1332 of the ACA and section 1115 of the Act. We believe these are the most likely authorities under which States could seek to provide alternative coverage to BHP enrollees. Similarly, we chose 5 years for the extension period because it aligns with the duration of typical extensions or amendment periods under section 1332 waiver and section 1115 demonstration projects. We considered a shorter extension period of 2 or 3 years, and allowing multiple

extension periods given both section 1332 waiver and 1115 demonstrations can be extended. We seek comment on these alternatives.

Under proposed § 600.140(b)(1)(vii), States requesting an extension of a previously-approved BHP suspension also would need to provide an evaluation of the alternative coverage in its application. In the case of alternative coverage provided through a section 1115 demonstration project or section 1332 waiver, the evaluation and application required for such demonstration projects and waivers would satisfy this requirement.

If individuals and/or standard health plans will experience a change in the terms of the coverage, including receiving additional benefits or being charged different cost sharing amounts, in § 600.140(b)(3), we propose to require that the state provide notice to them at least 90 days prior to the effective date of the suspension. The notices would need to include information regarding the State's assessment of their eligibility for all other insurance affordability programs in the State, and meet the accessibility and readability standards at 45 CFR 155.230(b).

In order to calculate a State's BHP payments, the State provides CMS an estimate of the number of BHP enrollees it projects will enroll in the upcoming BHP program quarter each quarter of program operations. We use those estimates to calculate the prospective payment, which is deposited in the State's BHP trust fund. Once the State provides us with actual enrollment data for those periods, the actual enrollment data is used to calculate the final BHP payment amount and make any necessary reconciliation adjustments to the prior quarters' prospective payment amounts due to differences between projected and actual enrollment.

We believe that having an accurate accounting of the balance of the State's trust fund is critical for any State suspending its BHP. Therefore, we propose to require in § 600.140(b)(4) that States that suspend their BHP must submit the data necessary to complete the BHP payment reconciliation process within 12 months of the effective date of the suspension. We believe that 12 months is a reasonable amount of time for a State to submit the actual enrollment data for the periods it was operating a BHP.

One reason it is important for a State to complete the BHP payment reconciliation process is to establish a baseline balance for calculating interest. Currently, States' BHP trust funds can accrue interest, and this interest is retained in the BHP trust fund. However, we believe that interest accrued on the BHP trust fund during any suspension must be remitted to HHS. Since the State is not operating a BHP during the suspension period, suspension should not generate additional funds for the State. We propose in § 600.140(b)(6) that while the State is not providing BHP coverage, any accrued interest on the trust fund must be remitted to HHS on an annual basis in the form and manner set out by HHS.

States currently submit the balance of their trust fund and any interest accrued through the BHP annual report described in § 600.170. We proposed revisions to §§ 600.140(b) and 600.170(a) to require States that suspend their BHP continue to submit an annual report in order to document the interest earned and to provide assurance that the coverage provided to BHP-eligible individuals meets the standards discussed above. We propose in § 600.140(b)(5) to require States that suspend their BHP continue to submit an annual report during the suspension period. We proposed amendments to § 600.170(a), which describes the requirements for the annual reports, to describe the standards that will apply to States that have suspended their BHP. Specifically, we propose to redesignate the introductory language in paragraph (a) as paragraph (a)(1), to redesignate paragraphs (a)(1) through (a)(4) as paragraphs (a)(1)(i) through (a)(1)(iv), and to add a new paragraph § 600.170(a)(2) to require that States that have suspended their BHP under § 600.140(b) must submit an annual report that includes (1) the balance of the BHP trust fund and any interest accrued on that balance; (2) an assurance that the coverage provided to individuals who would be eligible for a BHP under § 600.305 continues to meet the standards described in § 600.140(b)(1)(i) through (iii); and (3) any additional information specified by the Secretary at least 120 days prior to the date that the annual report is due.

If a State does not meet the proposed requirements (that is, completing the financial reconciliation process, remitting interest on the trust fund, and submitting the required information in its annual report), we propose in § 600.140(d) that the Secretary can withdraw approval of the suspension. Specifically, we propose that the Secretary can withdraw approval of the suspension if the State ends implementation of the alternative coverage program for any reason, or if the State fails to continue to meet the coverage and cost sharing requirements of the alternative coverage program. If the State seeks an amendment to the alternative coverage program, the State must inform CMS of this proposed change so that CMS may evaluate if the coverage is sufficient. In addition, we propose at paragraph (d) that we could also withdraw approval if we have significant evidence of harm, financial malfeasance, fraud, waste, or abuse consistent with § 600.142. In § 600.140(d)(1) through (4), we propose a process for withdrawing approval, which mirrors the process for withdrawing certification of a BHP Blueprint in § 600.142. Specifically, we propose that the Secretary will withdraw approval only after providing the State with notice of the findings upon which the Secretary is basing the withdrawal, a reasonable period for the State to address the finding, and an opportunity for a hearing before issuing a final finding. We propose that the Secretary shall make every reasonable effort to resolve proposed findings without withdrawing approval of the suspension plan and in the event of a decision to withdraw approval, will accept a request from the State for reconsideration. The effective date of an HHS determination withdrawing approval of the suspension plan would not be earlier than 120 days following issuance of a final finding. Within 30 days following a final finding under paragraph (d)(1) of this paragraph, the State shall submit a transition plan to HHS.

During the transition period from the BHP to other coverage the state may not use funds from the BHP trust fund toward the unwinding of the BHP program and transition to the new coverage program. Under section 1331(d)(2) of the ACA and current regulations at § 600.705(c), Federal funding for BHP can only be used to reduce the premiums and cost-sharing, or to provide additional benefits, for BHP-eligible individuals enrolled in standard health plans within the State. Therefore, Federal funding is not available for administrative expenses associated with transitioning BHP enrollees to a new coverage program or for costs associated with providing new coverage after the transition has occurred. States cannot use Federal BHP funding to cover premiums and cost sharing (or additional benefits) for individuals that would otherwise be eligible for BHP funding. We solicit comment on these proposals.

We seek comment on the proposed process for suspending a BHP. Specifically, we seek comment on how far in advance of suspension a state must submit a suspension application to CMS and how far in advance of

suspension CMS must approve or deny the suspension request. We also seek comment on duration of time a state may suspend their BHP, without terminating the program.

2. Submission and Review of BHP Blueprints

As noted above, under current § 600.110, States must submit to the Secretary and receive certification of a BHP Blueprint describing their operational design choices prior to implementation. Under the current § 600.125(a) a State that seeks to make significant changes to its BHP must submit a revised Blueprint to the Secretary for review and certification; however, the current regulation does not specify any timeframes for the submission and review of revised Blueprints. The current § 600.125(a) also describes a limited number of changes under which submission of a revised Blueprint is required. Most notably, the current regulation does not require the submission of a revised Blueprint in response to changes in Federal law or regulations. Additionally, under current § 600.125(a) and (b), any changes made in a revised Blueprint can be implemented prospective from the date of certification; no changes can be implemented until HHS certifies the revised Blueprint.

We believe that additional parameters are necessary in order to ensure effective and efficient operation of the BHPs and HHS review of a revised Blueprint, consistent with section 1331(a)(1) of the ACA. Therefore, we propose changes to § 600.125 to establish timeframes and procedures for the submission and review of BHP Blueprints, similar to the Medicaid and CHIP State plan amendment (SPA) submission and review processes. We note that these proposed timeframes only apply to the submission and review of revised Blueprints; we are not proposing changes to the timeframes for the submission and review of an initial Blueprint, set forth in current regulations at § 600.120, in the event additional States seek to establish BHPs.

Additionally, we believe States need flexibility to receive approval of a retroactive effective date for changes to their BHP Blueprint, similar to flexibilities allowed under regulations at §§ 430.20(b) and 457.60 for the submission of Medicaid and CHIP SPAs. We note, however, that in the event that a State implements a change to its BHP Blueprint that is ultimately disapproved by HHS, the State could be required to implement a corrective action plan under § 600.715.

Specifically, under existing regulations at § 600.125(a), States must submit a revised Blueprint whenever they seek to make significant change(s) that alter program operations the BHP benefit package, enrollment, disenrollment and verification policies described in its certified BHP Blueprint. Under the proposed revisions to § 600.125(a), we would broaden the circumstances requiring submission of a revised Blueprint to include States' significant changes that alter any core program operations under § 600.145(f). States also would be required to submit a revised Blueprint to HHS whenever necessary to reflect changes in Federal law, regulations, policy interpretations, or court decisions that affect provisions in their certified Blueprint. States would continue to be required to submit a revised Blueprint to make changes to the BHP benefit package or to enrollment, disenrollment, and verification policies described in the certified Blueprint, as currently required under § 600.125(a).

At § 600.125, we also propose to redesignate paragraph (b) as paragraph (d) and to add new paragraph (b) to provide that the effective date of a revised Blueprint may be as early as, but not earlier than, the first day of the quarter in which an approvable revision is submitted to HHS. This policy mirrors the standards for submission of a Medicaid SPA at § 430.20(b). The current regulations do not specify as to when revision is considered received. We believe that it is reasonable to consider a revised Blueprint to be received when HHS receives an electronic copy of a cover letter signed by the Governor or Governor's designee and a copy of the currently approved Blueprint with proposed changes indicated in track changes. In the event a State is unable to submit a revised Blueprint electronically, due to a disaster or other event outside of the State's control, CMS may consider other modes of submission on a case-by-case basis. Under current regulations at § 600.125(b), redesignated at § 600.125(d) in this proposed rule, the State is responsible for continuing to operate under the terms of the existing certified Blueprint until the State adopts a revised Blueprint, the State terminates or suspends the BHP, or the Secretary withdraws certification for the BHP.

We are also proposing to redesignate paragraph (c) as paragraph (g) and to add a new paragraph (c) to create clear timelines for HHS's review, approval, and disapproval of revised Blueprints similar to the timelines currently applicable to CHIP SPAs under § 457.150. Under proposed § 600.125(c)(1), a revised Blueprint will be deemed approved unless HHS, within 90 days after receipt of the revised Blueprint, sends the State written notice of disapproval or written notice of additional information HHS needs in order to make a final determination. If HHS requests additional information, the 90-day review period will be stopped and will resume the day after HHS receives all of the requested additional information from the State. Under proposed paragraph (c)(2), if 90 days from the date a Blueprint revision is received does not fall on a business day, the 90-day review period will end on the next business day. Under proposed paragraph (c)(3), HHS may send written requests for additional information as many times as needed to obtain all information necessary to certify the revised Blueprint. This mirrors the process used by CHIP, of having one 90-day review period that can start and stop multiple times with a request for additional information and response. It differs from Medicaid, which has a 90-day review period that can be stopped once by a request for additional information, followed by a second 90-day review period when the state responds. At paragraph (c), we propose that HHS may disapprove a Blueprint amendment if the Secretary determines that the Blueprint revision is not consistent with section 1331 of the ACA or the regulations set forth in this part at any time during the review process, including when the 90-day review clock is stopped due to a request for additional information.

Once a Blueprint is approved, current paragraph (b) specifies that the State is responsible for continuing to operate under the terms of the existing certified Blueprint until and unless a revised Blueprint that seeks to make significant change(s) is certified, except during a public health emergency, as described in paragraph (c). We propose to revise paragraph (b), redesignated as paragraph (d) in this proposed rulemaking, to provide that the State must continue to operate under the terms of an existing certified Blueprint until the State adopts a revised Blueprint, terminates the BHP following the procedures described in § 600.140(a), suspends the BHP following the procedures described in § 600.140(b), or the Secretary withdraws certification of the BHP under § 600.142.

Finally, we propose to apply some of the existing parameters for initial Blueprint submissions to Blueprint revisions. In paragraph (e), we propose that a State may withdraw the proposed revised Blueprint during HHS review if the State has not yet implemented the

proposed changes and provides written notice to HHS. This proposal mirrors current § 600.130 for initial BHP Blueprints. In paragraph (f), we propose that HHS will accept a State's request for reconsideration of a decision not to certify a revised Blueprint and provide an impartial review against standards for certification if requested. This proposal mirrors current § 600.135(c) for initial BHP Blueprints.

Under current § 600.135, HHS must act on all initial BHP Blueprint certification and revision requests in a timely matter. Because we are proposing to specify timeframes for the submission and review of revised BHP Blueprints under § 600.125, we propose to revise § 600.135 to apply only to the submission of initial BHP Blueprints. Specifically, we propose to revise the title to clearly state that this section is applicable to only initial Blueprints and to remove the reference to BHP Blueprint revisions in paragraph (a).

3. BHP Notices

Under current § 600.330, States must provide written notice to beneficiaries conveying final determination of eligibility or ineligibility. The regulation does not require States to provide those notices in a manner that is accessible to individuals with disabilities or limited English proficiency (LEP). Although HHS Office for Civil Rights regulations at 45 CFR 92.101, which apply to programs such as Medicaid, CHIP and BHP, require States to take reasonable steps to provide meaningful access for individuals with LEP and to ensure effective communication with individuals with disabilities, we believe it is important for these obligations to also be described clearly in the BHP regulations. Therefore, we are proposing to add paragraph (f) to § 600.330 to require that BHP eligibility notices be written in plain language and be provided in a manner which ensures that eligible individuals with LEP are provided with meaningful language access and individuals with disabilities are provided with effective communication.

4. BHP Appeals

Under current § 600.335(b), individuals must be given the opportunity to appeal BHP eligibility determinations through the appeals rules of the State's Medicaid program or the Exchange, as indicated in the State's Blueprint. Current BHP and Exchange regulations do not provide for appeals of health services matters. We believe all BHP enrollees should be afforded the opportunity to appeal not only eligibility determinations but also decisions about health services matters. The Exchange rules do not include an opportunity to appeal a health services matter, as such appeals are typically handled by State Departments of Insurance, as opposed to by the Exchange itself. Therefore, we propose in paragraph (b) to remove the option for States to conduct their BHP appeals process according to Exchange rules. In paragraph (b)(2), we propose to require States to provide individuals an opportunity to appeal a delay, denial, reduction, suspension, or termination of health services, in whole or in part, including a determination about the type or level of service, after individuals exhaust appeals or grievances through the BHP standard health plans.

Because current BHP regulations do not include provisions related to the appeal of health services matters, these appeals are not currently included in the list of core operations of a BHP in § 600.145. We believe that appeals of health services matter, like appeals of eligibility determinations, are a core function of a BHP. Therefore, in proposed § 600.145(f)(2), we include appeals of health services matters as specified in § 600.335 as a core operation of a BHP.

R. Updates to the Definitions of Certified Electronic Health Record Technology

1. Background

The American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5, enacted February 17, 2009) (ARRA), 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 (EHR) 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 information technology (IT), including EHRs. Requirements for certification are based on standards, implementation specifications, and certification criteria adopted by the Secretary pursuant to section 3004 of the Public Health Service Act. 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 Medicare Promoting Interoperability Program (previously known as the Medicare and Medicaid EHR Incentive Programs), the Shared Savings Program, and the Quality Payment Program, which includes the MIPS Promoting Interoperability performance category and the Advanced Alternative Payment Models (Advanced APMs). While these programs continue to require the use of CEHRT, the use of certified health IT has expanded to other government and non-government programs.

For CY 2019 and subsequent years, the definitions of CEHRT for the Promoting Interoperability Programs at 42 CFR 495.4, the Quality Payment Program at 42 CFR 414.1305, and the Shared Savings Program at 42 CFR 425.20 require the use of EHR technology that meets the 2015 Edition Base EHR definition at 45 CFR 170.102 and is certified to 2015 Edition health IT certification criteria under the ONC Health IT Certification Program. In addition, the CEHRT definitions in our regulations for these programs require technology to be certified to certain specific 2015 Edition health IT certification criteria, as specified in each of the definitions, including criteria necessary to be a meaningful EHR user under the Medicare Promoting Interoperability Program, and criteria necessary to report on applicable objectives and measures specified under the MIPS Promoting Interoperability performance category under the Quality Payment Program. Prior Editions of health IT certification criteria were associated with ''stages'' of the EHR Incentive Programs (now the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category), which linked new and updated functionality in certified health IT to significant revisions to the objectives and measures in the programs.

In the CY 2021 PFS final rule (85 FR 84815 through 84825), we finalized that the technology used by health care providers to satisfy the definitions of CEHRT at 42 CFR 495.4 and 42 CFR 414.1305 must be certified under the ONC Health IT Certification Program, in accordance with the updated 2015 Edition certification criteria (2015 Edition Cures Update), as finalized in the ONC 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (Cures Act) final rule (85 FR 25642). We further finalized aligning the transition period during which health care providers participating in the Medicare Promoting Interoperability Program, the MIPS Promoting Interoperability performance category, and the Advanced Alternative Payment Models (Advanced APMs) 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, Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency (85 FR 70064), for health IT developers to make updated certified health IT available (85 FR 84815 through 84825). After this date, health care providers were required to use only certified technology updated to the 2015 Edition Cures Update for an EHR reporting period or performance period in CY 2023.

In the ONC ''Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing'' proposed rule (88 FR 23746 through 23917) (hereafter referred to as ''ONC HTI–1 proposed rule''), which appeared in the **Federal Register** on April 18, 2023, ONC has proposed to discontinue the year themed ''editions,'' which ONC first adopted in 2012, to distinguish between sets of health IT certification criteria finalized in different rules (88 FR 23758). In the proposed rule, ONC noted public comments stating that the continued use and reference to the 2015 Edition inaccurately implies an age and outdatedness to the certification criteria ONC has adopted. Given these concerns, ONC stated that it believes there should be a single set of certification criteria, which will be updated in an incremental fashion in closer alignment to standards development cycles and regular health IT development timelines (88 FR 23750).

ONC further stated its belief that maintaining a single set of ''ONC Certification Criteria for Health IT'' would create more stability for the ONC Health IT Certification Program and for Federal partners who reference the ONC Health IT Certification Program, as well as make it easier for developers of certified health IT to maintain their product certificates over time (88 FR 23759). ONC stated this proposal to remove ''editions'' from the ONC Health IT Certification Program would also help users of certified health IT identify which certification criteria are necessary for their participation in programs, such as the Medicare Promoting Interoperability Program, the Shared Savings Program, and the Quality Payment Program's MIPS Promoting Interoperability performance category and Advanced APMs (88 FR 23760). For example, users would only need to know that their Health IT Module is certified to 45 CFR 170.315(b)(3), electronic prescribing, for successful participation in the MIPS Promoting Interoperability performance category related to electronic prescribing, as compared to the current state, where they must also know if the Health IT Module supports electronic prescribing as part of the 2014 Edition Certification Criteria or the 2015 Edition Certification Criteria, or 2015 Edition Cures Update Certification Criteria. To implement this approach, ONC has proposed to rename all criteria within the ONC Health IT Certification Program simply as ''ONC Certification Criteria for Health IT,'' proposing associated changes to the regulations at 45 CFR part 170 (88 FR 23759).

Similar to ONC's proposal to move away from ''editions'' and toward incremental changes to its certification criteria, we also have focused on implementing incremental changes to individual measures under, but not limited to, the Medicare Promoting Interoperability Program, the Shared Savings Program, and the Quality Payment Program, which includes the MIPS Promoting Interoperability performance category and the Advanced APMs in recent years. We expect to continue to prioritize incremental changes in future years to reduce burden on participants in these programs (including eligible hospitals and CAHs and MIPS eligible clinicians), and build on the established base of available certified health IT capabilities. We believe our approach is consistent with the strategy discussed in the ONC HTI–1 proposed rule, in which ONC proposes to pursue a framework for the ONC Health IT Certification Program that focuses on incremental updates to a single set of certification criteria.

2. Updates to the Definition of Certified Electronic Health Record Technology in the Medicare Promoting Interoperability Program and the Quality Payment Program

a. Background and Previously Finalized Certification Requirements

In consideration of the updates made to the 2015 Edition certification criteria as described in the CY 2021 PFS final rule (85 FR 84815 through 84828), we finalized that health care providers participating in the Medicare Promoting Interoperability Program and eligible clinicians participating in the Quality Payment Program must use certified health IT that satisfies the definitions of CEHRT at 42 CFR 495.4 and 42 CFR 414.1305, respectively, and is certified under the ONC Health IT Certification Program, in accordance with the 2015 Edition Cures Update certification criteria, as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642). We explained this included technology used to meet the 2015 Edition Base EHR definition at 45 CFR 170.102, technology certified to the criteria necessary to be a meaningful EHR user under the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, and technology certified to the criteria necessary to report on applicable objectives and measures. In this proposed rule, we are proposing revisions to the CEHRT definitions in the Medicare Promoting Interoperability Program and the Quality Payment Program (on which the Shared Savings Program's definition of CEHRT at § 425.20 also relies) to support the proposed transition from the historical state of year themed ''editions'' to the ''edition-less state'' in the ONC HTI–1 proposed rule.

We included Table IX.H.–04 in the Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2024 Rates proposed rule (88 FR 27170), which includes some, but not all, certification criteria for the Medicare Promoting Interoperability Program's measures and eCQMs for eligible hospitals and CAHs, and Table 48 in section IV.A.4.f.(4)(e)(iv) of this proposed rule, which includes some, but not all, certification criteria for measures under the MIPS Promoting Interoperability performance category. These tables are only applicable for the measures under the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, and do 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 50270). For further discussion on the complete list of changes to the certification criteria under the CEHRT definition, we refer readers to the ONC 21st Century Cures Act final rule (85 FR 25667), the CY 2021 PFS proposed rule (85 FR 50265), and the CY 2021 PFS final rule (85 FR 84818 through 84825).

b. Proposed Revisions to Certified Electronic Health Record Technology Definitions in Regulatory Text

We are proposing to revise the definitions of CEHRT in 42 CFR 495.4 and 42 CFR 414.1305 for the Medicare Promoting Interoperability Program and for the Quality Payment Program so these definitions would be consistent with the ''edition-less'' approach to health IT certification as proposed in the ONC HT–1 proposed rule, should the ONC proposal be finalized. First, with respect to references to the ''2015

Edition Base EHR definition'' defined at 45 CFR 170.102, we are proposing to add a reference to the revised name ''Base EHR definition,'' proposed in the ONC HTI–1 proposed rule, to ensure, if finalized, it is applicable for the CEHRT definitions going forward (88 FR 23759). Next, we are proposing to replace our references to ''2015 Edition health IT certification criteria,'' with ''ONC health IT certification criteria'' and to add the regulatory citation for ONC health IT certification criteria in 45 CFR 170.315. By removing the reference to the ''2015 Edition,'' and pointing to the regulations at 45 CFR 170.315, we believe this proposal, if finalized, will ensure the CEHRT definitions do not need to be updated to reflect modified terminology unless ONC changes the location of these certification criteria.

While these proposed revisions would allow us to maintain more permanent cross-references to ONC's regulations and terminology, we recognize that ONC has historically updated, and will likely in the future continue to update over time, the underlying certification criteria contained in 45 CFR 170.315.

Previously under the year-themed ''editions'' construct, we periodically revised the language in our regulatory CEHRT definitions to refer to a new Edition in order to incorporate ONC's updates to health IT certification criteria. Then, in the CY 2021 PFS final rule (85 FR 84818 through 84825), to incorporate ONC's updates to certification criteria in its 2015 Edition Cures Update, which ONC finalized under the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961), we did not revise the language of the CEHRT definitions for the Medicare Promoting Interoperability Program and the Quality Payment Program. Instead, we finalized that technology used to satisfy the CEHRT definitions must be certified under the ONC Health IT Certification Program, in accordance with the 2015 Edition Cures Update certification criteria as finalized in the ONC 21st Century Cures Act final rule.

Consistent with ONC's proposal to move away from year-themed ''editions,'' and in order to further simplify our regulatory approach, we are proposing revisions to our definitions of CEHRT to ensure we would not necessarily be required to update our regulatory text each time ONC proposed or finalized any updates to its definition of Base EHR or certification criteria.

This proposal would establish that any certification criteria adopted or updated in 45 CFR 170.315 would be applicable for the CEHRT definitions in our programs' regulations at 42 CFR 495.4 and 42 CFR 414.1305, if ONC's applicable regulations are referenced directly in our CEHRT definitions. If finalized, this proposal would allow the CEHRT definitions in our regulations to automatically incorporate ONC's updates to relevant certification criteria without pursuing additional rulemaking.

It is important to note that this proposal, if finalized, would not mean that any update to a certification criterion finalized by ONC would necessarily be immediately required for use in CEHRT for our Medicare Promoting Interoperability Program, Quality Payment Program, and Shared Savings Program. We remind readers that ONC sets timelines through their rulemaking for when health IT developers must ensure their health IT products meet ONC's new or updated certification criteria to maintain certification under the ONC Health IT Certification Program, including time for health IT developers to implement these updates for their customers who may participate in programs that require use of CEHRT (88 FR 23761). We also note that CMS will continue to determine when new or revised versions of measures that require the use of certified health IT would be required for participation under the Medicare Promoting Interoperability Program and the Quality Payment Program. In determining requirements for any potential new or revised measures, we will consider factors such as implementation time and provider readiness to determine when we propose requiring participants to complete measures that require the use of certified health IT.

We believe this approach would provide us with more flexibility to finalize updates and is more consistent with the incremental approach to revising measures and technology requirements described above. Moreover, this additional flexibility would allow eligible hospitals, CAHs, and MIPS eligible clinicians to adopt, implement, and use ONC's updated certification criteria for health IT, including EHRs, as it becomes available from their chosen vendor, without the need to wait for us to first amend the regulations at 42 CFR 495.4 and 42 CFR 414.1305 through separate rulemaking.

In summary, we are proposing to revise the definitions of CEHRT for the Medicare Promoting Interoperability Program at 42 CFR 495.4, and for the Quality Payment Program at 42 CFR 414.1305. Specifically, we are proposing to add a reference to the revised name of ''Base EHR definition,'' proposed in the ONC HTI–1 proposed rule, to ensure, if finalized, it is applicable for the CEHRT definitions going forward (88 FR 23759). We are also proposing to replace our references to the ''2015 Edition health IT certification criteria'' with ''ONC health IT certification criteria'' and add the regulatory citation for ONC health IT certification criteria in 45 CFR 170.315. We also propose to specify that technology meeting the CEHRT definitions must meet ONC's certification criteria in 45 CFR 170.315 ''as adopted and updated by ONC.'' We believe that these revisions to the CEHRT definitions, if finalized, would ensure that updates to the definition at 45 CFR 170.102 and updates to applicable health IT certification criteria in 45 CFR 170.315 would be incorporated into the CEHRT definitions, without additional regulatory action by CMS.

Finally, we note that while this proposal is consistent with the approach in ONC's HTI–1 proposed rule (88 FR 23746 through 23917), we do not believe that ONC must finalize its proposed revisions for us to be able to finalize the changes proposed in this section for our regulatory definitions of CEHRT.

We are inviting public comment on these proposals.

S. A Social Determinants of Health Risk Assessment in the Annual Wellness Visit

Medicare coverage for the Annual Wellness Visit (AWV) under Part B is primarily described in statute at section 1861(hhh) of the Act, and in regulation at 42 CFR 410.15. We propose to exercise our authority in section 1861(hhh)(2)(I) of the Act to add other elements to the AWV by adding a new Social Determinants of Health (SDOH) Risk Assessment as an optional, additional element with an additional payment. The proposed new SDOH Risk Assessment would enhance patient-centered care and support effective administration of an AWV. There are no deductible requirements or Part B coinsurance for the AWV. See §§ 410.160(b)(12) and 410.152(l)(13). Our proposal builds upon our separate proposal described earlier to establish a stand-alone G code (GXXX5) for SDOH Risk Assessment furnished in conjunction with an Evaluation and Management (E/M) visit (see section II.E. of this proposed rule).

1. Background

The AWV includes the establishment (or update) of the patient's medical and family history, application of a health risk assessment and the establishment (or update) of a personalized prevention

plan. The AWV also includes an optional Advance Care Planning (ACP) service. The AWV is covered for eligible beneficiaries who are no longer within 12 months of the effective date of their first Medicare Part B coverage period and who have not received either an Initial Preventive Physical Examination (IPPE) or AWV within the past 12 months. The goals of AWV are health promotion, disease prevention and detection and include education, counseling, a health risk assessment, referrals for prevention services, and a review of opioid use. Additional information about the AWV is available on the CMS website at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html*.

It is estimated [282] that around 50 percent of an individual's health is directly related to SDOH, which is defined by Healthy People 2030 [283] as, ''The conditions in the environment where people are born, live, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.'' Healthy People 2030 also defines the broad groups of SDOH as: economic stability, education access and quality, healthcare access and quality, neighborhood and built environment, and social and community context. These parameters include factors like housing, food and nutrition access, and transportation needs. Given the large impact on health these factors have, the health care system broadly has been working to take these factors into account when providing care and rendering services.

Several Federal agencies, including the CDC, AHRQ, ACL, ACF, SAMHSA, HRSA, and ASPE are developing policies and implementation frameworks to better address the impact SDOH has on patients, in support of HHS's Strategic Approach to Addressing Social Determinants of Health to Advance Health Equity.[284] At CMS, addressing SDOH is an essential piece of the CMS Framework for Health Equity,[285] and it is tied in heavily with the CMS Strategic Pillar to advance equity. SDOH was also a foundational concept with the CMS Innovation Center Accountable Health Communities (AHC) Model that ended in 2022. Given the importance of and focus surrounding SDOH and enhancing equity, CMS is exploring ways to recognize and quantify practitioner work currently being done in this area, and to provide support to enable practitioners to assess and intervene when SDOH is relevant to the assessment, prevention and treatment plan of a Medicare patient.

CMS tested the AHC Model between 2017 and 2022. One element of the model test was the development and application of the AHC Health-Related Social Needs (HRSN) Screening Tool, which helps providers to identify patients' SDOH related needs, including housing instability, food insecurity, family and community support and mental health. Additional information on the AHC model is available on the CMS website at *(https://innovation.cms.gov/innovation-models/ahcm).*

We have heard from many health care professionals and beneficiary groups that there are barriers to completing the AWV, including, but not limited to, language and communication, differences in cultural perspectives and expectations regarding engagement with the healthcare system. We increasingly understand the importance that SDOH be considered in an assessment of patient histories, patient risk, and in informing medical decision making, prevention, diagnosis, care and treatment.

In February 2018, Health Affairs published an article titled, ''Practices Caring for the Underserved Are Less Likely to Adopt Medicare's Annual Wellness Visit,'' which described findings from a statistical study of Medicare primary care providers and AWV's from 2011 to 2015. The article points out, ''One of our most striking results was that while underserved patients were less likely to receive an annual wellness visit regardless of where they sought care, practices in rural areas and those caring for underserved and sicker populations were less likely to provide such visits to any of their patients—which suggests these practices may face resource constraints or have priorities that compete with adoption of the visit.'' [286]

In August 2022, the Journal of the American Geriatrics Society published an article titled, ''Medicare's annual wellness visit: 10 years of opportunities gained and lost.'' The article expresses the concern, ''currently AWVs are a 'one size fits all','' approach. This uniform approach does not sufficiently take into consideration the medical, psychological, functional, racial, cultural and socio-economic diversity of older adults. Updated AWVs should be tailored to meet the needs and priorities of older adults receiving them.'' It goes on to recommend, ''Medicare AWVs should include screening and counseling for social determinants of health as a means of mitigating the growing disparities in health and longevity for underserved older adults.'' [287]

2. Statutory and Regulatory Authority

Section 4103 of The Patient Protection and Affordable Care Act (ACA) (Pub. L. 111–148) expanded Medicare coverage by adding the AWV benefit at section 1861(hhh) of the Act, effective for services furnished on or after January 1, 2011. We subsequently implemented the AWV in CMS regulations 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 is covered for eligible beneficiaries who are no longer within 12 months of the effective date of their first Medicare Part B coverage period and who have not received either an IPPE or AWV within the past 12 months. Section 1861(hhh)(2) of the Act describes a number of elements included in the AWV and section 1861(hhh)(2)(I) of the Act authorizes the addition of any other element determined appropriate by the Secretary.

We note that § 410.15(a) requires that the first AWV include 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.

[282] *https://aspe.hhs.gov/sites/default/files/documents/e2b650cd64cf84aae8ff0fae7474af82/SDOH-Evidence-Review.pdf.*

[283] *https://health.gov/healthypeople.*

[284] *https://aspe.hhs.gov/sites/default/files/documents/aabf48cbd391be21e5186eeae728ccd7/SDOH-Action-Plan-At-a-Glance.pdf.*

[285] *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

[286] Ganguli I, Souza J, McWilliams JM, Mehrotra A. Practices Caring For The Underserved Are Less Likely To Adopt Medicare's Annual Wellness Visit. Health Aff (Millwood). 2018 Feb;37(2):283–291. doi: 10.1377/hlthaff.2017.1130. PMID: 29401035; PMCID: PMC6080307.

[287] Coll PP, Batsis JA, Friedman SM, Flaherty E. Medicare's annual wellness visit: 10 years of opportunities gained and lost. J Am Geriatr Soc. 2022 Oct;70(10):2786–2792. doi: 10.1111/jgs.18007. Epub 2022 Aug 17. PMID: 35978538.

• 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 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.

++ Furnishing of a review of any current opioid prescriptions as that term is defined in this section.

++ 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.

++ Any other element determined appropriate through the national coverage determination process.

We note that § 410.15(a) requires that a 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.

++ Furnishing of a review of any current opioid prescriptions as that term is defined in this section.

++ 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.

++ Any other element determined appropriate through the national coverage determination process.

In the CY 2016 PFS final rule (80 FR 70885), we finalized a proposal to include ACP as an optional element (at beneficiary discretion) within the AWV. We stated in the final rule we are adding ACP as a voluntary, separately payable element of the AWV. We are instructing that when ACP is furnished as an optional element of AWV as part of the same visit with the same date of service, CPT codes 99497 and 99498 should be reported and will be payable in full in addition to payment that is made for the AWV under HCPCS code G0438 or G0439, when the parameters for billing those CPT codes are separately met, including requirements for the duration of the ACP services. Under these circumstances, ACP should be reported with modifier -33 and there will be no Part B coinsurance or deductible, consistent with the AWV (80 FR 70958). We also added this policy to the regulatory text at § 410.15(a).

3. Proposal

We propose to exercise our authority in section 1861(hhh)(2)(I) of the Act to add elements to the AWV by adding a new SDOH Risk Assessment as an optional, additional element of the AWV with an additional payment. We recognize that, for some patients, identification and consideration of SDOH is critical to furnishing a fully informed health assessment and personalized prevention plan in the AWV. We have heard from interested parties that the current elements of the AWV may not directly or adequately identify those SDOH challenges. We propose that the SDOH Risk Assessment be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same

date of service as the AWV. We propose that the SDOH Risk Assessment service include the administration of a standardized, evidence-based SDOH risk assessment tool, furnished in a manner that all communication with the patient be appropriate for the patient's educational, developmental, and health literacy level, and be culturally and linguistically appropriate. We believe that services that are culturally and linguistically appropriate are critical to providing effective, equitable, understandable, and respectful quality care that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy, and other communication needs of each patient. We recognize that patients with SDOH risks and challenges may often also experience communication barriers of various kinds when interacting with the health care system. We believe that the SDOH Risk Assessment would only be effective in informing the greater AWV (including the health assessment and personalized prevention plan) when furnished in a manner that is intelligible and appropriate to the individualized characteristics and circumstances of the patient. Additional information on culturally and linguistically appropriate services in healthcare can be found at (*https://thinkculturalhealth.hhs.gov/clas*). We believe the SDOH Risk Assessment Tool would be most effective and actionable when furnished in a setting with staff-assisted supports in place to ensure follow-up for health-related social needs associated to the visit. We also encourage partnerships with community-based organizations such as Area Agencies on Aging to help address identified social needs. We propose that the SDOH Risk Assessment be furnished as part of the same visit and on the same date of service as the AWV, so as to inform the care the patient is receiving during the visit, including taking a medical and social history, applying health assessments and prevention services education and planning. We believe our proposal will directly reduce barriers, expand access, promote health equity and improve care for populations that have historically been underserved by recognizing the importance that SDOH be considered and assessed, where appropriate, in support of the existing AWV. In addition, we hope that our proposal will help spread general awareness among health professionals about the importance of providing cultural and linguistically appropriate services, which in turn will encourage clinicians to adopt language services and technologies to achieve high quality communication between the practitioner and patient. Our goal is the development of a personalized prevention plan that takes SDOH into account and is truly tailored to the individual patient. We invite public comment on our proposal, including whether a SDOH Risk Assessment would ultimately inform and result in the development of steps to address and integrate SDOH in the patient's AWV health assessment and personalized prevention plan.

We recognize that SDOH risk assessments are an emerging and evolving tool in healthcare and so we do not restrict our proposal to a specific list of approved assessments. In selecting an evidence-based tool, we encourage clinicians to explore the many widely adopted and validated tools available, including the CMS Accountable Health Communities [288] tool, the Protocol for Responding to & Assessing Patients' Assets, Risks & Experiences (PRAPARE) tool,[289] and instruments identified for Medicare Advantage Special Needs Population Health Risk Assessment.[290] We also encourage clinicians, where feasible, to select screening instruments that maximize opportunities to collect and analyze standardized, quantifiable, and actionable data. For instance, clinicians are encouraged to utilize screening instruments where questions and responses are computable and mapped to health IT vocabulary standards (that is, have available LOINC® coding terminology), to ensure that data captured through assessments is interoperable and can be shared, analyzed and evaluated across the care continuum.

Our proposal builds upon our separate proposal described earlier to establish a stand-alone G code (GXXX5) for SDOH Risk Assessment furnished in conjunction with an E/M visit. See section II.E. for additional information on coding, pricing, and additional conditions of payment for the proposed new SDOH Risk Assessment service. Upon finalization of the CY 2024 PFS, CMS will issue public guidance in the Medicare Learning Network, the Medicare & You Handbook, and more formal, in-depth policy and payment instructions in the Medicare Benefit Policy Manual and the Medicare Claims Processing Manual on the CMS website.

Over the past several years, we have worked to develop payment mechanisms under the PFS to improve the accuracy of valuation and payment for the services furnished by physicians and other health care professionals, especially in the context of evolving models of care. Section 1862(a)(1)(A) of the Act generally excludes from coverage services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Practitioners across specialties have opined and recognized the importance of SDOH on the health care provided to their patients by recommending the assessment of SDOH through position or discussion papers,[291] [292] [293] organizational strategic plans,[294] and provider training modules,[295] among others. As described earlier in our proposed rule, we have discussed how the practice of medicine currently includes assessment of health-related social needs or SDOH in taking patient histories, assessing patient risk, and informing medical decision making, diagnosis, care and treatment. The taking of a social history is generally performed by physicians and other health professionals in support of patient-centered care to better understand and help address relevant problems that are impacting medically necessary care. Practitioners are expending resources to obtain information from the patient about health-related social needs, and to formulate diagnosis and treatment plans that take these needs into account as part of a person-centered care plan for the treatment of medical problems. This work currently is reported and paid for, in part, under the PFS under E/M visit codes, and we believe as such, is undervalued and not optimized to allow the health professional and patient to benefit from the full value of a dedicated SDOH assessment and have that assessment immediately inform the health assessment and prevention planning services in the AWV.

We propose that Medicare would pay 100 percent of the fee schedule amount for the SDOH Risk Assessment service (beneficiary cost sharing would not be applicable) when this risk assessment is furnished to a Medicare beneficiary as an optional element within an AWV (as part of the same visit with the same date of service as the AWV). Our proposal is

[288] *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.*

[289] *https://www.nachc.org/research-and-data/prapare/.*

[290] CMS–10825.

[291] *https://www.aafp.org/about/policies/all/social-determinants-health-family-medicine-position-paper.html.*

[292] *https://doi.org/10.7326/M17–2441.*

[293] *https://nam.edu/social-determinants-of-health-201-for-health-care-plan-do-study-act/.*

[294] *https://www.ama-assn.org/system/files/2021–05/ama-equity-strategic-plan.pdf.*

[295] *https://edhub.ama-assn.org/steps-forward/module/2702762.*

analogous to our current approach to the ACP service, which is an optional service for which beneficiary cost sharing is not applicable when furnished as part of the same visit and on the same date of service as the AWV. Beneficiary cost sharing is not applicable to the AWV and, because the SDOH Risk Assessment would be an optional element within the AWV, there would not be any beneficiary cost sharing for the SDOH Risk Assessment either. See §§ 410.160(b)(12) and 410.152(l)(13). We note that beneficiary cost sharing would apply to the SDOH Risk Assessment if furnished in conjunction with another service (outside of the AWV) that is subject to beneficiary cost sharing. We are proposing that the SDOH Risk Assessment would be optional for both the health professional and the beneficiary to empower clinicians and patients to employ this assessment only when appropriate and desired.

We propose to add regulatory text at § 410.15 that will include the new SDOH Risk Assessment service as an optional element within the AWV, at the discretion of the health professional and beneficiary. Furthermore, we propose to add regulatory text that the SDOH Risk Assessment be standardized, evidence-based, and furnished in a manner that all communication with the patient be appropriate for the beneficiary's educational, developmental, and health literacy level, and be culturally and linguistically appropriate. We invite public comment on our proposal.

We have also received feedback from interested parties that the AWV may be more effectively furnished if elements were allowed to be completed over multiple visits and days, or prior to the AWV visit. We invite public comment on this issue for consideration in future rulemaking.

4. Summary

In conclusion, we are proposing to add a new Social Determinants of Health (SDOH) Risk Assessment as an optional element within the AWV. We are also proposing the SDOH Risk Assessment be paid at 100 percent of the fee schedule amount of the risk assessment. We are proposing that the new SDOH Risk Assessment be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV. We believe our proposal will directly reduce barriers, expand access, promote health equity and improve care for populations that have historically been underserved by recognizing the importance that SDOH be considered and assessed, where appropriate, as an additional, optional element in the AWV service.

IV. Updates to the Quality Payment Program

A. CY 2024 Modifications to the Quality Payment Program

1. Executive Summary

a. Overview

This section of the proposed rule sets forth changes to the Quality Payment Program starting January 1, 2024, except as otherwise noted for specific provisions. We continue to move the Quality Payment Program forward, including focusing more on our measurement efforts and refining how clinicians would be able to participate in a more meaningful way, to achieve continuous improvement in the quality of health care services provided to Medicare beneficiaries and other patients through the Quality Payment Program's Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) for the CY 2024 performance period/2026 MIPS payment year.

Authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015), the Quality Payment Program is a payment incentive program, by which the Medicare program rewards clinicians who provide high-value, high-quality services in a cost-efficient manner. The Quality Payment Program includes two participation tracks for clinicians providing services under the Medicare program: MIPS and Advanced APMs. The statutory requirements for the Quality Payment Program are set forth in section 1848(q) and (r) of the Act for MIPS and section 1833(z) of the Act for Advanced APMs.

For the MIPS participation track, MIPS eligible clinicians (defined in 42 CFR at 414.1305) are subject to a MIPS payment adjustment (positive, negative, or neutral) based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. We assess each MIPS eligible clinician's total performance according to our established performance standards with respect to the applicable measures and activities specified in each of these four performance categories during a performance period to compute a final composite performance score (a ''final score'' as defined at § 414.1305). In calculating the final score, we must apply different weights for the four performance categories, subject to certain exceptions, as set forth in section 1848(q)(5) of the Act and at § 414.1380. Unless we assign a different scoring weight pursuant to these exceptions, for CY 2024 performance period/2026 MIPS payment year, the scoring weights are as follows: 30 percent for the quality performance category; 30 percent for the cost performance category; 15 percent for the improvement activities performance category; and 25 percent for the Promoting Interoperability performance category.

Once calculated, each MIPS eligible clinician's final score is compared to the performance threshold we have established in prior rulemaking for that performance period to calculate the MIPS payment adjustment factor as specified in section 1848(q)(6) of the Act, such that the MIPS eligible clinician will receive in the applicable MIPS payment year: (1) a positive adjustment, if their final score exceeds the performance threshold; (2) a neutral adjustment, if their final score meets the performance threshold; or (3) a negative adjustment, if their final score is below the performance threshold. The actual amount paid to the MIPS eligible clinician in MIPS payment year, once the MIPS payment adjustment factor is applied, is subject to further calculations such as application of the scaling factor and budget neutrality requirements, as further specified in section 1848(q)(6) of the Act.

Section 1848(q) of the Act sets forth other requirements applicable to MIPS, including opportunities for feedback and targeted review and public reporting of MIPS eligible clinicians' performance. Section 1848(r) of the Act sets forth more specific requirements for development of measures for the cost performance category under MIPS.

If an eligible clinician participates in an Advanced APM and achieves Qualifying APM Participant (QP) or Partial QP status, they are excluded from the MIPS reporting requirements and payment adjustment (though eligible clinicians who are Partial QPs may elect to be subject to the MIPS reporting requirements and payment adjustment). Eligible clinicians who are QPs for the 2023 performance year receive a 3.5 percent APM Incentive Payment in the 2025 payment year, and, beginning with the 2024 performance year (payment year 2026), a higher PFS payment rate (calculated using the differentially higher ''qualifying APM conversion factor'') than non-QPs. QPs will continue to be excluded from MIPS reporting and payment adjustments for the applicable year.

As we move into the seventh year of the Quality Payment Program, we are

proposing the updates set forth in this section of this proposed rule, encouraging continued improvement in clinicians' performance with each performance year and drive improved quality of health care through payment policy.

In developing and putting forth these proposals, we intend to continue our efforts to align the Quality Payment Program with broader CMS initiatives, such as the establishment of the Universal Foundation (*https://www.nejm.org/doi/full/10.1056/NEJMp2215539*) and the CMS National Quality Strategy (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Legacy-Quality-Strategy*). These initiatives unify strategic efforts across our programs, including the Quality Payment Program, to adopt measures most critical to providing high quality care and accelerate strategic improvements for quality programs and measures.

The vision for the CMS National Quality Strategy is to shape a resilient, high-value American health care system to achieve high-quality, safe, equitable, and accessible care for all. This strategy aims to promote the highest quality outcomes and safest care for all individuals. It also focuses on a person-centered approach as individuals journey across the continuum of care, care settings, and across payer types. The goals of this strategy incorporate lessons learned from the COVID–19 public health emergency (PHE) to inform both short and long-term direction for our health care system.

The Universal Foundation moves toward a building-block approach to advance the overall vision of the National Quality Strategy and increase alignment across CMS quality programs by capturing measures that are meaningful, broadly applicable, and capable of being digitally reported and stratified, in order to identify and track disparities over time. The Universal Foundation seeks to improve health outcomes, reduce provider burden, improve standardization of measurement, and promote interoperability by prioritizing measures to transition to interoperable digital data.

The implementation of MIPS Value Pathways (MVPs) aligns with many of the objectives and goals the CMS National Quality Strategy and the Universal Foundation strive to achieve. For example, in an effort to align implementation of the measures in the Universal Foundation across MIPS and APMs, we are proposing updates to consolidate the Promoting Wellness and Managing Chronic Conditions MVPs to align with the adult Universal Foundation measure set. We are also exploring the expansion of the APM Performance Pathway (APP) reported by clinicians in the Shared Savings Program and Advanced APMs to include the primary care universal measure set in the future. In our continued strategy to incentivize improved equity as well as advancing value, in Performance Year 2023 the Shared Savings Program will implement an upside-only adjustment to reward ACOs that provide excellent care for underserved populations (87 FR 69838 through 69857). In our goal to accelerate interoperability, we propose to require Shared Savings Program ACO clinicians to report the measures and objectives required by the MIPS Promoting Interoperability performance category. We are also proposing to modify our CEHRT use criterion for Advanced APMs to promote flexibility in adopting CEHRT that is clinically relevant to participants, emphasizing the importance of interoperability and health information technology. Moreover, we propose to expand our portfolio of available MVPs for the CY 2024 performance period and remain committed to our goal of ensuring more meaningful participation in the Quality Payment Program through MVPs.

b. Summary of Major Provisions

(1) Transforming the Quality Payment Program

The CMS National Quality Strategy addresses the urgent need for transformative action to advance towards a more equitable, safe, and outcomes-based health care system for all individuals. This vision is supported by the alignment of policies and quality measures in MIPS and APMs within the Quality Payment Program. Priorities for the Quality Payment Program include: achieving more equitable outcomes; utilizing clinically relevant measures for specialty performance that inform clinicians and beneficiaries; enhancing quality, patient safety, and efficiency through use of certified EHR technology (CEHRT); reducing burden and simplifying quality performance reporting; articulating meaningful outcomes, promoting alignment where possible, and moving to all digital reporting.

The Quality Payment Program allows eligible clinicians to engage in patient-centered care via two tracks: the Merit-Based Incentive Program (MIPS) and APMs. We believe the Quality Payment Program should continuously support the measurement and improvement of specialty and primary care. To this end, we are implementing MVPs to allow clinicians to report on measures that are directly relevant to their clinical practice. MVPs provide more clinically relevant performance measurement, engage more specialists in performance measurement, and reduce barriers to APM participation. CMS has recently laid out multiple steps intended to fulfill the potential of APMs. The CMS Innovation Center strategy refresh acknowledges that whole person care requires the depth and scope of services that includes both primary and specialty care and aims to provide ACOs with tools to better engage specialists, test ways to better link primary and specialty care upstream in the patient journey, and further movement into value-based care.[296]

(2) Major MIPS Provisions

We are requesting comment on how the Quality Payment Program can facilitate continuous improvement of Medicare beneficiaries' healthcare and best build on existing CMS Innovation Center model policies and Medicare programs, such as the Medicare Shared Savings Program. We are seeking feedback on how we might modify our policies, requirements, and performance standards to encourage clinicians to continuously improve the quality of care, particularly for clinicians with little room for improvement in MIPS.

(a) MIPS Value Pathways Development and Maintenance

In an effort to promote high-quality, safe, and equitable care and to implement the vision outlined in the CMS National Quality Strategy, we are proposing five new MVPs around the topics of: Women's Health; Infectious Disease, Including Hepatitis C and HIV; Mental Health and Substance Use Disorder; Quality Care for Ear, Nose, and Throat (ENT); and Rehabilitative Support for Musculoskeletal Care. In addition, we are proposing MVP maintenance updates to our MVP inventory that are in alignment with the MVP development criteria, and in consideration of the feedback from interested parties we have received through the maintenance process.

(b) Subgroup Reporting

We are proposing to codify previously finalized subgroup policies in the preamble to regulation text. Additionally, we are proposing updates

[296] CMMI Strategy Refresh. October 20, 2021. *https://innovation.cms.gov/strategic-direction-whitepaper.*

to previously finalized subgroup policies to help guide clinicians and groups to meaningfully participate in MVPs through subgroup reporting. Specifically, we are proposing to update the subgroup policy for reweighting of MVP performance categories, update the facility-based scoring as well as the complex patient bonus for subgroups under final score calculation, and add subgroups to the targeted review regulation text.

(c) MIPS Performance Category Measures and Activities

(i) Quality Performance Category

We are proposing six modifications to the quality performance category. First, we propose to expand the definition of the collection type to include Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs). Second, we propose to establish the quality performance category data submission criteria for eCQMs that requires the utilization of CEHRT. Third, we propose to establish the data submission criteria for Medicare CQMs. Fourth, we propose to require the administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey in the Spanish translation. Fifth, we propose to maintain the data completeness criteria threshold to at least 75 percent for the CY 2026 performance period/2028 MIPS payment year, and increase the data completeness criteria threshold to at least 80 percent for the CY 2027 performance period/2029 MIPS payment year. Sixth, we propose to establish the data completeness criteria for Medicare CQMs. Finally, we propose to establish a measure set inventory of 200 MIPS quality measures.

(ii) Cost Performance Category

We are proposing to add five new episode-based measures to the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year. These five proposed measures are Depression, Emergency Medicine, Heart Failure, Low Back Pain, and Psychoses and Related conditions; several of these have relevance to the CMS Behavioral Health Strategy (*https://www.cms.gov/cms-behavioral-health-strategy*). We are proposing to use a 20-episode case minimum for each of these new measures, and are requesting comments on our clarification of the indented interpretation of the language on the case minimums codified at § 414.1350(c). We are also proposing to remove the Simple Pneumonia with Hospitalization episode-based measure beginning with the CY 2024 performance period/2026 MIPS payment year. Finally, we are proposing to update the operational list of care episode and patient condition groups and codes to add all five new measures and remove the Simple Pneumonia with Hospitalization episode-based measure from the operational list of care episode and patient condition groups and codes.

(iii) Improvement Activities Performance Category

We are proposing to add five new, modify one existing, and remove three existing improvement activities from the Inventory. The new and modified activities help fill gaps we have identified in the Inventory as well as seek to ensure that activities reflect current clinical practice across the category. Four of the new activities being proposed relate to CMS Health Equity, Increase All Forms of Accessibility to Health Care Services and Coverage. We are also recommending the removal of three activities, both to align with current clinical guidelines and practice as well as to eliminate duplication, so that the Inventory offers flexibility and choice without potentially causing burden with too many activities to choose from.

(iv) Promoting Interoperability Performance Category

We are proposing five policy modifications for the Promoting Interoperability performance category. Specifically, we propose to: (1) lengthen the performance period for this category from 90 days to 180 days; (2) modify one of the exclusions for the Query of Prescription Drug Monitoring Program (PDMP) measure; (3) provide a technical update to the e-Prescribing measure's description to ensure it clearly reflects our previously finalized policy; (4) modify the Safety Assurance Factors for Electronic Health Record Resilience (SAFER) Guide measure to require MIPS eligible clinicians to affirmatively attest to completion of the self-assessment of their implementation of safety practices; and (5) continue to reweight this performance category at zero percent for clinical social workers for the CY 2024 performance period/2026 MIPS payment year. In section III.R.2.b. of this proposed rule, we are proposing to revise our regulatory definition of CEHRT for the Promoting Interoperability performance category to be more flexible in reflecting any changes the Office of the National Coordinator for Health Information Technology (ONC) may make to its Base EHR definition, certification criteria, and other standards for health information technology.

(d) MIPS Final Scoring Methodology

(i) Performance Category Scores

We are proposing updates to our scoring flexibilities policy. We are proposing to update the criteria by which we assess the scoring impacts of coding changes and apply our scoring flexibilities. We are also proposing that eCQM measure specifications would be required to include the ability to be truncated to a 9-month performance period.

(ii) Cost Improvement Scoring

We are proposing two modifications to the cost improvement scoring method that was established in the CY 2018 Quality Payment Program final rule. First, we are proposing to change improvement scoring from a measure-level to a category-level method and to remove the statistical significance requirement. Second, we are proposing that the maximum cost improvement score is zero percentage points for the 2020 through 2024 MIPS payment years, and one percentage point beginning with the CY 2023 performance period/2025 MIPS payment year.

(e) MIPS Payment Adjustments

We are proposing to revise our policy for identifying the ''prior period'' by which we will establish the performance threshold beginning with the CY 2024 performance period/2026 MIPS payment year. Specifically, we are proposing to define the ''prior period'' by which we establish the performance threshold as three performance periods, instead of a single prior performance period, and codify this policy at § 414.1405(g)(2). To determine the performance threshold for the CY 2024 performance period/2026 MIPS payment year, we are proposing to use the CY 2017/2019 MIPS payment year through CY 2019 performance period/2021 MIPS payment year as the prior period. Based on the mean final score from that prior period, we are proposing to establish the performance threshold as 82 points for the CY 2024 performance period/2026 MIPS payment year.

(f) MIPS Targeted Review

We are proposing to add virtual groups and subgroups as being eligible to submit a request for targeted review. We are proposing to codify this addition at § 414.1385(a).

We are proposing to amend at § 414.1385(a)(2) with respect to the

timeline for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM entities to request a targeted review of our calculation of their MIPS payment adjustment factor(s). Specifically, we are proposing to permit submission of a request for targeted review beginning on the day we make available the MIPS final score and ending 30 days after publication of the MIPS payment adjustment factors for the MIPS payment year. This proposal would modify the current time period to submit a request for targeted review, which is 60 days beginning on the day that CMS makes available the MIPS payment adjustment factors for the MIPS payment year.

We also are proposing to amend § 414.1385(a)(5). Specifically, we are proposing to require that, if CMS requests additional information under the targeted review process, then that additional information must be provided to and received by CMS within 15 days of receipt of such request. This proposal would modify the current timeline to respond to CMS' request set forth at § 414.1385(a)(5), which is within 30 days of receipt of such request.

(g) Third Party Intermediaries

In this proposed rule, in addition to codifying previously finalized policies and proposing to make technical updates for clarity, we propose to: (1) Add requirements for third party intermediaries to obtain documentation of their authority to submit on behalf of a MIPS eligible clinician; (2) Specify the use of a simplified self-nomination process for existing QCDRs and qualified registries; (3) Add requirements for QCDRs and qualified registries to provide measure numbers and identifiers for performance categories; (4) Add a requirement for QCDRs and qualified registries to attest that the information contained in the qualified posting about them is correct; (5) Modify requirements for QCDRs and qualified registries to support MVP reporting to increase flexibility for measures supported; (6) Specify requirements for a transition plan for QCDRs and qualified registries withdrawing from the program; (7) Specify requirements for data validation audits; (8) Add additional criteria for rejecting QCDR measures; (9) Add a requirement for QCDR measure specifications to be displayed throughout the performance period and data submission period; (10) Eliminate the Health IT vendor category; (11) Add failure to maintain updated contact information as criteria for remedial action; (12) Revise corrective action plan requirements; (13) Specify the process for publicly posting remedial action; and (14) Specify the criteria for audits.

(h) Public Reporting on Compare Tools

In an effort to expand the information available to patients and caregivers when choosing a doctor or clinician, we are proposing to modify the existing policy for public reporting on individual clinician and group profile pages, including proposals to revise:

- The telehealth indicator, such that, we would use the most recent CMS coding policies at the time the information is updated to identify the telehealth services provided on clinician profile pages instead of only using specific Place of Service (POS) and claims modifier codes.
- Utilization data, such that we have additional procedure code grouping flexibility; can address procedure volume limitations and provide a more complete scope of a clinician's experience by adding Medicare Advantage (MA) data to procedure counts; and align the data in the Provider Data Catalog (PDC) with the procedural groupings shown on profile pages.

Additionally, we solicit feedback from interested parties through a request for information on ways to publicly report data submitted on measures under the MIPS cost performance category on the Compare tool.

(3) Major APM Provisions

(a) APM Performance Pathway

In section IV.A.4.e. of this proposed rule, we are proposing to include the Medicare Clinical Quality Measure (Medicare CQM) for Accountable Care Organizations Participating in the Medicare Shared Savings Program collection type in the APM Performance Pathway (APP) measure set.

(b) Overview of the APM Incentive

In section IV.A.4.m. of this proposed rule, we are proposing to end the use of APM Entity-level QP determinations and instead make all QP determinations at the individual eligible clinician level. We are also proposing to modify the ''sixth criterion'' under the definition of ''attribution-eligible beneficiary,'' which is listed at § 414.1305.[297] Specifically, we are proposing to include any beneficiary who has received a covered professional service furnished by the NPI for the purpose of making QP determinations. We are also proposing to amend § 414.1430 to reflect the statutory QP and Partial QP threshold percentages for both the payment amount and patient count methods under the Medicare Option and the All-Payer Option with respect to payment year 2025 (performance year 2023) in accordance with amendments made by the CAA, 2023. Relatedly, we are proposing to amend § 414.1450 to reflect the statutory APM Incentive Payment amount for the 2025 payment year (performance year 2023) of 3.5 percent of the eligible clinician's estimated aggregate payments for covered professional services in accordance with amendments made by the CAA, 2023. In section IV.A.4.j. of this proposed rule, we are proposing to amend § 414.1385 to adjust the Targeted Review period to address operational challenges that have arisen ahead of the required transition beginning for payment year 2026 (performance year 2024) from the APM Incentive Payment to the higher PFS payment rate for QPs (calculated using the differentially higher ''qualifying APM conversion factor).

(c) Advanced APMs

In section IV.A.4.n. of this proposed rule, we are proposing to modify the CEHRT use criterion for Advanced APMs to provide greater flexibility for APMs to tailor CEHRT use requirements to the APM and its participants. We are proposing to amend the CEHRT use criterion for Advanced APMs at § 414.1415(a)(1)(i) effective beginning for CY 2024 to no longer apply the 75 percent CEHRT use minimum, and to instead specify that the APM must require all APM participants to use CEHRT as defined in a proposed revised definition of CEHRT under § 414.1305. We are also proposing to amend the Other-Payer Advanced APM CEHRT use criterion at § 414.1420(b) to conform to the proposed changes at § 414.1415(a)(1)(i).

[297] Currently, there are six criteria required for a beneficiary to be an ''attribution-eligible beneficiary'' during the QP Performance Period, which can be found at § 414.1305. The sixth criterion provides that an ''attribution-eligible beneficiary'' must have ''a minimum of one claim for evaluation and management services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period or, for an Advanced APM that does not base attribution on evaluation and management services and for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to have at least one claim for evaluation and management services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period, the attribution basis determined by CMS based upon the methodology the Advanced APM uses for attribution, which may include a combination of evaluation and management and/or other services.''

2. Definitions

At § 414.1305, we are proposing to revise the definitions of the following terms:

- Attribution-eligible beneficiary;
- Certified Electronic Health Record Technology (CEHRT); and
- Collection type.
- Qualified posting

These terms and definitions are discussed in detail in the relevant sections of this proposed rule.

3. Transforming the Quality Payment Program

a. Advancing CMS National Quality Strategy Goals

(1) Increasing Alignment Across Value-Based Programs

The CMS National Quality Strategy [298] addresses the urgent need for transformative action to advance towards a more equitable, safe, and outcomes-based health care system for all individuals. One of the CMS National Quality Strategy goals is to improve quality and health outcomes across the health care journey through implementation of a ''Universal Foundation'' of impactful measures across all CMS quality and value-based programs.[299] Adoption of the Universal Foundation [300] [301] will focus clinician attention on specific quality measures, reduce burden, help identify disparities in care, prioritize development of interoperable, digital quality measures, allow for cross-comparisons across programs, and help identify measurement gaps.

We identified adult and pediatric measures for the Universal Foundation to be used across CMS programs and populations, including the Quality Payment Program, to the extent they are applicable. The Quality Payment Program measure inventory already includes quality measures in the adult core set from the Universal Foundation. In addition, we propose in this proposed rule to consolidate the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single consolidated primary care MVP that aligns with the adult Universal Core set of quality measures. We refer readers to section IV.A.4.b. and Appendix 3: MVP Inventory, Table B.11 of this proposed rule for our proposed updates to the Promoting Wellness and Chronic Disease Management MVPs. We will continue to identify additional measures, which may be included in future MVPs, to capture aspects of specialist quality in the Universal Foundation.[302] We also refer readers to section III.G.2.c. of this proposed rule for discussions on expanding the APM Performance Pathway (APP) reported by clinicians in the Shared Savings Program and Advanced APMs to include Medicare Clinical Quality Measure (Medicare CQM) collection types and further alignment with the Universal Foundation.

(2) Advancing Health Equity

We also articulated a detailed strategy to advance health equity and accountability in order to design, implement, and operationalize policies to support health for all people served by our programs, eliminate avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and provide the care and support that our beneficiaries need to thrive.[303] Specifically, the CMS Office of Minority Health released the *CMS Framework for Health Equity,*[304] which updates the CMS Equity Plan with an enhanced and more comprehensive 10-year approach to further embed health equity across CMS programs including Medicare, Medicaid, Children's Health Insurance Program, and the Health Insurance Marketplaces. The CMS Office of Minority Health also released Paving the Way to Equity: A Progress Report [305] in 2021, which describes the CMS Equity Plan for Medicare and progress from 2015 to 2021.

In accordance with our health equity strategy, both MVPs and APMs share a goal of incenting improved equity as well as advancing value (87 FR 70035). For example, beginning in Performance Year 2023 the Shared Savings Program will implement an upside-only Health Equity Adjustment (HEA) to an ACO's MIPS Quality performance category score to reward ACOs that provide excellent care for underserved populations (87 FR 69838 through 69857).

(3) Accelerating Interoperability

The CMS National Quality Strategy also calls for supporting the transition to a digital and data driven health care system. The CMS National Quality Strategy proposed to achieve this through the development of requirements for sharing, receipt, and use of digital data, including digital quality measures.[306] We believe that, as clinicians strive to make improvements in patient care, clinicians should demonstrate increasingly more advanced and innovative uses of health information technology. In section III.G.2.h. of this proposed rule, we propose to require Shared Savings Program ACO clinicians to report the measures in the MIPS Promoting Interoperability performance category. Additionally, in section III.G.2.h.(2) of this proposed rule, we propose to modify our requirements for use of CEHRT for Advanced APMs to promote flexibility in adopting CEHRT that is clinically relevant to participants, emphasizing the importance of interoperability and health information technology. We believe these proposals, in addition to ongoing efforts to build CMS infrastructure and develop technical solutions, are an important step towards evolving our health information technology ecosystem.

b. Quality Payment Program Vision and Goals

(1) Emphasizing the Importance of Value-Based Care

The Quality Payment Program was designed and implemented to improve health outcomes, promote smarter spending, minimize burden of participation, and provide fairness and transparency in operations (81 FR 77010). The Quality Payment Program allows for eligible clinicians to engage in value-based, patient-centered care via

[298] The National Quality Strategy: A Person-Centered Approach to Improving Quality . . ., *https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality*.

[299] CMS National Quality Strategy. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*.

[300] Aligning Quality Measures across CMS. *https://www.cms.gov/aligning-quality-measures-across-cms-universal-foundation https://www.cms.gov/aligning-quality-measures-across-cms-universal-foundation*.

[301] CMS National Quality Strategy. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*. CMS National Quality Strategy. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*.

[302] Aligning Quality Measures across CMS—The Universal Foundation. Jacobs, Schreiber, Seshamani, Tsai, Fowler, and Fleisher. *https://www.nejm.org/doi/full/10.1056/NEJMp2215539*.

[303] CMS National Quality Strategy. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*.

[304] CMS Equity Plan for Improving Quality in Medicare. *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf*.

[305] CMS, Paving the Way to Equity: A Progress Report (2015–2021) *https://www.cms.gov/sites/default/files/2021-01/Paving%20the%20Way%20to%20Equity%20CMS%20OMH%20Progress%20Report.pdf*.

[306] CMS National Quality Strategy. *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/cms-quality-strategy*.

two tracks: the Merit-Based Incentive Program (MIPS) and Advanced Alternative Payment Models (APMs). MIPS encourages collection and submission of data for evidence-based, specialty-specific quality measures, completion of practice-based improvement activities, consideration of cost measures, and use of certified electronic health record (EHR) technology (CEHRT) to support interoperability (81 FR 77010). APMs are models operating under section 1115A of the Act, the Shared Savings Program under section 1899 of the Act (that is, Accountable Care Organizations), or a demonstration under section 1866C or required by Federal law. In the Advanced APM track of the Quality Payment Program, APM entities and eligible clinicians take responsibility for improving the quality of care, care coordination and health outcomes for a group of beneficiaries through participation in Advanced APMs.[307] Advanced APMs can ensure that beneficiaries get the right care at the right time by reducing fragmentation between clinicians, which can reduce unnecessary duplication of services and preventable medical errors.[308] Advanced APMs also support our goal that all Traditional Medicare beneficiaries be in a care relationship with clinicians accountable for quality and total cost of care by 2030, as outlined by the CMS Innovation Center strategy refresh.[309]

CMS recently established, and is implementing, various strategies that are intended to fulfill the potential of Advanced APMs. The CMS Innovation Center strategy refresh acknowledges that whole person care requires the depth and scope of services that includes both primary and specialty care, and aims to provide Accountable Care Organizations (ACOs) with tools to better engage specialists, test ways to better link primary and specialty care upstream in the patient journey, and further movement into value-based care.[310] Our ongoing alignment of the Shared Savings Program and the Quality Payment Program supports new as well as long term participation in ACOs for clinicians choosing to participate in accountable care relationships. In the CY 2021 PFS final rule, we finalized the Alternative Payment Model (APM) Performance Pathway (APP) under MIPS, in part, to reduce reporting burden, and create new scoring opportunities for MIPS eligible clinicians participating in MIPS APMs (85 FR 84720).

(2) MVP Reporting in the Quality Payment Program

We believe the Quality Payment Program should continuously support the measurement and improvement of specialty and primary care practice. To this end, we are implementing MVPs in MIPS to allow for clinicians to report on measures that are directly relevant to their clinical practice. Rather than selecting individual measures and activities from a large inventory to report under each of the siloed MIPS performance categories under traditional MIPS, eligible clinicians who select an MVP (for example, the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP) can select from a smaller, cohesive set of measures and activities focused on the clinician's performance in rendering care for their specialty or clinical condition.

We also developed MVPs with the intention to support clinicians in their journey of continuous performance improvement and to reduce barriers to APM participation as clinicians and practices prepare to take on, and successfully manage financial risk (84 FR 62946 through 62949).

c. Promoting Continuous Improvement in MIPS

For the MIPS program, we developed policies and methodologies to assess clinicians' performance, and to support performance improvement across four performance categories (quality, cost, improvement activities, and Promoting Interoperability) in accordance with section 1848(q)(1)(A)(i) and (ii) of the Act. We believe we should evaluate our policies, requirements, and standards for MIPS periodically to determine if we need to raise the bar in order to foster the availability of opportunities for continuous performance improvement. We are considering how we can implement policies to support continuous improvement for clinicians who consistently perform well in MIPS. One challenge we face is that, after a clinician has achieved high performance scores on the same measures and activities year over year, there may be little or no room for the clinician to improve their performance. Another challenge is that some MIPS eligible clinicians choose measures and activities on which that they are already performing well, rather than measures and activities where they would be required to implement changes in their workflow, clinical care, or practices in order to achieve a positive payment adjustment. This selection practice, to repeatedly choose the same measures and activities on which the clinician is confident they will perform well, can mean that the clinician has less incentive to transform the way that care is delivered and continuously improve quality of the care they provide. For these reasons, we are considering modifying our policies to encourage clinicians who have consistently been high performers in MIPS to continuously improve various areas of their clinical practice, including implementing more rigorous standards under MIPS and supporting participation in an APM.

We are interested in feedback on approaches to modifying our policies, requirements, and standards under MIPS, while remaining cognizant of the burden any changes may place on MIPS eligible clinicians. Section 1848(q)(1)(A) and (5)(A) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to performance standards for applicable measures and activities in each performance category applicable to the MIPS eligible clinician for a performance period. We are particularly interested in how we can balance the impact of any policy changes on MIPS eligible clinicians who have become accustomed to our current program requirements with the benefit of potential modifications that foster clinicians' continuous improvement. For example, we could increase reporting requirements in traditional MIPS and MVPs, or we could require that specific measures be reported, instead of allowing choice of measures, once MVPs are mandatory to encourage improvement for clinicians with continuously perform well under MIPS.

d. Request for Feedback

We are seeking comment on how we can modify our policies under the Quality Payment Program to foster clinicians' continuous performance

[307] Medicare Value-Based Care Strategy: Alignment, Growth and Equity. The Medicare Value-Based Care Strategy: Alignment, Growth, And Equity. Health Affairs, Jacobs, Fowler, Fleisher, and Seshamani. *https://www.healthaffairs.org/content/forefront/medicare-value-based-care-strategy-alignment-growth-and-equity*.

[308] CMS Announces Increase in 2023 in Accountable Care Organizations and Beneficiaries Benefiting from Coordinated Care in Accountable Care Relationship. *https://www.cms.gov/newsroom/press-releases/cms-announces-increase-2023-organizations-and-beneficiaries-benefiting-coordinated-care-accountable*.

[309] Innovation Center Strategy Refresh. *https://innovation.cms.gov/strategic-direction-whitepaper*.

[310] CMMI Strategy Refresh. October 20, 2021. *https://innovation.cms.gov/strategic-direction-whitepaper*.

improvement and positively impact care outcomes for Medicare beneficiaries. Such modifications for MIPS may include requiring more rigorous performance standards, emphasizing year-to-year improvement in the performance categories, or requiring that MIPS eligible clinicians report on different measures or activities once they have demonstrated consistently high performance on certain measures and activities.

In accordance with implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation request for information is exempt from the PRA.

We request public comment on specifically the following questions:

- What potential policies in the MIPS program would provide opportunities for clinicians to continuously improve care?
- Should we consider, in future rulemaking, changes in policies to assess performance to ensure ongoing opportunities for continuous performance improvement?
- Should we consider, for example, increasing the reporting requirements or requiring that specific measures are reported once MVPs are mandatory?
- Should we consider creating additional incentives to join APMs in order to foster continuous improvement, and if so, what should these incentives be?
- What changes to policies should CMS consider to assess continuous performance improvement and clinicians interested in transitioning from MIPS to APMs?
- We acknowledge the potential increase in burden associated with increasing measure reporting or performance standards. How should we balance consideration of reporting burden with creating continuous opportunities for performance improvement?
- While we are aware of potential benefits of establishing more rigorous policies, requirements, and performance standards, such as developing an approach for some clinicians to demonstrate improvement, we are also mindful that this will result in an increasing challenge for some clinicians to meet the performance threshold. Are there ways to mitigate any unintended consequences of implementing such policies, requirements, and performance standards?

4. MVP Development, Maintenance, and Scoring

a. Development of New MIPS Value Pathways (MVPs)

In the in the CY 2023 PFS final rule (87 FR 70035 and 70037), we finalized modifications to our MVP development process to include feedback from the general public before the notice and comment rulemaking process. We will evaluate a submitted candidate MVP through the MVP development process, and if we determine it is ''ready'' for feedback, we would post a draft version of the submitted candidate MVP on the Quality Payment Program (QPP) website (*https://qpp.cms.gov*) and solicit feedback for a 30-day period. The general public would have the opportunity to submit feedback on the candidate MVP for CMS's consideration through an email inbox. We stated that we would review the feedback received, and determine if any changes should be made to the candidate MVP prior to potentially including the MVP in a notice of proposed rulemaking. If we determine changes should be made to the candidate MVP, we would not notify the interested parties who originally submitted the candidate MVP for CMS consideration in advance of the rulemaking process. We refer readers to the MVP Candidate Feedback Process web page, available on the Quality Payment Program website, to review the public feedback we received for each candidate MVP (*https://qpp.cms.gov/mips/candidate-feedback*).

Through our development processes for new MVPs (*see* 85 FR 84849 through 84856, 87 FR 70035 through 70037), we aim to gradually develop new MVPs that are relevant and meaningful for all clinicians who participate in MIPs. In this proposed rule, we are proposing the inclusion of five new MVPs:

- Focusing on Women's Health;
- Prevention and Treatment of Infectious Disease Including Hepatitis C and HIV;
- Quality Care in Mental Health and Substance Use Disorder;
- Quality Care for Ear, Nose, and Throat (ENT); and
- Rehabilitative Support for Musculoskeletal Care

We continue to develop MVPs based on needs and priorities, as described in the MVP Needs and Priorities document at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1803/MIPS%20Value%20Pathways%20(MVPs)%20Development%20Resources.zip*. We refer readers to Appendix 3: MVP Inventory, in this proposed rule for discussion of each proposed new MVP.

b. MVP Maintenance on Previously Finalized MVPs

In the CY 2023 PFS final rule (87 FR 70037), we finalized a modification to the annual maintenance process for MVPs that were previously adopted through notice and comment rulemaking (86 FR 65410). Interested parties and the general public may submit their recommendations for potential revisions to established MVPs on a rolling basis throughout the year. We would then review the submitted recommendations and determine whether any are potentially feasible and appropriate. We stated that if we identify any submitted recommendations that are potentially feasible and appropriate, we would host a public facing webinar, open to interested parties and the general public through which they may offer their feedback on the potential revisions we have identified. We would publish details related to the timing and registration process for the webinar through our Quality Payment Program Listserv. We held our first MVP maintenance webinar in February 2023 (*https://youtu.be/4cuZGUr88SA*), to discuss any feedback we received from interested parties regarding previously finalized MVPs.

In the CY 2022 PFS final rule (86 FR 65998 through 66031), we finalized seven MVPs that are available for reporting beginning with the CY 2023 performance period/2025 MIPS payment year:

- Advancing Rheumatology Patient Care;
- Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes;
- Advancing Care for Heart Disease;
- Optimizing Chronic Disease Management;
- Adopting Best Practices and Promoting Patient Safety within Emergency Medicine;
- Improving Care for Lower Extremity Joint Repair; and
- Patient Safety and Support of Positive Experiences with Anesthesia.

In addition, in the CY 2023 PFS final rule (87 FR 70037), we finalized five additional MVPs that are available for reporting beginning with the CY 2023 performance period/2025 MIPS payment year:

- Advancing Cancer Care;
- Optimal Care for Kidney Health;
- Optimal Care for Neurological Conditions;
- Supportive Care for Cognitive-Based Neurological Conditions; and
- Promoting Wellness.

In this proposed rule, we are proposing modifications to these twelve

MVPs to propose the addition and removal of measures and improvement activities based on the MVP development criteria (85 FR 84849 through 84854), feedback received through the MVP maintenance process, and based off the proposed removals of certain improvement activities from the improvement activities inventory and the proposed addition of other relevant existing quality measures for MVP participants to select from. In addition, through the MVP maintenance process, we are proposing to consolidate the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single consolidated primary care MVP titled Value in Primary Care MVP, that aligns with the Adult Universal Core Set, as described in the journal article, ''*Aligning Quality Measures across CMS—The Universal Foundation*'' (*https://www.nejm.org/doi/full/10.1056/NEJMp2215539*). (*https://www.nejm.org/doi/full/10.1056/NEJMp2215539*). We refer readers to Appendix 3: MVP Inventory of this final rule for the proposed modifications to the established MVPs.

c. Scoring MVP Performance

In the CY 2022 PFS final rule, we finalized policies for MVP scoring that take effect beginning with the CY 2023 performance period/2025 MIPS payment year. We refer readers to 86 FR 65419 through 65427 for the details of those finalized policies. We previously finalized at § 414.1365(d)(2) that, unless otherwise indicated in § 414.1365(d), the performance standards described at § 414.1380(a)(1)(i) through (iv) apply to the measures and activities included in the MVP (86 FR 65419 through 65421). We noted that in general, we intend to adopt scoring policies from traditional MIPS for MVP participants unless there is a compelling reason to adopt a different policy to further the goals of the MVP framework (86 FR 65419).

We refer readers to section IV.A.4.g.(1)(c)(i) of this proposed rule for proposed policies on MIPS scoring flexibilities in the quality performance category scoring; section IV.A.4.g.(1)(d)(i) in this proposed rule for the proposed change to scoring improvement in the cost performance category; section IV.A.4.f.(3)(b) and Appendix 2: Improvement Activities, of this proposal rule for the proposed improvement activity ''IA_MVP, Practice-wide quality improvement in the MIPS Value Pathway Program (MVP)'' in the improvement activities performance category; section IV.A.4.f.(4) in this proposed rule for the proposed policies for the Promoting Interoperability performance category, including modifications of the SAFER Guide Measure's requirements and the Query of Prescription Drug Monitoring Program (PDMP) measure's exclusion, a technical update to the e-Prescribing measure, an increase in the length of the performance period from 90 continuous days to 180 continuous day, and continuation of our reweighting policy of the performance category for clinical social workers.

In addition, we refer readers to section IV.A.4.d. of this proposed rule for proposed policies regarding subgroups, including reweighting proposals, addition of subgroups to our Targeted Review policies, and a clarification regarding the scoring of facility-based clinicians at the subgroup level.

We refer readers to section IV.A.4.j. of this proposed rule for proposed policies regarding Targeted Review process, including the addition of virtual groups to our Targeted Review policies.

d. Subgroup Reporting

(1) Background

In the CY 2022 PFS final rule, we finalized the option for clinicians to participate as subgroups for reporting MIPS value pathways (MVPs) beginning in the CY 2023 performance period/2025 MIPS payment year (86 FR 65392 through 65394). We refer readers to Title 42 of the Code of Federal Regulations (CFR) at §§ 414.1318 and 414.1365, the CY 2022 PFS final rule (86 FR 65398 through 65405), and the CY 2023 PFS final rule (87 FR 70038 through 70045) for additional details on previously finalized subgroup policies.

In this section, we are proposing to: (1) update the subgroup policy for reweighting of MVP performance categories at § 414.1365(e)(2); (2) update the facility-based scoring and complex patient bonus for subgroups under final score calculation at § 414.1365(e)(3) and (4); (3) update the targeted review policy for subgroups at § 414.1385; and (4) codify in our regulations the subgroup policies finalized in previous years' rules.

(2) Subgroup Reweighting

In the CY 2022 PFS final rule (86 FR 65425 through 65426), we finalized at § 414.1365(e)(2)(ii) that for an MVP Participant that is a subgroup, any reweighting applied to its affiliated group will also be applied to the subgroup. Additionally, we finalized that if reweighting is not applied to an affiliated group, then the subgroup may receive reweighting under the circumstances described at §§ 414.1365(e)(2)(ii)(A) and (B). In establishing this policy, we noted our concern about extreme and uncontrollable circumstances (EUC) that would impact only the subgroup (fire or natural disaster at a specific practice location) and does not affect the entire affiliated group. We also finalized that if a subgroup submits data for a performance category which was reweighted, the subgroup data submission will void the reweighting applied to the performance category.

Upon further consideration of the previously finalized policy, we identified technical constraints that affect our ability to implement the policy. Specifically, we are concerned that the time necessary to adjudicate reconsideration requests for both a subgroup and its affiliated group may deprive the subgroup of knowledge of its reweighting status during a significant portion of the relevant performance period and undermine its ability to plan data submission needs accordingly.

There may be instances when a subgroup and its affiliated group have separate reasons to submit reweighting applications. Those separate applications may request the reweighting of different performance categories. Under § 414.1380(c)(2), clinicians, groups, and APM Entities submit reweighting applications annually on a rolling basis throughout the performance period, or a date specified by CMS. However, the requirement in § 414.1365(e)(2)(ii) that any reweighting applied to a subgroup's affiliated group is also applied to the subgroup means that when a subgroup and its affiliated group both submit reweighting applications, the subgroup will not know its reweighting status until CMS makes a determination regarding the group's reweighting application. Depending on when the group submitted its reweighting request, this may not happen until after the close of the performance period for which the reweighting application was made.

We believe the uncertainty created for a subgroup by not knowing its reweighting status until later in the performance period would disrupt its ability to best plan for the measures and activities on which it will be scored. We recognize that there may be instances when only the subgroup is affected by an extreme and uncontrollable circumstance (natural disaster, fire, hurricane, etc.) and would want to request its own reweighting, independent of the affiliated group. However, we believe that the need for a subgroup to know of its data submission requirements outweighs the

benefit of being able to request its own reweighting independent of the affiliated group.

Separately, there are certain special status designations (non-patient facing, small practice, etc.) that automatically qualify a group for reweighting of the Promoting Interoperability performance category. A subgroup can learn about its affiliated group's special status designation as described in the second paragraph under the definition of MIPS determination period at § 414.1305. Given that subgroup eligibility and special status determinations are made at the group level, we believe that applying an affiliated group's reweighting to a subgroup, and removing the ability of a subgroup to submit a separate reweighting application, would enable subgroups to receive their reweighting status and identify their data submission obligations in a timely manner. We are therefore proposing to revise § 414.1365(e)(2)(ii) to limit the reweighting applied to a subgroup to that which is also applied to its affiliated group beginning with the CY 2024 performance period/2026 MIPS payment year.

In order to operationalize the previously established policy, we intend to implement a manual process for reviewing subgroup reweighting applications for the CY 2023 performance period/2025 MIPS payment year. We considered also using the manual process for reviewing subgroup reweighting applications in future performance periods. However, we are concerned that manually reconciling the reweighting requests would delay the approval of the reweighting requests received from a subgroup. Additionally, we are concerned that it may create confusion for a subgroup to determine whether a performance category has been reweighted and its potential impact on subgroup data submission, specifically in instances when both the subgroup and its affiliated group submit a reweighting application for one or more of the MVP performance categories. For the above reasons, we would use the manual process only for the CY 2023 performance period/2025 MIPS payment year.

We acknowledge that there may be instances when an extreme and uncontrollable circumstance impacts only a subgroup and not the entire affiliated group (for example, fire or natural disaster at the subgroup's practice location). Because subgroup reporting is not mandatory at this time, we believe that in these instances, when a registered subgroup is unable to participate in MVP reporting as a subgroup, the eligible clinicians in the registered subgroup would participate in MIPS via another available reporting option. These clinicians could either participate as individuals or as a group, if its affiliated group chooses to participate in traditional MIPS, or in MVP reporting. Additionally, we established the policy in § 414.1318(b)(1) to not assign a score for a registered subgroup that did not submit data for the applicable performance period (87 FR 70045). In the scenario that the registered subgroup did not submit data, we would assign the highest of the available final scores associated with the clinician's TIN/NPI for the eligible clinicians in the subgroup (86 FR 65536 and 65537). We refer readers to the CY 2023 PFS proposed rule (87 FR 46272 through 46275) for examples that illustrate how the final score is applied for a clinician who is part of a group TIN where only some of the clinicians under that TIN choose to participate in MIPS through subgroups. We will continue to monitor subgroup participation trends and will revisit this policy in the future, as needed.

For the above reasons, we are proposing to revise § 414.1365(e)(2)(ii) to state that an MVP Participant that is a subgroup will receive the same reweighting that is applied to its affiliated group, but that for the CY 2023 performance period/2025 MIPS payment year, if reweighting is not applied to the affiliated group, the subgroup may receive reweighting in the circumstances independent of the affiliated group as described in § 414.1365(e)(2)(ii)(A) and (B).

We request comments on this proposal.

(3) Subgroup Scoring Policies

(a) Facility-Based Score for Subgroups

We established policies for facility-based measurement and scoring for MIPS eligible individual clinicians and groups at § 414.1380(e). Under these standards, we calculate a MIPS eligible clinician's final facility-based score using the clinician's performance in another value-based purchasing program (83 FR 59866 through 59867). In the CY 2022 PFS final rule (86 FR 65425), we finalized at § 414.1365(e)(3) that if an MVP Participant that is not an APM Entity is eligible for facility-based scoring, a facility-based score will also be calculated in accordance with § 414.1380(e). We recognize that we inadvertently overlooked excluding MVP Participants that are subgroups from facility-based scoring. We note that it was not our intent to calculate a facility-based score at the subgroup level.

In the course of implementing MVPs, we have offered clinicians and groups the opportunity to elect to report via MVPs and via traditional MIPS. If a facility-based MIPS eligible clinician participates in MVP reporting as an individual or as part of a group, we will calculate a final score for the MIPS eligible clinician based on the MVP reporting. We would not use the facility-based scores to calculate the clinician's final scores under the MVP because we currently do not have an MVP specifically focused on facility-based measurement. We believe eligible clinicians would choose to participate in MVP reporting with the intent to report on measures applicable to the scope of care provided and therefore, it would be appropriate for facility-based clinicians participating in MVP reporting to receive a score based on the data submitted for the measures and activities in an MVP. We would also calculate a score for traditional MIPS for this clinician or group and assign the higher of the scores. If a facility-based clinician chooses to participate in MVP for a MIPS performance period, a facility-based score would be calculated as part of traditional MIPS and not as part of MVP reporting. Subgroup reporting is limited to MVPs, and subgroup reporting is not available for clinicians reporting on measures in traditional MIPS. Therefore, we are proposing to modify the text at § 414.1365(e)(3) to state that if an MVP Participant, that is not an APM Entity or a subgroup, is eligible for facility-based scoring a facility-based score will also be calculated in accordance with § 414.1380(e).

We are requesting comments on this proposal.

(b) Complex Patient Bonus for Subgroups

In the CY 2018 Quality Payment Program final rule (82 FR 53776), we finalized at § 414.1380(c)(3)(i) that we will add a complex patient bonus to the final score of certain MIPS eligible clinicians that submit data on at least one performance category during the applicable performance period. We finalized that this complex patient bonus would be calculated on the basis of the average Hierarchical Condition Category (HCC) risk score and the dual eligible ratio for beneficiaries seen by clinicians and groups. In the CY 2022 PFS final rule (86 FR 65425), we finalized at § 414.1365(e)(4) that a complex patient bonus will be added to the final score for an MVP Participant in

accordance with § 414.1380(c)(3). We also revised § 414.1380(c)(3) to permit subgroups to receive the complex patient bonus as, in the case of subgroups, we intended to apply the bonus based on the patient population of the subgroup.

Since then, however, we have identified issues with using claims data associated with the clinicians in a subgroup that prevents us from calculating the complex patient bonus at the subgroup level. Specifically, we are unable to identify the beneficiaries seen by the clinicians in a subgroup, and therefore we cannot calculate the average HCC score and dual eligible ratio scores. At the time the relevant claims data is retrieved, the composition of the subgroup may not be known, making it impossible to calculate the required data elements for the complex patient bonus (for example, clinicians, beneficiaries that received care, etc.) at the subgroup level. Additionally, the group may have subgroups that do not collectively represent the entire group, restricting our ability to gather the beneficiary data necessary to calculate the complex patient bonus score at the subgroup level.

We recognize that we would need to retroactively modify the previously established policy at § 414.1365(e)(4) for the CY 2023 performance period/2025 MIPS payment year to address the fact that we cannot calculate the complex patient bonus at the subgroup level. 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. We believe that the failure to apply the proposed change retroactively would be contrary to the public interest because the current rule provides for the calculation of the complex patient bonus score at the subgroup level when it would be impossible for CMS to do so. For the reason stated previously in this section, we are proposing to add § 414.1365(e)(4)(i) to provide that for subgroups, beginning with the CY 2023 performance period/2025 MIPS payment year, the affiliated group's complex patient bonus will be added to the final score. Additionally, we are proposing conforming changes in § 414.1380(c)(3)(v) by removing the term ''subgroups'' so that beginning with the CY 2022 performance period/2024 MIPS payment year, the complex patient bonus is limited to MIPS eligible clinicians, groups, APM Entities, and virtual groups with a risk indicator at or above the risk indicator calculated median. Similarly, we are proposing conforming changes in § 414.1380(c)(3)(vi) by removing the term ''subgroups'' so that beginning with the CY 2022 performance period/2024 MIPS payment year, for MIPS eligible clinicians and groups, the complex patient bonus components are calculated as described under § 414.1365(c)(3)(vi).

We are requesting comments on this proposal.

(4) Targeted Review for Subgroups

We previously established at § 414.1385(a) that a MIPS eligible clinician or group may request a targeted review of the calculation of the MIPS payment adjustment factor under section 1848(q)(6)(A) of the Act and, as applicable, the calculation of the additional MIPS payment adjustment factor under section 1848(q)(6)(C) of the Act (collectively referred to as the MIPS payment adjustment factors) applicable to such MIPS eligible clinician or group for a year (81 FR 77353 through 77358 and 77546). We also finalized the process to submit a targeted review application, codified at § 414.1385(a) (81 FR 77353 through 77358 and 77546). Similar to the previously established targeted review process for individual clinicians and groups, MIPS eligible clinicians who participate in MVP reporting and are scored as a subgroup may request a targeted review beginning with the CY 2023 performance period/2025 MIPS payment year. We recognize that we did not propose changes in the existing language for targeted review at § 414.1385(a) to reflect the availability of the targeted review process for subgroups. We are proposing to modify § 414.1385(a) to state that a MIPS eligible clinician, group, or subgroup may request a targeted review of the calculation of the MIPS payment adjustment factors applicable to such MIPS eligible clinician, group, or subgroup for a year. We are also proposing to modify § 414.1385(a)(1) to state that a MIPS eligible clinician, group or subgroup (including their designated support staff), or a third party intermediary as defined at § 414.1305, may submit a request for a targeted review. Additionally, we are proposing to make conforming changes at § 414.1385(a)(3), (5), and (6) to remove the term ''MIPS eligible clinician or group'' and add in its place the term ''MIPS eligible clinician, group, or subgroup.'' With these proposals, a subgroup that would like to request a review of the calculation for the MIPS payment adjustment factor for MVP data submission in the CY 2023 performance period/2025 MIPS payment year may also submit a targeted review application. We note that we are proposing additional changes to the targeted review process set forth in § 414.1385(a) as further described in section IV.A.4.j. of this proposed rule.

We are requesting comments on the above proposals.

(5) Codification of Previously Finalized Subgroup Policies From Preamble

We have identified that some subgroup policies were finalized in prior rulemaking but were not codified in the CFR. Additionally, we neglected to propose to include subgroups in our previously established definition of ''attestation'' in § 414.1305. We have reviewed the existing language and identified policies that should be codified. We now propose to correct these errors.

It is necessary for each of the proposed changes to the policies described below to be effective beginning with the CY 2023 performance period/2025 MIPS payment year in order for MIPS Value Pathways to operate effectively. 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. Here, we believe that the failure to apply the proposed changes retroactively would be contrary to the public interest because the discrepancies remedied by the below proposals may cause undue confusion for clinicians participating as subgroups and may also create unintended errors in program implementation.

(a) Definitions

(i) Attestation

At § 414.1305, we currently define attestation to mean 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. Beginning in the CY 2023 performance period/2025 MIPS payment year, clinicians participating as subgroups would submit data for the Promoting Interoperability and improvement activities performance categories in an MVP as described at § 414.1365(c). As described previously in this section, we are proposing to adopt this change retroactively pursuant to section 1871(e)(1)(A)(ii). We believe that the failure to apply the proposed

change retroactively would be contrary to the public interest because it would create ambiguity in the requirement for a subgroup to submit data through an attestation for the Promoting Interoperability and improvement activities performance categories as described in § 414.1365(c). Therefore, we are proposing to add the term ''subgroup'' and revise the definition of attestation in § 414.1305 to state that attestation means a secure mechanism, specified by CMS, with respect to a particular performance period, whereby a MIPS eligible clinician, group, or subgroup may submit the required data for the Promoting Interoperability or the improvement activities performance categories of MIPS in a manner specified by CMS.

We are requesting comments on this proposal.

(ii) Submitter Type

At § 414.1305, we defined a submitter type to mean 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. In accordance with the subgroup reporting requirements at § 414.1318(c), we inadvertently overlooked adding subgroups in the definition of submitter type at § 414.1305. As described previously in this section, we are proposing to adopt this change retroactively pursuant to section 1871(e)(1)(A)(ii). We believe that the failure to apply the proposed change retroactively would be contrary to the public interest because it would create ambiguity in the requirement for a subgroup to submit data as described at § 414.1318(c). Therefore, we are proposing to add the term ''subgroup'' and revise the definition of submitter type at § 414.1305 to state that a submitter type means the MIPS eligible clinician, group, Virtual Group, subgroup, APM Entity, or third party intermediary acting on behalf of a MIPS eligible clinician, group, Virtual Group, subgroup, or APM Entity, as applicable, that submits data on measures and activities under MIPS.

We are requesting comments on this proposal.

(b) Data Submission Criteria for the Improvement Activities Performance Category

We refer readers to § 414.1360 for data submission criteria for the improvement activities performance category. In the CY 2022 PFS final rule (86 FR 65462), we finalized revisions to the data submission criteria at § 414.1360(a)(2) to allow subgroups to perform and attest to their improvement activities separately and to apply the 50 percent threshold within their subgroup. We inadvertently overlooked codifying subgroups in the regulation text at § 414.1360(a). The existing regulation text at § 414.1360(a) refers to data submission criteria in the improvement activities performance category for only MIPS eligible clinicians and groups. As described above, we are proposing to adopt this change retroactively pursuant to section 1871(e)(1)(A)(ii). We believe that the failure to apply the proposed change retroactively would be contrary to the public interest because it would create ambiguity in the data submission requirements established in § 414.1360(a)(2) regarding the reporting of improvement activities by subgroups. Therefore, we are proposing to revise § 414.1360(a) to state that for purposes of the transition year of MIPS and future years, MIPS eligible clinicians, groups, or subgroups must submit data on MIPS improvement activities in one of the following manners described at § 414.1360(a)(1) through (a)(1)(i).

We are requesting comments on this proposal.

e. APM Performance Pathway

(1) Overview

In the CY 2021 PFS final rule (85 FR 84859 through 84866), we finalized the APM Performance Pathway (APP) at § 414.1367 beginning in performance year 2021, which was designed to provide a predictable and consistent MIPS reporting option to reduce reporting burden and encourage continued APM participation. We also established that ACOs will be required to report quality data for purposes of the Shared Savings Program via the APP (85 FR 84722).

Under policies finalized under the CY 2023 PFS (87 FR 69858), to meet the quality performance standard under the Shared Savings Program through the 2024 performance year, we stated that ACOs must report the ten CMS Web Interface measures or the three eCQMs/MIPS CQMS and the CAHPS for MIPS survey. Beginning in the 2025 performance year and subsequent performance years, ACOs must report the three eCQMS/MIPS CQMs and the CAHPS for MIPS survey (87 FR 69858 through 69859).

(2) Proposal for the Medicare Clinical Quality Measure for Accountable Care Organizations Participating in the Medicare Shared Savings Program

As discussed in section III.F.2.b.(2) of this proposed rule, we are proposing to establish the Medicare Clinical Quality Measure for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQM) collection type in the APP measure set. The Medicare CQM collection type would be available to only ACOs participating in the Shared Savings Program. ACOs in the Shared Savings Program would have the option to report the Medicare CQM under the APP on only their attributed Medicare fee-for-service beneficiaries who meet the definition of a ''beneficiary eligible for Medicare CQM(s)'' as proposed in section III.F.2.b.(2) of this proposed rule, instead of their all payer/all patient population, beginning with the 2024 performance year. The Medicare CQM would also serve as another collection type in addition to the existing eCQM/MIPS CQM option, which is an all payer/all patient collection type under the APP.

In the CY 2023 PFS final rule, we stated that we will monitor the impact of policies such as the sunsetting of the CMS Web Interface in the 2024 performance year and the requirement to report all payer/all patient eCQMs/MIPS CQMs beginning in the 2025 performance year (87 FR 69833). We also stated that we may revisit these and related issues in future rulemaking based on lessons learned as we gain more experience with ACOs reporting eCQMs/MIPS CQMs (87 FR 69833). As discussed in section III.F.2.b.(2) of this proposed rule, we are committed to supporting ACOs in the transition to all payer/all patient eCQMs/MIPS CQMs and in the transition to digital quality measurement reporting. We encourage readers to review additional background on our proposal to include the Medicare CQM collection type in the APP measure set discussed at section III.F.2.b.(2) of this proposed rule.

f. MIPS Performance Category Measures and Activities

(1) Quality Performance Category

(a) Background

Section 1848(q)(1)(A)(i) and (ii) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards and, using such methodology, to provide for a final score for each MIPS eligible clinician. Section 1848(q)(2)(A)(i) of the Act provides that

the Secretary must use the quality performance category in determining each MIPS eligible clinician's final score, and section 1848(q)(2)(B)(i) of the Act describes the measures that must be specified under the quality performance category.

We refer readers to §§ 414.1330 through 414.1340 and the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77097 through 77162 and 82 FR 53626 through 53641, respectively), and the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 59754 through 59765, 84 FR 63949 through 62959, 85 FR 84866 through 84877, 86 FR 65431 through 65445, and 87 FR respectively) for a description of previously established policies and statutory basis for policies regarding the quality performance category.

In this proposed rule, we are proposing to:

- Amend the definition of the term ''collection type'' to include the Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs).
- Amend (through technical modifications) the data submission criteria for MIPS quality measures and establish the data submission criteria for Medicare CQMs.
- Require administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey in the Spanish translation.
- Maintain the data completeness criteria threshold of at least 75 percent for the CY 2026 performance period/2028 MIPS payment year, and increase the data completeness criteria threshold to at least 80 percent for the CY 2027 performance period/2029 MIPS payment year.
- Establish data completeness criteria for Medicare CQMs.
- Modify the MIPS quality measure set as described in Appendix 1 of this proposed rule, including the addition of new measures, updates to specialty sets, removal of existing measures, and substantive changes to existing measures.

(b) Definition of Collection Type

With the proposed establishment of a new collection type, the Medicare Clinical Quality Measures for Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (Medicare CQMs) specific to the APM Performance Pathway (APP) as described in section III.G.2. of this proposed rule, we are proposing to amend the definition of the term ''collection type'' to include Medicare CQMs in order account for the new collection type available only to Medicare Shared Savings Program ACOs meeting the reporting requirements of the APP. Specifically, starting with the CY 2024 performance period, we are proposing to amend the definition of the term ''collection type'' in § 414.1305 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); Qualified Clinical Data Registry (QCDR) measures; Medicare Part B claims measures; CMS Web Interface measures (except as provided in paragraph (1) of this definition, for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years); the CAHPS for MIPS survey measure; administrative claims measures; and Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs). The Medicare CQMs collection type would serve as a transition collection type under the APP and be available as determined by CMS.

We seek public comment on the proposal to amend the definition of the term collection type to include the Medicare CQMs as an available collection type in MIPS.

(c) Quality Data Submission Criteria

(i) Data Submission Criteria for Quality Measures

In this proposed rule, we are proposing technical amendments to data submission criteria for MIPS quality measures and proposing to establish data submission criteria for Medicare CQMs. The participants in MIPS have expanded from MIPS eligible clinicians and groups to virtual groups starting with the CY 2018 performance period (82 FR 53593 through 53617), APM Entities starting with the CY 2021 performance period (85 FR 84860), and subgroups starting with the CY 2023 performance period (86 FR 65392 through 65394). In order to account for the expansion of participants in MIPS and the applicability of data submission criteria for MIPS quality measures, we are proposing technical amendments. We are proposing technical amendments to recognize that a virtual group, subgroup, and APM Entity are able to meet the data submission requirements pertaining to the quality performance category at § 414.1325(a)(1), (c), and (d). Also, we are proposing technical amendments to recognize that a virtual group and an APM Entity are able to meet the data submission requirements established at § 414.1335(a)(1)(i) and (ii) for the data submission criteria pertaining to Medicare Part B claims measures, MIPS CQMs, eCQMs, and QCDR measures. Additionally, in § 414.1335(a)(1)(ii), we are proposing to modify references of MIPS eligible clinicians and groups, to refer to such clinicians and groups in the singular to ensure that § 414.1335 uniformly references the various types of MIPS participants in the singular. We are making a grammatical correction to § 414.1335(a)(1)(i) to ensure subject-verb agreement. We note that the technical amendments in § 414.1335(a)(1)(i) and (ii) are not applicable to subgroups because MIPS subgroup participation is part of the MVP framework, which has separate data submission criteria specified in § 414.1365.

We are proposing technical amendments to the data submission criteria for the CAHPS for MIPS Survey measure, which would identify the CAHPS for MIPS Survey as a measure in § 414.1335(a)(3). The current rule does not reference the CAHPS for MIPS Survey as a measure, which is erroneous. Also, we are proposing a revision to § 414.1335(a)(3) to recognize that a virtual group, subgroup, and APM Entity are able to administer the CAHPS for MIPS Survey in § 414.1335(a)(3)(i).

Additionally, we are proposing amendments to the data submission criteria for quality performance category at § 414.1325(a)(1)(i) and (ii) in order to clarify that the data submission of MIPS quality measures specific to eCQMs must be submitted utilizing certified electronic health record technology (CEHRT). Section 1848(q)(5)(B)(ii) of the Act provides that under the methodology for assessing the total performance of each MIPS eligible clinician, the Secretary shall: (1) Encourage MIPS eligible clinicians to report on applicable measures under the quality performance category through the use of CEHRT and QCDRs; and (2) For a performance period for a year, for which a MIPS eligible clinician reports applicable measures under the quality performance category through the use of CEHRT, treat the MIPS eligible clinician as satisfying the CQMs reporting requirement under section 1848(o)(2)(A)(iii) of the Act for such year. To encourage the use of CEHRT for quality improvement and reporting on measures under the quality performance category, we established a scoring incentive for MIPS eligible clinicians who use their CEHRT systems to capture and report quality information, specifically the end-to-end electronic reporting bonus points (81 FR 77294

through 77297). We sunset the end-to-end electronic reporting bonus points starting with the CY 2022 performance period (CY 2021 performance period/2023 MIPS payment year was the last performance period in which the end-to-end electronic reporting bonus points were available (85 FR 84907 through 84908)).

With the framework for transforming MIPS through MVPs, we noted in the CY 2021 PFS final rule that we will find ways to incorporate digital measures without needing to incentivize end-to-end electronic reporting with bonus points (85 FR 84907 through 84908). In the CY 2018 Quality Payment Program final rule (82 FR 53636), we encouraged interested parties to consider electronically specifying their quality measures as eCQMs, to encourage MIPS eligible clinicians, groups, and virtual 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 duration of the program. Since the inception of MIPS, our intention has been to encourage the utilization of CEHRT, which encompasses the requirement of CEHRT pertaining to eCQM data submission.

With the sunset of the end-to-end electronic reporting bonus points, there is ambiguity regarding the requirement of utilizing CEHRT for the data submission of eCQMs. While the sunsetting of the end-to-end electronic reporting bonus points was merely to eliminate such bonus points, our intention was to continue the requirement of utilizing CEHRT for eCQM data submission. However, with the sunset of the end-to-end electronic reporting bonus points, there is an inadvertent absence in policy that would continue the requirement of utilizing CEHRT for eCQM data submission. As a result of such inadvertent absence of policy establishing the overarching CEHRT requirements for eCQM data submission for purposes of the quality performance category (aside from the CEHRT requirements under the end-to-end electronic reporting bonus point criteria), we are rectifying the issue by establishing the requirement to utilize CEHRT for the data submission of eCQMs. We are proposing to establish the quality performance category data submission criteria for eCQMs that requires the utilization of CEHRT in § 414.1335(a)(1). Specifically, in § 414.1335(a)(1)(i)(A) and (ii)(A), we are proposing that the data submission criteria for eCQMs requires the utilization of CEHRT, as defined in § 414.1305. Furthermore, we are proposing to amend the definition of CEHRT in § 414.1305(2)(ii) by broadening the applicability of the health IT certification criteria identified in 42 CFR 170.315 that are necessary to report objectives and measures specified under MIPS (would no longer be limited to the Promoting Interoperability performance category). As a result of this proposal, the health IT certification criteria identified in § 414.1305(2)(ii) would be applicable, where necessary, for any MIPS performance category, including the criteria that support eCQMs identified in § 414.1305(2)(ii)(B).

We note that the proposal pertaining to the data submission criteria for eCQMs requiring the utilization of CEHRT would not require third party intermediaries that report eCQMs on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to obtain certification. Currently, third party intermediaries may facilitate reporting on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity for an eCQM while not having been certified to the certification criteria at 45 CFR 170.315(c)(1) through (3). However, if a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity is relying on a third party intermediary for elements of the required certification capabilities for the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to meet the CEHRT definition applicable for their participation, then the third party intermediary would need to provide the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity with a certified Health IT Module for the needed capability or capabilities.

We note that the definition of CEHRT in § 414.1305 references several certification criteria in the ONC Health IT Certification Program for clinical quality measurement, including: ''Clinical quality measures (CQMs)—record and export'' (45 CFR 170.315(c)(1)), as part of the 2015 Base EHR definition in 45 CFR 170.102; ''Clinical quality measures (CQMs)—import and calculate'' (45 CFR 170.315(c)(2)); ''Clinical quality measures (CQMs)—report'' (45 CFR 170.315(c)(3)); and, optionally, ''Clinical quality measures (CQMs)—filter'' (45 CFR 170.315(c)(4)). Under this proposal, at a minimum, a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity would need to utilize technology certified to the criteria at 45 CFR 170.315(c)(1) through (3) to report on eCQMs. We reiterate that certified Health IT Modules meeting these criteria are not required to be provided by the same health IT developer; a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity may use Health IT Modules to meet the certification requirements provided by more than one developer. For example, a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity could use certified health IT meeting the criteria in 45 CFR 170.315(c)(1) and (c)(2) provided as part of their EHR system while a third party intermediary that supports reporting on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity could supply a Health IT Module that meets the criterion in 45 CFR 170.315(c)(3) to generate a measure report and thus, enable a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to meet the requirement to use CEHRT for eCQMs.

Lastly, we are proposing to establish data submission criteria for the Medicare CQM collection type (as proposed under the APP in section III.G.2. of this proposed rule) in § 414.1335(a)(4). Specifically, in § 414.1335(a)(4)(i), we are proposing that the data submission criteria pertaining to Medicare CQMs would be met by, a MIPS eligible clinician, group, and APM Entity reporting on the Medicare CQMs (reporting quality data on beneficiaries eligible for Medicare CQMs as defined at § 425.20) within the APP measure set and administering the CAHPS for MIPS Survey as required under the APP.

We seek public comment on the proposals regarding the technical amendments that pertain to the data submission criteria for MIPS quality measures and the establishment of data submission criteria for Medicare CQMs.

(ii) Data Submission Criteria for the CAHPS for MIPS Survey Measure

The CAHPS for MIPS Survey measures patients' experience of care within a group, virtual group, subgroup, and APM Entity, including Shared Savings Program ACOs. The survey measures ten dimensions of patient experience of care, known as summary survey measures, for which patients may be the best, if not only source of information. The CAHPS for MIPS Survey is optional for all groups, virtual groups, subgroups, and APM Entities of 2 or more eligible clinicians reporting via traditional MIPS or MIPS Value Pathways (MVPs), and is required for Shared Savings Program ACOs reporting via the APM Performance Pathway (APP).

(A) Require the Administration of the CAHPS for MIPS Survey in the Spanish Translation

We have created official translations of the CAHPS for MIPS Survey in 7 languages, including Spanish, Cantonese, Korean, Mandarin, Portuguese, Russian, and Vietnamese, in addition to the required administration of English survey. However, use of these translations is generally voluntary, with the exception of the requirement to administer the Spanish translation of the CAHPS for MIPS Survey for patients residing in Puerto Rico. Groups, virtual groups, subgroups, and APM Entities that elect CAHPS for MIPS Survey must contract with a CMS-approved survey vendor to administer the CAHPS for MIPS Survey, and must request survey translations for the vendor to administer the CAHPS for MIPS Survey in an optional language. Generally, the CAHPS for MIPS Survey translations are an additional cost to the groups, virtual group, subgroup, and APM Entities.

Our analysis of historic CAHPS data indicates that the use of survey translations has not been widespread and there is unmet need for access to surveys in the 7 available translations. The analysis of survey translation use by groups and Shared Savings Program ACOs fielding the CY 2021 performance period CAHPS for MIPS Survey indicates that 406 out of 559 organizations have about one percent to 9 percent respondents reporting they speak a language other than English at home, and 141 out of 559 organizations have 10 percent or more respondents reporting they speak a language other than English at home. Among these 141 organizations with 10 percent or more respondents reporting they speak a language other than English at home, 114 organizations have all of their survey responses in English. These data highlight a potential gap in the need for and access to a CAHPS for MIPS Survey translation within at least 20 percent (114 out of 559 organizations) of the groups and Shared Savings Program ACOs administering the 2021 CAHPS for MIPS Survey. For the CAHPS for MIPS Survey, the most common non-English language spoken at home by patients is Spanish. We analyzed data from the U.S. Census Bureau, specifically from the 2021 American Community Survey, and found that Spanish is spoken by 61 percent of those who speak a language other than English at home.[311] Among those age 65 and older who speak a language other than English at home, 49 percent speak Spanish. Requiring groups, virtual groups, subgroups, and APM Entities to administer the CAHPS for MIPS Survey in English and Spanish would therefore address much of the unmet need. The requirement would indirectly require vendors to offer the administration of the Spanish translation of the CAHPS for MIPS Survey, and would increase costs to groups, virtual groups, subgroups, and APM Entities.

We propose to require the administration of the CAHPS for MIPS Survey in the Spanish translation; more specifically, we propose to require groups, virtual groups, subgroups, and APM Entities to contract with a CMS-approved survey vendor that, in addition to administering the survey in English, would administer the Spanish translation to Spanish-preferring patients using the procedures detailed in the CAHPS for MIPS Quality Assurance Guidelines. Also, we are recommending that groups, virtual groups, subgroups, and APM Entities administer the survey in the other available translations (Cantonese, Korean, Mandarin, Portuguese, Russian, and Vietnamese) based on the language preferences of their patients. The proposal and recommendation would make the survey more accessible to survey respondents who can only respond in Spanish or another available translation, and provide an opportunity to better understand their experiences of care and any disparities in care.

Furthermore, the requirement of the administration of the Spanish translation and the recommendation of utilizing the other translations of the CAHPS for MIPS Survey align with CMS's effort to provide culturally and linguistically appropriate services (CLAS), which are intended to advance health equity, improve quality, and help eliminate health care disparities.[312] Other CMS-administered CAHPS Surveys, such as the Medicare Advantage and Prescription Drug Plan CAHPS, require the administration of Spanish translation survey. For the fiscal year (FY) 2024 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) Prospective Payment System (PPS) proposed rule, the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program is proposing to require hospitals to collect information about the language that the patient speaks while in the hospital (whether English, Spanish, or another language), and that the official Spanish translation of the Hospital CAHPS Survey be administered to all patients who prefer Spanish (88 FR 27114).

We seek public comment on the proposal to require the administration of CAHPS for MIPS Survey in the Spanish translation. In addition, we are interested in comments from organizations that administer the CAHPS for MIPS Survey on whether they consider contracting with vendors to administer the survey in one or more of the available survey translations based on the language preferences of patients. If so, we are also interested in learning about the factors that more or less likely affect the administration of survey translations where there is need for one or more of the available translations. These comments may inform future rulemaking.

(d) Data Completeness Criteria

(i) Data Completeness Criteria for Quality Measures, Excluding the Medicare CQMs

As described in the CY 2017 Quality Payment Program proposed rule (81 FR 28188 and 28189), to ensure that data submitted on quality measures are complete enough to accurately assess each MIPS eligible clinician's quality performance, we established a data completeness requirement. Section 1848(q)(5)(H) of the Act provides that analysis of the quality performance category may include quality measure data from other payers, specifically, data submitted by MIPS eligible clinicians with respect to items and services furnished to individuals who are not individuals entitled to benefits under Part A or enrolled under Part B of Medicare. In the CY 2017 and CY 2018 Quality Payment Program final rules and the CY 2020 PFS final rule, we also noted that we would increase the data completeness criteria threshold over time (81 FR 77121, 82 FR 53632, and 84 FR 62951). For the CY 2017 performance period/2019 MIPS payment year (first year of the implementation of MIPS), CMS established the data completeness criteria threshold to reflect a threshold of at least 50 percent (81 FR 77125). We increased the data completeness criteria threshold from at least 50 percent to at least 60 percent for the CY 2018 performance period/2020 MIPS payment year (81 FR 77125 and 82 FR 53633) and maintained a threshold of at

[311] U.S. Census Bureau, 2021 American Community Survey, S1603: Characteristics of People by Language Spoken at Home, 2021 American Community Survey 5-Year Estimate Subject Tables. Available at *https://data.census.gov/table?q=S1603&tid=ACSST5Y2021.S1603.*

[312] Centers for Medicare & Medicaid Services. Achieving Health Equity. Available at *https://www.cms.gov/Outreach-and-Education/MLN/WBT/MLN1857916-OMH-AHE/OMHAHE/ahe/lesson01/09/index.html.*

least 60 percent for the CY 2019 performance period/2021 MIPS payment year (82 FR 53633 and 53634). For the CY 2020 performance period/2022 MIPS payment year, we increased the data completeness criteria threshold from at least 60 percent to at least 70 percent (84 FR 62952). We maintained data completeness criteria threshold of at least 70 percent for the CY 2021, CY 2022, and CY 2023 performance periods/2023, 2024, and 2025 MIPS payment years (86 FR 65435 through 65438). For the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years, we increased the data completeness criteria threshold from at least 70 percent to at least 75 percent (87 FR 70049 through 70052). We continue to believe that it is important to incrementally increase the data completeness criteria threshold as MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities gain experience with MIPS.

The incorporation of higher data completeness criteria thresholds in future years ensures a more accurate assessment of a MIPS eligible clinician's performance on quality measures and prevents selection bias to the extent possible (81 FR 77120, 82 FR 53632, 83 FR 59758, 86 FR 65436, and 87 FR 70049). We have encouraged all MIPS eligible clinicians to perform the quality actions associated with the quality measures on their patients (82 FR 53632, 86 FR 65436, and 87 FR 70049). The data submitted for each measure is expected to be representative of the individual MIPS eligible clinician, group, or virtual group's overall performance for that measure. A data completeness criteria threshold of less than 100 percent is intended to reduce burden and accommodate operational issues that may arise during data collection during the initial years of the program (82 FR 53632, 86 FR 65436, and 87 FR 70049).

We previously noted concerns raised by interested parties regarding the unintended consequences of accelerating the data completeness thresholds too quickly, which may jeopardize a MIPS eligible clinicians' ability to participate and perform well under MIPS (81 FR 77121, 82 FR 53632, 84 FR 62951, and 87 FR 70049). We want to ensure that an appropriate, yet achievable, data completeness criteria threshold is applied to all eligible clinicians participating in MIPS. Based on our analysis of data completeness rates from data submission for the CY 2017 performance period,[313] it is feasible for eligible clinicians and groups to achieve a higher data completeness criteria threshold without jeopardizing their ability to successfully participate and perform in MIPS.

As MIPS eligible clinicians, groups, and virtual groups have gained experience participating in MIPS, particularly meeting the data completeness criteria threshold over the last 7 years (from CY 2017 performance period to CY 2023 performance period), such experience has prepared MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entity to meet incremental increases in the data completeness criteria threshold. We have maintained a data completeness criteria threshold of at least 70 percent for four years from the CY 2020 performance period to the CY 2023 performance period and as a result, individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities had 4 years of a maintained data completeness criteria threshold of at least 70 percent before transitioning to an increased data completeness criteria threshold of at least 75 percent for a 2-year timeframe (CY 2024 and CY 2025 performance periods) with more than 12 months to prepare for an increased data completeness criteria threshold of at least 75 percent before such threshold becomes effective for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years.

As we assessed the timeframe for increasing the data completeness criteria threshold, we determined that maintaining the data completeness criteria threshold of at least 75 percent for a total of 3 years would provide sufficient time for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities to transition to another increase in the data completeness criteria threshold. For the CY 2026 performance period/2028 MIPS payment year, we are proposing to maintain the data completeness criteria threshold of at least 75 percent. This would provide MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities with sufficient time to prepare for an incrementally increase in the data completeness criteria threshold starting with the CY 2027 performance period/2029 MIPS payment year. Therefore, MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities could continue transitioning to an incrementally increased data completeness criteria threshold of at least 75 percent to at least 80 percent. In establishing data completeness criteria thresholds in advance of an applicable performance period, it is advantageous to delineate the expectations for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities, so they can adequately prepare for a transition to higher data completeness criteria threshold, particularly the increase in data completeness criteria threshold to at least 80 percent. Thus, we are proposing to increase the data completeness criteria threshold from 75 percent to 80 percent for the CY 2027 performance period/2029 MIPS payment year.

The use of electronic health records (EHRs) and eCQMs can reduce burden associated with meeting higher data completeness standards as the collection of eCQM data within the EHR can allow eligible clinicians to report on 100 percent of the eligible population with data in the EHR for a measure. We continue to encourage individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities, including small and rural practices, to explore EHR adoption and the reporting of eCQMs to reduce burden and technical challenges to ensure data accuracy as we seek to increase the data completeness criteria threshold. Individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities that continue to utilize other means of data collection for MIPS CQMs, including the collection of MIPS CQM data reported by registries and/or QCDRs, would need have the logic code of their EHRs to be updated to account for the increased data completeness criteria threshold. Increasing the data completeness criteria threshold would not pose a substantial burden to MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities, unless they are manually extracting and reporting quality data. However, increasing the data completeness criteria threshold provides for the more accurate assessment of performance.

For the aforementioned reasons, it is important to incrementally increase the data completeness criteria threshold. In this proposed rule, we are proposing to maintain the data completeness threshold for an additional year before incrementally increasing the data completeness criteria threshold. Specifically, in § 414.1340(a), we are proposing the following data completeness criteria thresholds pertaining to QCDR measures, MIPS CQMs, and eCQMs:

- At paragraph (a)(4), for the CY 2026 performance period/2028 MIPS

[313] As described in the CY 2020 PFS final rule (84 FR 62951), the average data completeness rates were as follows: for individual eligible clinicians, it was 76.14; for groups, it was 85.27; and for small practices, it was 74.76.

payment year, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs must submit data on at least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients that meet the measure's denominator criteria, regardless of payer.

- At paragraph (a)(5), for the CY 2027 performance period/2029 MIPS payment year, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs must submit data on at least 80 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients that meet the measure's denominator criteria, regardless of payer.

Similarly, in § 414.1340(b), respectively, we are proposing the following data completeness criteria thresholds pertaining to Medicare Part B claims measures:

- At paragraph (b)(4), for the CY 2026 performance period/2028 MIPS payment year, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on Medicare Part B claims measures must submit data on at least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients seen during the corresponding performance period to which the measure applies.
- At paragraph (b)(5), for the CY 2027 performance period/2029 MIPS payment year, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on Medicare Part B claims measures must submit data on at least 80 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients seen during the corresponding performance period to which the measure applies.

Also, for the data completeness criteria pertaining to the quality performance category, we are proposing technical amendments to recognize that a virtual group, subgroup, and APM Entity must meet the data completeness criteria requirements established at § 414.1340(a), (b), and formerly paragraph (d), new paragraph (e) due to the proposal to establish the data completeness criteria for the new collection type, Medicare CQM, in § 414.1340(d) as discussed in the following section, IV.A.4.f.(1)(d)(ii), of this proposed rule.

We seek public comment on these proposals.

(ii) Data Completeness Criteria for the Medicare CQMs

As we propose to establish a new collection type, the Medicare CQMs specific to the APM Performance Pathway (APP) as described in section III.G.2. of this proposed rule, we are also proposing to establish the data completeness criteria thresholds for the Medicare CQMs. Specifically, in § 414.1340(d), respectively, we are proposing the following data completeness criteria thresholds pertaining to Medicare CQMs:

- At paragraph (d)(1), for the CY 2024, CY 2025, and CY 2026 performance periods/2026, 2027, and 2028 MIPS payment years, an APM Entity, specifically a Shared Savings Program ACO that meets the reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on at least 75 percent of the APM Entity's applicable beneficiaries eligible for the Medicare CQM, as proposed to be defined at § 425.20, who meet the measure's denominator criteria.
- At paragraph (d)(2), for the CY 2027 performance period/2029 MIPS payment year, an APM Entity, specifically a Shared Savings Program ACO that meets the reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on at least 80 percent of the APM Entity's applicable beneficiaries eligible for the Medicare CQM, as proposed to be defined at § 425.20, who meet the measure's denominator criteria.

We are proposing to establish the aforementioned data completeness criteria thresholds for the Medicare CQMs collection type in advance of the applicable performance periods. We recognize that it is advantageous to delineate the expectations for ACOs as they prepare to meet the quality reporting requirements for the Medicare CQMs collection type under the APP. We will assess the availability of the Medicare CQMs as a collection type under the APP during the initial years of implementation and determine the timeframe to sunset the Medicare CQM as a collection type in future rulemaking.

(e) Selection of MIPS Quality Measures

Section 1848(q)(2)(D)(i) of the Act requires the Secretary, through notice and comment rulemaking, to establish an annual final list of quality measures from which MIPS eligible clinicians may choose for the purpose of assessment under MIPS. Section 1848(q)(2)(D)(i)(II) of the Act requires that the Secretary annually update the list by removing measures from the list, as appropriate; adding to the list, as appropriate, new measures; and determining whether measures that have undergone substantive changes should be included on the updated list.

Previously finalized MIPS quality measures can be found in the CY 2023 PFS final rule (87 FR 70250 through 70633), CY 2022 PFS final rule (86 FR 65687 through 65968); CY 2021 PFS final rule (85 FR 85045 through 85377); 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 CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). We are proposing changes to the MIPS quality measure set, as described in Appendix 1 of this proposed rule, include the following: the addition of new measures; updates to specialty sets; removal of existing measures, and substantive changes to existing measures. For the CY 2024 performance period, we are proposing a measure set of 200 MIPS quality measures in the inventory.

The new MIPS quality measures that we are proposing to include in MIPS for the CY 2024 performance period and future years can be found in Table Group A of Appendix 1 of this proposed rule. For the CY 2024 performance period, we are proposed 14 new MIPS quality measures, which includes one composite measure; and 7 high priority measures, of which 4 are also patient-reported outcome measures.

In addition to the establishment of new individual MIPS quality measures, we develop and maintain specialty measure sets to assist MIPS eligible clinicians with selecting quality measures that are most relevant to their scope of practice. We are proposing modifications to existing specialty sets and new specialty sets as described in Table Group B of Appendix 1 of this proposed rule. 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. Specialty and subspecialty sets are not inclusive of every specialty or subspecialty.

On January 3, 2023, we announced that we would be accepting recommendations for potential new specialty measure sets or revisions to existing specialty measure sets for year 8 of MIPS under the Quality Payment

Program.[314] These recommendations were based on the MIPS quality measures finalized in the CY 2022 PFS final rule and the 2022 Measures Under Consideration List; the recommendations include the addition or removal of current MIPS quality measures from existing specialty sets, or the creation of new specialty sets. All specialty set recommendations submitted for consideration were assessed and vetted, and as a result, the recommendations that we agree with were proposed in this proposed rule.

In addition to establishing new individual MIPS quality measures and modifying existing specialty sets and new specialty sets as described in Tables Group A and Group B of Appendix 1 of this proposed rule, we refer readers to Table Group C of Appendix 1 of this proposed rule for a list of quality measures and rationales for measure removal. We have previously specified certain criteria that will be used when we are considering the removal of a measure (81 FR 77136 and 77137; 83 FR 59763 through 59765; 84 FR 62957 through 62959). For the CY 2024 performance period, we are proposing to remove 12 MIPS quality measures and partially remove 3 MIPS quality measures that are proposed for removal from traditional MIPS and proposed for retention for use in MVPs. We refer readers to Table Group DD of Appendix 1 of this proposed rule for further information regarding the proposals to retain such measures for retention for use in relevant MVPs. Of the 12 MIPS quality measures proposed for removal, the following pertains to such measures: 2 MIPS quality measures are duplicative to a proposed new MIPS quality measure; 3 quality measures are duplicative of current measures; 5 MIPS quality measures that are under the topped-out lifecycle; one measure is extremely topped out; and one MIPS quality measure is constructed in a manner that makes it difficult to attribute the quality action to the clinician, which creates burden. We have continuously communicated to interested parties our desire to reduce the number of process measures within the MIPS quality measure set (*see,* for example, 83 FR 59763 through 59765). The proposal to remove the quality measures described in Table Group C of the this proposed rule would lead to a more parsimonious inventory of meaningful, robust measures in the program, and that our approach to removing measures should occur through an iterative process that includes an annual review of the quality measures to determine whether they meet our removal criteria.

Also, we are proposing substantive changes to several MIPS quality measures, which can be found in Table Group D of Appendix 1 of this proposed rule. We have previously established criteria that would apply when we are considering making substantive changes to a quality measure (81 FR 77137, and 86 FR 65441 through 65442). We are proposing substantive changes to 59 MIPS quality measures, which includes 3 MIPS quality measures proposed to be retained for utilization under MVPs (we refer readers to Table Group DD of Appendix 1 of this proposed rule for such measures that are proposed for retention for use in relevant MVPs). 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.

Lastly, we are proposing substantive changes to the CMS Web Interface measures that are available as a collection type and submission type for the Medicare Shared Savings Program ACOs meeting reporting requirements under the APP. The substantive changes to the CMS Web Interface measures can be found in Table Group E of Appendix 1 of this proposed rule.

We seek public comment on the proposals to modify the quality performance category measure set, a measure set of 200 MIPS quality measures in the inventory for the CY 2024 performance period, which includes the following:

- Implementation of 14 new MIPS quality measures: one composite measure; and 7 high priority measures, of which 4 are also patient-reported outcome measures;
- Removal of 12 MIPS quality measures: 2 quality MIPS measure are duplicative to a proposed new quality measure; 3 MIPS quality measures are duplicative to current quality measures; 5 MIPS quality measures are under the topped-out lifecycle; one MIPS quality measure is extremely topped out; and one MIPS quality measure is constructed in a manner that makes it difficult to attribute the quality action to the clinician, which creates burden;
- Partial removal of 3 MIPS quality measures: 3 MIPS quality measures removed from traditional MIPS and retained for use in MVPs; and
- Substantive changes to 59 MIPS quality measures.

(2) Cost Performance Category

Section 1848(q)(2)(A) of the Act includes resource use as a performance category under the MIPS. We refer to this performance category as the cost performance category. As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of the MIPS are 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 cost performance category.

In this proposed rule, we are proposing to add five new episode-based measures to the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year. These five measures are: Depression, Emergency Medicine, Heart Failure, Low Back Pain, and Psychoses and Related Conditions. We are proposing that MIPS eligible clinicians must meet or exceed a minimum of 20 cases for each of these measures to be assessed on such measure, and we are seeking comments on our interpretation of the language on the case minima codified at § 414.1350(c). We are also proposing to remove the Simple Pneumonia with Hospitalization episode-based measure from the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year. Finally, we are proposing to add the five new episode-based measures and remove the Simple Pneumonia with Hospitalization episode-based measure from the operational list of care episode and patient condition groups and codes.

For a description of the statutory basis for and existing policies pertaining to the cost performance category, we refer readers to § 414.1350 and the CY 2017 Quality Payment Program final rule (81 FR 77162 through 77177), CY 2018 Quality Payment Program final rule (82 FR 53641 through 53648), CY 2019 PFS final rule (83 FR 59765 through 59776), CY 2020 PFS final rule (84 FR 62959 through 62979), CY 2021 PFS final rule (85 FR 84877 through 84881), CY 2022 PFS final rule (86 FR 65445 through 65461), and CY 2023 PFS final rule (87 FR 70055 through 70057).

(a) Addition of Episode-Based Measures

(i) Background

Under § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance

[314] Message to the Quality Payment Program listserv on January 3, 2023, entitled: ''The Centers for Medicare & Medicaid Services (CMS) is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure Sets and/or Revisions to the Existing Specialty Measure Sets for the 2024 Performance Year of the Merit-based Incentive Payment System (MIPS).''

category. There are currently 25 cost measures in the cost performance category for the CY 2023 performance period/2025 MIPS payment year, comprising of 23 episode-based measures covering a range of conditions and procedures and two population-based measures. We worked with the measure development contractor to identify the proposed five new episode-based measures for development through empirical analyses and public comment. These proposed measures cover clinical topics and MIPS eligible clinicians currently with limited or no applicable cost measures. As such, these proposed measures would help fill gaps in the cost performance category's measure set. In addition, these proposed measures would support the transition from traditional MIPS to MIPS Value Pathways (MVPs) by allowing for new MVPs to be created and enhancing existing MVPs. Further, the addition of these proposed measures would address interested parties' feedback about the need for more clinically refined episode-based measures in the cost performance category. This proposal would also increase the cost coverage of care episode and patient conditions groups, moving closer towards the statutory goal of covering 50 percent of expenditures under Medicare Parts A and B, as specified under section 1848(r)(2)(i)(I) of the Act.

At a high level, episode-based measures represent the cost to Medicare and beneficiaries for the items and services furnished during an episode. They aim to compare MIPS eligible clinicians on the basis of the cost of care that is clinically related to their treatment and management of a patient and provided during the episode's timeframe. Specifically, for such measures, we define and measure the cost of care for the episode based on the allowed amounts on Medicare claims, which include both Medicare trust fund payments and any applicable beneficiary deductible and coinsurance amounts. The cost of care for these measures includes amounts paid under Medicare Parts A and B, and, on a case-by-case basis, Medicare Part D that have been standardized to remove price variation from non-clinical factors. The Parts A and B payment standardization methodology and the Part D payment standardization methodology are available at *https://resdac.org/articles/cms-price-payment-standardization-overview.* Information about how the Part D standardization methodology incorporates rebates into standardized amounts is available at *https://www.cms.gov/files/document/2023-part-d-rebate-methodology.pdf.* We refer the readers to section IV.A.4.f.(2)(a)(iii) of this proposed rule for more information on the five episode-based measures we are proposing.

In this proposed rule, we provide detail about the new measures that we are proposing to include in the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year. In section IV.A.4.f.(2)(a)(ii) of this proposed rule, we summarize the timeline for development of these proposed measures, including engagement activities undertaken by the measure development contractor. In section IV.A.4.f.(2)(a)(iii) of this proposed rule, we summarize the proposed new measures that would be included in the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year. For the proposed Emergency Medicine episode-based measure, we provide detail about the measure's construction, which evaluates a MIPS eligible clinician's or clinician group's risk-adjusted cost of care to Medicare for patients who receive treatment in the Emergency Department (ED) setting. In section IV.A.4.f.(2)(b) of this proposed rule, we discuss our proposal that MIPS eligible clinicians must meet or exceed a minimum of 20 cases for each of these proposed measures to be assessed on such measure and request comments on our interpretation of case minima regulatory language.

(ii) Overview of Measure Development Process for New Episode-Based Measures

In this section, we describe the development process for the five proposed episode-based measures.

Development of episode-based measures for the cost performance category must comply with the statutorily required processes set forth in section 1848(r) of the Act. We note that the measure developer uses a ''wave'' approach to indicate cycles of measure development where clinical expert panels convene to select episode groups to develop into cost measures and to provide input on the measures' specifications. All five of the proposed measures have been developed with extensive engagement from interested parties, including clinicians, persons with lived experience, and the general public. The term ''persons with lived experience,'' as used in this section IV.A.4.f.(2) of this proposed rule, refers to persons and family of persons who have experienced these conditions or diseases. Our approach to engagement is outlined in the CY 2018 Quality Payment Program final rule (82 FR 53644 through 53645), the CY 2019 PFS final rule (83 FR 59767 through 59769), and the CY 2022 PFS proposed rule (86 FR 39396 through 39397). These processes have been refined over time to incorporate feedback from interested parties, such as to extend the development timeline from 12 months in Wave 2 to 18 months in Waves 3 and 4, and to integrate bidirectional conversations between persons with lived experience and clinical experts.

Four of these measures began development in 2020 in Wave 4 of development, and one of these measures has been in development and refinement since 2018 (as part of Wave 2 of measure development). Specifically, the Depression, Emergency Medicine, Heart Failure, and Low Back Pain episode-based measures were developed in the Wave 4 cycle of measure development through an 18-month process. As a first step, the measure development contractor held a public comment period from December 2020 through February 2021 to gather feedback on which clinical areas to prioritize for development. During the public comment period, the measure developer received 36 comments on the candidate episode groups for development in Wave 4. This feedback, in conjunction with empirical testing by the measure development contractor, was used to inform the decision to develop these specific clinical areas—depression, emergency medicine, heart failure, and low back pain—into episode-based measures. The summary of the public comments is available in this document *https://www.cms.gov/files/document/wave-4-public-comment-summary.pdf.*

Following our decision to develop measures for depression, emergency medicine, heart failure, and low back pain, the measure development contractor convened four clinician expert panels, comprised of a total of 73 members, affiliated with 63 organizations and specialty societies. Each panel also incorporated the perspective of persons with lived experience following a new approach where their input is collected via structured focus groups, interviews or surveys, and then summarized and presented to the clinical expert panels.

Then, the measure development contractor held a national field testing period from January 14, 2022 to March 25, 2022. During this field testing period, MIPS eligible clinicians and clinician groups meeting a minimum threshold of episodes for each measure could review field test reports and an episode-level file with detailed

information to understand the types of services that comprise a large or small share of their episode costs. Supplemental materials, such as testing information on measures, a Frequently Asked Questions document, and mock field test reports were posted publicly for interested parties' review. The measure development contractor gathered all feedback via a survey and a summary of this feedback from the field testing period is available at *https://www.cms.gov/files/document/2022-field-testing-feedback-summary-report.pdf*.

The measure development contractor also has a standing technical expert panel (TEP), composed of 20 members from different clinical areas, academia, health care and hospital administration, and persons with lived experience, which provides overarching input on cross-measure topics, such as testing approaches and methodology. For example, the TEP discussed challenges in developing chronic condition episode-based measures and ways that the framework can address those challenges, provided feedback on the attribution rules (that is, the algorithms and the types of codes used in each algorithm) that would demonstrate a relationship between a clinician group and a patient with a chronic condition(s), and discussed service assignment, risk adjustment, and exclusions. This input helped inform the specifications for the chronic condition episode-based measure framework, which serves as the framework for three of the chronic condition episode-based measures (that is, Depression, Heart Failure, and Low Back Pain episode-based measures) developed in Wave 4 and being proposed in this proposed rule.

Separately from the other four proposed measures, the Psychoses and Related Conditions measure originally had begun development in 2018 as part of Wave 2, alongside 10 other episode-based measures. However, this measure has not yet been implemented in the cost performance category. During the 2018 through 2019 measure development cycle, a convened clinical expert workgroup met four times to provide detailed input on the measure and the measure was field tested as part of the field testing period in 2018. The summaries of the workgroup webinars as well as the comments received on the original version of the measure during field testing are available on the QPP Cost Measure Information page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Cost-Measures.*

We included the Psychoses and Related Conditions measure in the ''2018 Measures Under Consideration List'' (*https://www.cms.gov/files/document/2018rmuc-listclearancerpt.pdf*) and the Measure Application Partnership (MAP) reviewed the measure during the 2018–2019 review cycle. In December 2018, the MAP Clinician Workgroup provided the Psychoses and Related Conditions episode-based measure a preliminary recommendation of ''Conditional support for rulemaking,'' on the condition of endorsement by a consensus-based entity (CBE). In January 2019, the MAP Coordinating Committee overturned the MAP Clinician Workgroup's recommendation and voted to replace it with a recommendation of ''Do not support for rulemaking.'' The MAP Coordinating Committee's concerns with the Psychoses and Related Conditions measure related to: (1) the measure's attribution model and its potential to hold clinicians responsible for costs outside of their influence; (2) geographic variation in community resource availability; (3) effects of physical comorbidities on measure score; and (4) the potential to exacerbate access issues in mental health care. For more detail please refer to the final report at *http://www.qualityforum.org/Publications/2019/03/MAP_Clinicians_2019_Considerations_for_Implementing_Measures_Final_Report.aspx.*

In the CY 2020 PFS proposed rule (84 FR 40760), we responded to the MAP Coordinating Committee's concerns, as we believed that these concerns had already been addressed through the development and testing processes, and solicited comments as part of the request for information (RFI) on the potential use of the original draft version of the Psychoses and Related Conditions episode-based measure in the cost performance category in a future MIPS performance period.

The measure development contractor considered the MAP Coordinating Committee's comments and responses to the RFI that we received when refining the Psychoses and Related Conditions measure in 2021–2022. In October 2021, the measure developer reconvened the Psychoses and Related Conditions Clinical Expert Workgroup to consider measure refinements to address concerns, noting that the measure concept continued to be important as it would encourage value in mental health care. The details of these refinements are outlined in section IV.A.4.f.(2)(a)(iii) of this proposed rule. Then, the measure development contractor field tested the Psychoses and Related Conditions measure alongside the other four proposed new episode-based measures discussed previously in this section of the proposed rule. The feedback received during field testing was further discussed by the Psychoses and Related Conditions Clinical Expert Workgroup in April 2022.

More information about the measure development and interested parties engagement process for the five proposed episode-based measures for inclusion in the cost performance category is available in materials on the QPP Cost Measure Information page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Cost-Measures.* Summaries of the public comment period and clinician expert workgroup meetings organized by the measure development contractor are also available on the QPP Cost Measure Information page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Cost-Measures*.

Similar to previous years, the measure development contractor has continued to engage clinicians and interested parties through the standing TEP, public comment periods, measure-specific Clinical Expert Workgroups, Person and Family Engagement opportunities, and national field testing, as well as conduct extensive education and outreach activities. For more information on the methods through which the measure development contractor gathered expert input during measure development and other interested parties engagement activities, please refer to the ''2023 Summary of Cost Measures'' document that is available at *https://www.cms.gov/files/document/2023-mips-summary-cost-measures.pdf.*

After these extensive measure development and refinement activities, we included the five proposed episode-based measures on our 2022 Measures Under Consideration (MUC) List (available for download at *https://mmshub.cms.gov/sites/default/files/2022-MUC-Lst.xlsx*) to be considered for potential use in MIPS. The MAP reviewed the measures during the 2022–2023 review cycle. This process involved reviews by the MAP Health Equity and MAP Rural Health Advisory Groups, as well as two public comment periods. In December 2022, the MAP Clinician Workgroup discussed the measures, taking into consideration the input from the MAP Health Equity and MAP Rural Health Advisory Groups and the public comments. The MAP Clinician Workgroup reached consensus to conditionally support all five episode-based measures for rulemaking, pending the endorsement of the

measures by a CBE. The MAP Clinician Workgroup's concerns related to the inclusion of Medicare Part D covered items and services in certain measures, potential unintended consequences of assessing costs related to mental health care, appropriateness of the attribution methodology, and request for additional detail on testing into adjusting for social determinants of health (for example, geographic location and socioeconomic status) and evidence of care stinting. In January 2023, the MAP Coordinating Committee upheld the MAP Clinician Workgroup's preliminary recommendation. More information about these recommendations is available in the 2022–2023 MAP Final Recommendations document at *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&itemID=98102*.

We believe that the concerns raised regarding these proposed measures have been addressed during measure development and the MAP meetings. Additionally, some interested parties recognized the importance of these measures, specifically highlighting the importance of episode-based measures assessing mental health care. We agree with these interested parties. On these bases, we are proposing all five of these episode-based measures for inclusion in the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year.

(iii) New Episode-Based Measures Beginning With the CY 2024 Performance Period/2026 MIPS Payment Year

In this section of this proposed rule, we discuss the five new episode-based measures, which we propose to add to the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year.

In conjunction with our measure development contractor, we developed these measures with consideration of the common standards that are described in the CY 2022 PFS final rule (86 FR 65455 through 65459) to ensure consistency across episode-based measures being developed. Specifically, the CY 2022 PFS final rule requires that any episode-based measure for the cost performance category include the following: (1) episode definition based on trigger codes that determine the patient cohort; (2) attribution; (3) service assignment; (4) exclusions; and (5) risk adjustment. The five new episode-based measures we are proposing meet all requirements described in CY 2022 PFS final rule, including these features. We provide more information on the specific requirements for each of the proposed episode-based measures later in this section of the proposed rule.

Generally, for all episode-based measures, we exclude episodes where costs cannot be fairly compared to the costs for the whole cohort in the episode-based measure. These exclusions, like other features of each episode-based measure, are developed with extensive clinician and interested parties' engagement. We have specified exclusions for all five proposed episode-based measures, and discuss certain exclusions for the Psychoses and Related Conditions and the Emergency Medicine measure in further detail in this section of this proposed rule.

Generally, we also apply a risk adjustment model to all episode-based measures in the cost performance category. The model includes standard risk adjustors that are applied to all episode-based measures (for example, CMS Hierarchical Condition Category [HCC] variables, comorbidities, age brackets, disability status, ESRD status), and measure-specific risk adjustors (for example, patient transfers from another setting for the Emergency Medicine measure). We assess the risk adjustment model at the level of each stratification to ensure that only like patients are compared to each other. The risk adjustment model we use in development of the cost performance category's episode-based measures is described in greater detail in CY 2019 PFS final rule (83 FR 59767 through 59773). As mentioned previously in this section, all five proposed episode-based measures have been risk adjusted in accordance with this model.

More information on the episode-based measure development requirements, which were outlined so that external interested parties could develop measures in the future, are available in the Blueprint for the CMS Measures Management System (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint*) and the Meaningful Measures Framework (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page*).

The episode-based measures that we are proposing for CY 2024 performance period/2026 MIPS payment year and future performance periods are listed in the Table 43.

TABLE 43: Proposed Episode-Based Measures Beginning with CY 2024 Performance Period/CY 2026 MIPS Payment Year

Measure Name	Episode Type
Depression	Chronic condition
Emergency Medicine	Care Setting
Heart Failure	Chronic condition
Low Back Pain	Chronic condition
Psychoses and Related Conditions	Acute inpatient medical condition

The three chronic condition episode-based measures assess outpatient treatment and ongoing management of the following chronic conditions: depression, heart failure, and low back pain. The measure construction for these three proposed measures follows the approach described in the CY 2022 PFS final rule (86 FR 65445 through 65461), which also includes detailed discussion of the attribution methodology and examples of how episodes are attributed.

The attribution methodology that identifies a clinician-patient care relationship is slightly different at the clinician group and individual MIPS eligible clinician levels, to reflect that care provided at the clinician group and individual MIPS eligible clinician levels, respectively. At a high level, these proposed chronic condition episode-based measures attribute episodes to the clinician group that renders services that constitute a trigger event, which is identified by the occurrence of two claims billed in close proximity by the same clinician group.

Both claims must have a diagnosis code indicating the same chronic condition related to the specific episode-based measure. For example, for the Heart Failure measure, both claims of the trigger event must have a diagnosis indicating heart failure. The services that trigger an event for these chronic condition episode-based measures are identified first by Evaluation and Management (E/M) codes for outpatient services, and then by a second claim with either another E/M code for outpatient services or a condition-related Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) code (CPT/HCPCS) related to the treatment or management of the chronic condition. The trigger event opens a year-long attribution window from the date of the initial E/M outpatient service, during which the same clinician group could reasonably be considered responsible for managing the patient's chronic condition. If we see evidence that the relationship is ongoing, represented by another E/M or condition-related procedure code that we refer to as the reaffirming claim, then this window can be extended.

For individual MIPS Eligible clinicians, we would attribute episodes to each individual MIPS eligible clinician within an attributed clinician group that renders at least 30 percent of trigger or reaffirming codes on Part B Physician/Supplier claim lines during the episode, such as office visits or diagnostic services. We also apply conditions to ensure the MIPS eligible clinicians to whom the episode is attributed are reasonably responsible for the management of the patient's chronic condition. Specifically, the MIPS eligible clinician must have provided condition-related care to this patient prior to or on the episode start date.

Additionally, we use the provider-level prescription billing patterns to ensure that we are capturing the MIPS eligible clinicians directly involved in providing ongoing chronic care management, rather than clinicians who might have only refilled a patient's prescription once, as a courtesy to the patient. Specifically, for some measures (that is, Diabetes, Asthma/COPD episode-based measure that were finalized for use in the MIPS cost performance category for the CY 2022 PFS final rule (86 FR 64996), and Heart Failure episode-based measure that is being proposed in this rule.

The Psychoses and Related Conditions measure is an acute inpatient medical condition episode-based measure, which focuses on patients hospitalized for schizophrenia, delusional disorders, brief psychotic disorder, schizoaffective disorder, manic episode with psychotic symptoms, bipolar disorder with psychotic symptoms, major depressive disorder with psychotic symptoms, or unspecific psychosis. This acute inpatient medical condition was developed in accordance with the previously established framework for episode-based measures, which we described in detail in the CY 2019 PFS final rule (83 FR 59769 through 59771). We selected the Psychoses and Related Conditions measure for development because empirical analyses have identified psychoses-related hospitalizations are one of the most common inpatient stays, so it has a strong potential to be impactful on Medicare spending. This measure would also contribute to filling the current identified gap in the cost performance category's measurement of mental health care, as currently there are no episode-based or other cost measures assessing this clinical area.

As noted in the previous section of this proposed rule, the Psychoses and Related Conditions measure has been refined since the RFI in CY 2020 PFS proposed rule (84 FR 40760 through 40761) considering expert and other interested parties' input and to further address the MAP Coordinating Committee's previously expressed concerns in the 2018–2019 measure development cycle about the ability of inpatient clinicians to affect post-discharge care. In response to this input and these concerns, we implemented three refinements of this measure. First, we reduced the length of the episode window reduced from 90 to 45 days. This shortened episode window helps to ensure that MIPS eligible clinicians can reasonably be held accountable for post-discharge care, while still capturing readmissions and ED visits shortly after the trigger event, which persons with lived experience had noted as being important outcomes to identify and measure because these outcomes could be avoided with better discharge planning and follow-up care. Second, we refined this measure's specifications to account for specific scenarios where MIPS eligible clinicians have limited ability to influence a patient's care. Specifically, this measure now excludes episodes with involuntary holds at admission and episodes which are transfers to State hospitals. Third, we refined this measure's specifications to risk adjust for facility type to account for differences in payment policies between Inpatient Prospective Payment System (IPPS) and Inpatient Psychiatric Facility (IPF) hospitals. While we continue to believe that the original measure had accounted for concerns about the ability of inpatient clinicians to influence costs after discharge as described in the CY 2020 PFS proposed rule (84 FR 40760 through 40761), we also believe that these changes further refine the measure to meaningfully assess costs related to the role of clinicians caring for patients during mental health hospitalizations.

The Emergency Medicine measure assesses the cost of care clinically related to the treatment of a patient during an ED visit. The intent of this measure is to comprehensively assess all types of care in an ED, so the construction of the measure reflects the goal of capturing this broad scope of care. As such, this measure is characterized as a ''care setting'' episode type.

A CPT/HCPCS code indicating that a clinician has furnished care in the ED setting triggers the Emergency Medicine measure. The clinician billing the trigger code is attributed the episode. A clinician group is attributed by aggregating all episodes attributed to clinicians that bill to the clinician group. The trigger code also opens a 14-day episode window, during which the attributed clinician is responsible for costs.

The Emergency Medicine measure stratifies episodes based on the type of care the patient received during their ED visit and by disposition status. First, episodes are divided into 28 mutually exclusive groups called ED visit types that characterize the focus of care a patient received during their visit. These represent more granular, exhaustive patient populations defined by clinical criteria including the three-digit diagnosis codes available on a patient's ED visit claims, as well as a Medicare Severity Diagnosis Related Group (MS–DRG) of a subsequent inpatient stay if present. Given the goal of the Emergency Medicine measure to capture the broader universe of care provided in the emergency setting, dividing this measure's episodes into ED visit types is a technique to ensure clinical comparability. Examples of a few of the most frequent ED visit types associated with this Emergency Medicine measure are respiratory, gastrointestinal or liver, and kidney and urinary conditions. The 28 ED visit types are further stratified by whether (1) the ED visit resulted in subsequent observation care or inpatient admission or (2) the patient was discharged without subsequent observation care or inpatient admission. For example, ED visits for a stroke which end in

discharge are only compared with other ED visits for a stroke that also end in discharge.

The Emergency Medicine measure includes all Medicare Parts A and B services during the 14-day episode window, except for certain services determined to not be clinically relevant to the ED visit type. This reflects the intent of the measure and the broad clinician role in the ED setting. The ED visit type associated with the specific episode determines whether a service is clinically unrelated and therefore excluded from the episode. For example, if a patient visits the ED for ear, nose and throat (ENT) and eye disorders, any subsequent services for psychoses or behavioral and developmental disorders are excluded. However, if a patient visits the ED to receive care for an altered mental state, these subsequent services for psychoses or behavioral and developmental disorders are not excluded.

The Emergency Medicine measure risk adjusts costs just like all other episode-based measures. This measure uses the standard risk adjustment model described previously in this section. Also, as discussed, we assessed the risk adjustment model at the level of each stratification. This means that for the Emergency Medicine measure, the risk adjustment is applied to each combination of ED visit type and disposition status. For example, the risk adjustment model would assess separately a kidney and urinary episode that resulted in an inpatient stay, a kidney and urinary episode that resulted in a discharge, a fracture episode that resulted in an inpatient stay, and a fracture episode that resulted in a discharge.

Similar to other episode-based measures in use in the cost performance category and the episode-based measures proposed in this rule, we exclude episodes in cases where costs cannot be fairly compared to the costs for the whole cohort in the Emergency Medicine measure. For example, episodes are excluded for patients transferred to another ED facility from the triggering ED facility.

The proposed specifications for all five proposed episode-based measures are available at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.* The specifications documents for each proposed measure consist of a methods document that describes the steps for constructing the measure and a measure codes list file that contains the medical codes used in that methodology. First, the methods document provides detailed methodology describing each step to construct the measure, including: identifying patients receiving care, defining an episode-based measure, attributing episodes to MIPS eligible clinicians and clinician groups, assigning costs, defining exclusions, risk adjusting, and calculating measure score. Second, the measure codes list file contains the codes used in the measure specifications, including the episode triggers, attribution, stratification, assigned items and services, exclusions, and risk adjustors.

More information about the five proposed episode-based measures is available in the measure justification forms, which provide a comprehensive characterization of the measures, their justification, and testing results of these measures' specifications. These documents are available through the QPP Cost Measure Information page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Cost-Measures.*

We are seeking public comment on our proposal to add the five episode-based measures, which are listed in Table 43.

(b) Reliability and Case Minimum

In this section of the proposed rule, we discuss the proposed case minima to use for the five proposed episode-based measures and provide clarification on the interpretation of our regulation at § 414.1350(c) regarding the case minima for episode-based measures. Specifically, we propose a 20-episode case minimum for each of the five proposed measures based on our analysis of the reliability of each measure. We also provide clarification regarding application of our regulatory language under § 414.1350(c)(4) through (6). Currently, § 414.1350(c)(4) through (6) establishes the case minima for each type of episode-based measure (that is, procedural, acute inpatient medical condition, and chronic condition, respectively) beginning with a certain CY performance period/MIPS payment year specified therein. In this proposed rule, we are clarifying that the case minima established in § 414.1350(c)(4) through (6) applies to both the episode-based measure(s) we specified as beginning in the indicated performance period when the applicable regulatory provision was codified and for all episode-based measures of the same type that we specify to begin in subsequent performance periods, unless we specify otherwise for individual measure(s) in future rulemaking. We also note that, consistent with our past and current practice, we will continue testing the mean reliability of any potential episode-based measures that we propose to adopt in future rulemaking before applying the case minimum established in these regulations, as described later in this section.

Reliability is a metric that evaluates the extent that variation in a measure comes from clinician performance (''signal'') rather than random variation (''noise''). Higher reliability suggests that a measure is effectively capturing meaningful differences between clinicians' performance. However, we continue to caution against using reliability as the sole metric to evaluate a measure because of the tradeoffs between accuracy and reliability, and the role of service assignment in reducing noise. These and other considerations are detailed in the CY 2022 PFS final rule (86 FR 65453 through 65455). We also note that increasing case minima necessarily reduces the number of clinicians who meet the case minimum for a given measure. Because these are clinically refined measures, we aim to have as many clinicians as possible to be able to have their costs evaluated by them. Therefore, we consider that a mean reliability of 0.4 represents moderate reliability because it accounts for these considerations and is a sufficient threshold to ensure that the measure is performing as intended when assessed in conjunction with other testing.

We previously established at § 414.1350(c)(5) a case minimum of 20 episodes for acute inpatient medical condition episode-based measures in the CY 2019 PFS final rule (83 FR 59773 through 59774). We also established at § 414.1350(c)(6) a case minimum of 20 episodes for chronic condition episode-based measures in the CY 2022 final rule (86 FR 65453 through 65455). We have not adopted any care setting episode-based measures in the cost performance category, and therefore we have not established any case minimums for this type of episode-based measures. In this proposed rule, we considered a case minimum of 20 for each of the five proposed episode-based measures and then examined the reliability of the measures against this case minima.

We examined the reliability of the five proposed episode-based measures, and Table 44 presents the percentage of tax identification numbers (TINs) and TIN/National Provider Identifiers (NPIs) that meet the 0.4 reliability threshold and the mean reliability for TINs and TIN/NPIs at our proposed case minimum of 20 for each of the episode-based measures. At a 20-episode case minimum, the mean reliability for the

proposed Depression, Heart Failure, Low Back Pain, and Psychoses and Related Conditions measures exceeds 0.4 for both groups and individual clinicians, and the majority of groups and individual clinicians meet the 0.4 reliability threshold. Similarly, at a 20-episode case minimum, the mean reliability for the proposed Emergency Medicine measure exceeds 0.4 for both groups and individual clinicians, and all groups and individual clinicians meet the 0.4 reliability threshold.

TABLE 44: Percent of TINs and TIN/NPIs that Meet 0.4 Reliability Threshold and TIN and TIN/NPI Mean Reliability

Measure name (case minimum)	% TINs meeting 0.4 reliability threshold	Mean reliability for TINs	% TIN/NPIs meeting 0.4 reliability threshold	Mean reliability for TIN/NPIs
Depression	99.62%	0.87	98.61%	0.80
Emergency Medicine	100.00%	0.91	100.00%	0.78
Heart Failure	91.81%	0.68	86.79%	0.60
Low Back Pain	96.27%	0.75	95.66%	0.73
Psychoses and Related Conditions	100.00%	0.83	100.00%	0.86

We believe that calculating these five proposed episode-based measures with these case minimums will accurately and reliably assess the performance of clinicians and clinician group practices. Therefore, we are proposing to adopt a case minimum of 20 episodes for each of the five proposed new episode-based measures. Given that we have not previously established any case minimums for the care setting episode-based measures, we also propose to codify the 20-episode case minimum for care setting episode-based measures under § 414.1350(c)(7).

Additionally, as we were reviewing our existing regulatory language under § 414.1350(c), we recognized the need to clarify the intended interpretation of the language because we acknowledge that the current framing is open to reasonable interpretation. Specifically, we clarify that the regulatory language at § 414.1350(c)(4) through (6) establishes the case minima for episode-based measures of each episode type (that is, procedural, acute inpatient medical condition, and chronic condition, respectively) such that the case minimum specified therein applies to all episode-based measures of that episode type, regardless of when the measure is adopted for inclusion in the cost performance category, unless otherwise specified for individual measure(s). For example, under § 414.1350(c)(6), the chronic condition episode-based measures that were specified beginning with the CY 2022 performance period/2024 MIPS payment year when this regulatory provision was codified (that is, the Diabetes and the Asthma/COPD measure) and any chronic condition episode-based measure specified after the CY 2022 performance period/2024 MIPS payment year will have a case minimum of 20 episodes, unless we specify otherwise for an individual measure.

We are proposing to update the regulatory language under § 414.1350(c)(4) through (6) to more clearly reflect this clarification. In addition, we are proposing that this interpretation will also apply to § 414.1350(c)(7) for care setting episode-based measures, which we are proposing under this section of this proposed rule.

We believe that it is appropriate to use case minimum based on the measure type for current and future measures in MIPS, as each measure episode type uses a consistent framework across measures so the case minimum should be also consistent, where possible. Additionally, consistent case minimum simplifies the level of information a MIPS eligible clinician or clinician group must monitor for the episode-based measures as the number of measures used in the cost performance category continues to grow. We note that for any future measure under consideration to be implemented in the cost performance category, case minima would still be evaluated against reliability testing, and could be different from the standard case minima established for the respective measure type under § 414.1350(c), as needed.

We are inviting comment on our proposals in this section IV.A.4.f.(2)(b), including our proposal to adopt these five episode-based measures in the cost performance category proposals and our interpretation of the existing regulatory language on the case minima for episode-based measures.

(c) Removal of Simple Pneumonia With Hospitalization Measure From the MIPS Cost Performance Category Beginning With the CY 2024 Performance Period/2026 MIPS Payment Year

In this section of the proposed rule, we are proposing to remove the Simple Pneumonia with Hospitalization episode-based measure from the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year.

The Simple Pneumonia with Hospitalization episode-based measure was implemented for use in the MIPS cost performance category starting with CY 2019 performance period/2021 MIPS payment year (83 FR 59767 through 59773). Due to the impact of the COVID–19 pandemic, in accordance with § 414.1380(c)(2)(i)(A)(2), we assigned a weight of zero percent to the cost performance category for the CY 2020 performance period/2022 MIPS payment year and CY 2021 performance period/2023 MIPS payment year, and redistributed the prescribed weight to another performance category or categories, as established at § 414.1380(c)(2)(ii)(D). Therefore, no clinician or clinician group was scored on any episode-based measures, including the Simple Pneumonia with Hospitalization episode-based measure, for those 2 years.

For the CY 2022 performance period/2024 MIPS payment year, we announced via email communication

(subject: *2021 Quality Payment Program Experience Report and Infographic Now Available; Policy Update: Excluded MIPS Cost Measure for 2022 Performance Period*) on June 12, 2023, that in accordance with § 414.1380(b)(2)(v)(A), we would suppress the Simple Pneumonia with Hospitalization episode-based measure, so that eligible clinicians and clinician groups would not be scored on this measure for that performance period. This is a direct result of the International Classification of Diseases, Tenth Revision (ICD–10) coding updates related to COVID–19 that impacted the underlying population originally intended to be captured by this measure. Specifically, on January 1, 2021, an ICD–10 diagnosis code for pneumonia due to COVID–19 (J12.82) came into effect. Our guidance in the FY 2021 ICD–10–CM Official Guidelines for Coding and Reporting stated that this should be coded as secondary to COVID–19 (U07.1) (*https://www.cms.gov/files/document/2021-coding-guidelines-updated-12162020.pdf*). However, these two diagnosis codes (J12.82 and U07.1) map to different Medicare Severity Diagnosis Related Groups (MS–DRGs). J12.82 maps to the trigger codes for the Simple Pneumonia with Hospitalization measure (MS–DRGs 193–195, Simple Pneumonia and Pleurisy with MCC, with CC, and without CC/MCC, respectively), while U07.1 maps to Respiratory Infections and Inflammations (MS–DRGs 177–179, Respiratory Infections and Inflammations with MCC, with CC, and without CC/MCC, respectively), which are not used in this measure's trigger codes. That is, while this cost measure should include pneumonia due to COVID–19, it is unable to because it does not use MS–DRGs 177–179 in its trigger logic. For more information on the codes used to trigger Simple Pneumonia with Hospitalization measure episodes and the measure construction steps in general, please refer to the codes list file document available for download from the QPP Cost Measure Information page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Cost-Measures.*

Once sufficient data became available from claims submitted in CY 2022 for our review and analysis, we conducted empirical testing. This empirical testing demonstrated that these coding changes have resulted in a marked decrease in the number of Simple Pneumonia with Hospitalizations episodes. Specifically, we have seen a significant decrease in the number of episodes, by almost half, as a direct result of this coding change. The measure does not use MS–DRGs 177–179 in its trigger logic and, therefore, the measure is unable to capture many pneumonia episodes, per the original measure intent. Empirical testing further showed that this significant decrease has resulted in many clinicians no longer meeting the 20-episode case minimum for attribution of the measure On these bases, we have excluded the Simple Pneumonia with Hospitalization measure from scoring for the CY 2022 performance period under § 414.1380(b)(2)(v)(A) because (1) these coding changes present a significant change external to care; and (2) these changes impacted calculation of the cost measures such that it would lead to misleading or inaccurate results, as demonstrated by the empirical analysis described in this section.

Given that these underlying coding issues affect the measure's ability to capture the intended population and that their uneven impact on MIPS eligible clinicians is expected to continue, we are proposing to remove the Simple Pneumonia with Hospitalization measure from the cost performance category beginning with CY 2024 performance period/2026 MIPS payment year. We do not believe that it is appropriate to continue to use the measure as currently specified without any changes to address the coding changes that formed our basis to suppress this measure in the CY 2022 performance period/2024 MIPS payment year. In other words, because we have already determined that the Simple Pneumonia with Hospitalization measure warranted exclusion under § 414.1380(b)(2)(v)(A) because the coding changes lead to misleading or inaccurate results in calculating the measure's score, it would be inappropriate to retain this measure for the CY 2024 performance period/2026 MIPS payment year as currently specified. This will continue to be true while the triggering methodology is specified in a way that is incongruous with billing practices. While we are exploring substantive changes to the measure's triggering methodology in response to the coding changes, the scope of these changes and the potential impacts of these changes on other elements of the measure require careful consideration and feedback from the Simple Pneumonia with Hospitalization Clinician Expert Workgroup and other interested parties prior to implementation. Because of these circumstances, we propose to remove the Simple Pneumonia with Hospitalization measure as it is currently specified from use in MIPS beginning with the CY 2024 performance period/2026 MIPS payment year.

We note that we have been comprehensively re-evaluating the Simple Pneumonia with Hospitalization measure, given the significant coding changes impacting calculation of this measure. The purpose of comprehensive re-evaluation is to ensure that measures continue to meet criteria for importance, scientific acceptability, and usability in line with the CMS Measures Management System Blueprint (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint*). In this process, we holistically review the measure, seek public comment, and consider whether any changes need to be made to measure specifications after a measure has been in use for 3 years. A new version of the measure—Respiratory Infection Hospitalization—may be considered for implementation in MIPS in future years, after undergoing the pre-rulemaking and the notice-and-comment rulemaking processes. For more information on the re-evaluation efforts of the Simple Pneumonia with Hospitalization episode-based measure or other measures, please refer to the documents under the ''Wave 1 cost measure comprehensive reevaluation (2022–2023)'' section of the QPP Cost Measure Information page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Cost-Measures.*

We are inviting comments on this proposal.

(d) Proposed Revisions to the Operational List of Care Episode and Patient Condition Groups and Codes

We are proposing revisions to the operational list of care episode and patient condition groups and codes to reflect the proposal of any new episode-based measures. Section IV.A.4.f.(2)(d) of this proposed rule provides context on the statutory requirements for care episode and patient condition groups and proposes changes to the operational list.

Section 1848(r) of the Act specifies a series of steps and activities for the Secretary to undertake to involve physicians, practitioners, and other interested parties in enhancing the infrastructure for cost measurement, including for purposes of MIPS and APMs. Section 1848(r)(2) of the Act requires the development of care episode and patient condition groups,

and classification codes for such groups, and provides for care episode and patient condition groups to account for a target of an estimated one-half of expenditures under Medicare Parts A and B (with this target increasing over time as appropriate). Sections 1848(r)(2)(E) through (G) of the Act require the Secretary to post on the CMS website a draft list of care episode and patient condition groups and codes for solicitation of input from interested parties, and subsequently, post an operational list of such groups and codes. Section 1848(r)(2)(H) of the Act requires that not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, revise the operational list of care episode and patient condition codes as the Secretary determines may be appropriate, and that these revisions may be based on experience, new information developed under section 1848(n)(9)(A) of the Act, and input from physician specialty societies and other interested parties.

For more information about past revisions to the operational list that we made as we developed and proposed episode-based measures, we refer readers to CY 2020 PFS final rule (84 FR 62968 through 62969) and CY 2022 PFS final rule (86 FR 65445 through 65461). The current operational list and prior operational lists is available at the QPP Cost Measure Information page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Cost-Measures.*

Additionally, as required by section 1848(r)(2)(I) of the Act, information on resource use (or cost) measures currently in use in MIPS, cost measures under development and the time-frame for such development, potential future cost measure topics, a description of engagement with interested parties, and the percent of expenditures under Medicare Parts A and B that are covered by cost measures must be provided on the website of CMS not later than December 31 of each year.

In accordance with section 1848(r)(2)(H) of the Act, we are proposing to revise the operational list beginning with the CY 2024 performance period/2026 MIPS payment year to include five new care episode and patient condition groups, based on input from clinician specialty societies and other interested parties, as discussed in section IV.A.4.f.(2)(a)(ii) of this proposed rule. We propose including Emergency Medicine and Psychoses and Related Conditions as care episode groups and Heart Failure, Low Back Pain, and Depression as patient condition groups. These care episode and patient condition groups serve as the basis for the five new episode-based measures that we are proposing in section IV.A.4.f.(2)(a)(iii) of this proposed rule for the cost performance category. The codes that define these five care episode and patient condition groups align with the trigger codes of the proposed episode-based measures in section IV.A.4.f.(2)(a)(iii) of this proposed rule. As described in section IV.A.4.f.(2)(a)(ii), these specifications are developed with extensive input from interested parties.

Additionally, we propose to revise the operational list to remove the Simple Pneumonia with Hospitalization care episode group. As discussed in section IV.A.4.f.(2)(c)of this proposed rule, we are proposing to remove this episode-based measure from the cost performance category, so the codes that define this care episode group would no longer need to remain in the operational list.

Our proposed revisions to the operational list are available on our QPP Cost Measure Information page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Cost-Measures.*

We are inviting comments on this proposal.

(3) Improvement Activities Performance Category

(a) Background

For previous discussions on the general background of the improvement activities performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77177 and 77178), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), the CY 2019 PFS final rule (83 FR 59776 and 59777), the CY 2020 PFS final rule (84 FR 62980 through 62990), CY 2021 PFS final rule (85 FR 84881 through 84886), the CY 2022 PFS final rule (86 FR 65462 through 65466), and the CY 2023 PFS final rule (87 FR 70057 through 70061). We also refer readers to 42 CFR 414.1305 for the definitions of improvement activities and attestation, § 414.1320 for standards establishing the performance period, § 414.1325 for the data submission requirements, § 414.1355 for standards related to the improvement activity performance category generally, § 414.1360 for data submission criteria for the improvement activity performance category, and § 414.1380(b)(3) for improvement activities performance category scoring.

We are not proposing any changes to the traditional MIPS improvement activities policies for the CY 2024 performance period/2026 MIPS payment year. We are proposing policies for group reporting in MIPS Value Pathways (MVPs). In addition, we are proposing changes to the improvement activities Inventory for the CY 2024 performance period/2026 MIPS payment year and future years as follows: adding five new improvement activities; modifying one existing improvement activity; and removing three previously adopted improvement activities.

(b) Improvement Activities Inventory

(i) Annual Call for Activities Background

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 consisting of approximately 95 activities (81 FR 77817 through 77831). We took several steps to ensure the Inventory was inclusive of activities in line with statutory and program requirements. We discussed that we had conducted numerous interviews with highly performing organizations of all sizes and had conducted an environmental scan to identify existing models, activities, or measures that met all or part of the improvement activities performance category, including patient-centered medical homes, the Transforming Clinical Practice Initiative (TCPI), CAHPS surveys, and AHRQ's Patient Safety Organizations. In addition, we reviewed the CY 2016 PFS final rule with comment period (80 FR 71259) and the comments received in response to the MIPS and APMs RFI in relation to the improvement activities performance category, which sought input on what activities could be classified as clinical practice improvement activities according to the definition under section 1848(q)(2)(C)(v)(III) of the Act.

For the CY 2018 performance period/2020 MIPS payment year, 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 CY 2018 performance period/2020 MIPS payment year and future years through subregulatory guidance.[315] In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), for the CY 2019 performance period/2021 MIPS

[315] CMS, *Annual Call for Measures and Activities: Fact Sheet, https://www.cms.gov/Medicare/Quality-IniCtiatives-Patient-Assessment-Instruments/MMS/Downloads/Annual-Call-for-Measures-and-Activities-for-MIPS_Overview-Factsheet.pdf.*

payment year and for future years, we finalized a formal Annual Call for Activities process for the addition of possible new activities and for possible modifications to current activities in the improvement activities Inventory. This process included the requirement to submit a nomination form similar to the one we utilized for the CY 2018 performance period/2020 MIPS payment year (82 FR 53656 through 53659). In order to submit a request for a new activity or a modification to an existing improvement activity, the interested party must submit a nomination form (OMB control # 0938–1314) available at *www.qpp.cms.gov* during the Annual Call for Activities.

(ii) 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 to the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199), Tables F and G in the Appendix to the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229), Tables A and B in the Appendix 2 to the CY 2019 PFS final rule (83 FR 60286 through 60303), Tables A, B, and C in the Appendix 2 to the CY 2020 PFS final rule (84 FR 63514 through 63538), Tables A, B, and C in the Appendix 2 to the CY 2021 PFS final rule (85 FR 85370 through 85377), Tables A, B, and C in the Appendix 2 to the CY 2022 PFS final rule (86 FR 65969 through 65997), and Tables A, B, and C in the Appendix 2 to the CY 2023 PFS final rule (70633 through 70650) for our previously finalized improvement activities Inventories. We also refer readers to the Quality Payment Program website under Explore Measures and Activities at *https://qpp.cms.gov/mips/explore-measures?tab=improvement Activities&py=2022#measures* for a complete list of the current improvement activities. In the CY 2017 Quality Payment Program final rule (81 FR 77539), we codified the definition of improvement activities at § 414.1305 to mean an activity that relevant MIPS eligible clinicians, organizations, and other relevant interested parties identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.

We are proposing to add five new improvement activities, modify an existing improvement activity, and remove three previously adopted improvement activities for the CY 2024 performance period/2026 MIPS payment year and future years. The proposed new and modified activities will help fill gaps we have identified in the Inventory, while the removal of three activities will help ensure that the Inventory reflects current clinical practice. We note that the proposed removal of one activity, IA_BMH_6, titled ''Implementation of co-location PCP and MH services,'' in the Behavioral and Mental Health subcategory is being proposed in order to ensure that the improvement activities Inventory best reflects current clinical practice, and in no way reflects a de-emphasis of the ongoing priority CMS is placing on behavioral and mental health in general, and on substance use disorder in particular. We also note that two of the five proposed new activities are in the Behavioral and Mental Health subcategory. We refer readers to Appendix 2 of this proposed rule for more details.

Four of the recommended new improvement activities are in the Population Management and the Behavioral and Mental Health subcategories. One proposed new activity, IA_PM_XX, titled ''Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services'' would allow MIPS eligible clinicians to receive credit for establishing policies and procedures to improve practice capacity to increase HIV prevention screening and linkage to appropriate prevention resources through taking action with the goals of increasing capacity to expand HIV prevention screening, improving HIV prevention education and awareness, and reducing disparities in pre-exposure prophylaxis (PrEP) uptake. Another activity, IA_PM_XX, titled ''Decision Support Improves Adherence to Cervical Cancer Screening and Management Guidelines'' would allow MIPS eligible clinicians to receive credit for incorporating cervical cancer clinical decision support (CDS) within the electronic health record (EHR) system. This activity leverages the convenience and efficiency of more sophisticated decision support tooling to assist clinicians in applying complex data-driven guidelines to provide optimal care and better engagement with their patient population, including historically underserved populations. This activity proposal was submitted by the CDC.

Two of the five proposed new activities are in the Behavioral and Mental Health (BMH) subcategory, reflecting this important Federal priority. IA_BMH_XX, titled ''Behavioral/Mental Health and Substance Use Screening & Referral for Pregnant and Postpartum Women'' would allow MIPS eligible clinicians to receive credit for screening for perinatal mood and anxiety disorders (PMADs) and substance use disorder (SUD) in pregnant and postpartum women, as well as screening and referring to treatment and/or referring to appropriate social services in patient care plans. The second new activity being proposed in the BMH subcategory, IA_BMH_XX, titled ''Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults'' would allow MIPS eligible clinicians to receive credit for the completion of age-appropriate screening for mental health and substance use in older adults, as well as screening and referring to treatment and/or referring to appropriate social services in patient care plans.

Of the five proposed new improvement activities, four activities directly align with CMS' Priority 5 for advancing health equity, Increase All Forms of Accessibility to Health Care Services and Coverage. Therefore, the activities aim to create a fair and just opportunity for all people to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, and/or other factors that affect access to care and health outcomes. These four proposed new improvement activities are the following: IA_PM_XX, titled ''Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services''; IA_PM_XX, titled ''Decision Support Improves Adherence to Cervical Cancer Screening and Management Guidelines''; IA_BMH_XX, titled ''Behavioral/Mental Health and Substance Use Screening & Referral for Pregnant and Postpartum Women''; IA_BMH_XX, titled ''Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults.'' The fifth new proposed improvement activity is focused on MVP: IA_MVP, titled ''Practice-wide quality improvement in the MIPS Value Pathways Program (MVP).''

With the advent of MVPs, MIPS eligible clinicians can report measures that are more relevant to their specialized practice, including through subgroup reporting. The proposed IA_MVP activity would require a clinician to complete a formal model for quality improvement action that is linked to a minimum of three of the measures within the specific MVP. We believe this activity would expand and formalize quality improvement (QI) activities across practices, ultimately leading to improvements in quality of

care and fostering a culture of participation among staff. In addition, this activity would incentivize voluntary MVP adoption. It is important to note that, a clinician who reports an MVP can attest to the MVP improvement activity. However, a clinician in traditional MIPS is ineligible report the MVP improvement activity. Also, registration for an MVP is not sufficient for reporting the MVP improvement activity. Reporting the chosen MVP and attesting to having completed the necessary elements of the MVP improvement activity are both required. We refer readers to section IV.A.3.b(2). of this proposed rule for more information on MVPs.

We are proposing to modify one existing activity's description, titled ''Use decision support and standardized treatment protocols to manage workflow in the team to meet patient needs,'' and its validation criteria to explicitly promote the use of clinical decision support (CDS), particularly open-source, freely available, interoperable CDS. Additionally, we are proposing to remove three previously finalized improvement activities to ensure that the improvement activities Inventory best reflects current clinical practice.

(iii) Improvement Activity Reporting Policies

Regarding group reporting, we are not revising group reporting policies for MVPs at this time. In the CY 2020 PFS final rule (84 FR 62981 through 62988) and codified at § 414.1360(a)(2), we finalized the policy that, beginning with the 2020 performance year, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of § 414.1360 must be performed by at least 50 percent of the NPIs billing under the group's TIN or virtual group's TINs or that are part of the subgroup, as applicable. Additionally, the NPIs must perform the same activity during any continuous 90-day period within the same performance year. We would like to clarify the relationship between a subgroup's successful completion of an improvement activity and its impact on the affiliated group. If a subgroup consists of 50 percent or more of the clinicians in the affiliated group, and the subgroup attests to completing an activity, then the group would receive credit for this improvement activity as this meets our standard for a group's completion of an improvement activity specified at § 414.1360.

(4) Promoting Interoperability Performance Category

(a) Background

Section 1848(q)(2)(A) of the Act includes the meaningful use of certified electronic health record (EHR) technology (CEHRT) as a performance category under MIPS. We refer to this performance category as the Promoting Interoperability performance category (and in past rulemaking, we referred to it as the advancing care information performance category).

For our previously established policies regarding the Promoting Interoperability performance category, we refer readers to our regulation at § 414.1375 and the CY 2017 Quality Payment Program final rule (81 FR 77199 through 77245), CY 2018 Quality Payment Program final rule (82 FR 53663 through 53688), CY 2019 PFS final rule (83 FR 59785 through 59820), CY 2020 PFS final rule (84 FR 62991 through 63006), CY 2021 PFS final rule (85 FR 84886 through 84895), CY 2022 PFS final rule (86 FR 65466 through 65490), and the CY 2023 PFS final rule (87 FR 70060 through 70087).

(b) Promoting Interoperability Performance Category Performance Period

In the CY 2021 PFS final rule (85 FR 84886), we established that for the CY 2024 MIPS payment year and each subsequent MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of any 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 the policy at § 414.1320(g)(1) of our regulations, and subsequently re-designated that section as § 414.1320(h)(1) in the CY 2022 PFS final rule (86 FR 65671).

We are proposing that for the CY 2026 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of any continuous 180-day period within CY 2024, up to and including the full CY 2024 (January 1, 2024, through December 31, 2024). This proposal would minimally increase the information collection burden on data submitters.

We believe that having additional data available from a longer performance period is beneficial to further improve the Promoting Interoperability performance category, and an integral step towards promoting health information exchange. Reporting on additional data during a longer performance period would provide MIPS eligible clinicians the opportunity to continuously monitor their performance, identify gaps in their reporting, and identify areas that may require their investigation and corrective action. We believe that requiring MIPS eligible clinicians to report additional data during a longer performance period will encourage MIPS eligible clinicians to produce more comprehensive and reliable data demonstrating that they are meaningful users of CEHRT.

Our long-term goal for the Promoting Interoperability performance category is to ensure the meaningful use of CEHRT and information exchange throughout the year, for all data, all clinicians, and all patients. Currently, when MIPS eligible clinicians select a 90-day performance period, this data is often not representative of their overall use of CEHRT throughout the entire calendar year. Instead, it reflects their best performing 90-days during the calendar year. In order for MIPS eligible clinicians to have a more accurate understanding of their overall performance, we want to move towards reporting on a full years' performance, which can be achieved by incrementally increasing the number of days in the performance period.

We continue to focus on patient safety, and the Promoting Interoperability performance category continues to focus on the safety and safe use of patient data by demonstrating the meaningful use of CEHRT. If a MIPS eligible clinician were to only focus on their best 90-day performance period, they may not focus on improving their overall performance in meaningfully using CEHRT throughout the year, and ultimately, observe, correct, and mitigate any potential patient safety concerns that may arise due to gaps in interoperability throughout the calendar year. If a MIPS eligible clinician does not meaningfully use CEHRT throughout the entire CY, there is a possibility for gaps in the transfer of key patient data necessary for supporting a diagnosis, continued treatment, or overall care planning.

Therefore, we are proposing to modify § 414.1320(h) for the Promoting Interoperability performance category performance period to remove the reference to subsequent years after the CY 2024 MIPS payment year, and instead specify that the policy applies only through the CY 2025 MIPS payment year. We further propose to add a new paragraph at § 414.1320(i)(1) to reflect our proposed performance period of a minimum of a continuous 180-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 Promoting Interoperability performance category, beginning with the CY 2026 MIPS payment year.

We are inviting public comment on our proposal to require a continuous 180-day performance period for the Promoting Interoperability performance category beginning with the CY 2024 performance period/2026 MIPS payment year, and the proposed changes to the regulation text at § 414.1320.

(c) Certified Electronic Health Record Technology Requirements

Section 1848(q)(2)(B)(iv) of the Act requires that, for the Promoting Interoperability performance category, the MIPS eligible clinician must meet the requirements established for the specified performance period under section 1848(o)(2) of the Act for determining whether the MIPS eligible clinician is a meaningful electronic health record (EHR) user. Section 1848(o)(2)(A) of the Act requires that, to be treated as a meaningful EHR user for an EHR reporting period for a payment year, a MIPS eligible clinician must be using certified EHR technology (CEHRT). Section 1848(o)(4) of the Act defines CEHRT as a qualified electronic health record (as defined in section 3000(13) of the Public Health Service Act, or PHSA) that is certified by the Office of the National Coordinator for Health Information Technology (ONC) pursuant to section 3001(c)(5) of the PHSA in accordance with the certification standards that ONC adopted under section 3004 of the PHSA.

Accordingly, the MIPS Promoting Interoperability performance category regulation at § 414.1375(b)(1) requires a MIPS eligible clinician to use CEHRT as defined at § 414.1305 for the performance period. Since the CY 2019 performance period, in general, this has consisted of EHR technology (which could include multiple technologies) certified under ONC's 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 of CEHRT at § 414.1305.

As discussed in section III.R. of this proposed rule, in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing proposed rule (88 FR 23758), which appeared in the April 18,2023 **Federal Register**, ONC has proposed to discontinue the year-themed ''editions,'' which ONC first adopted in 2012, to distinguish between sets of health IT certification criteria finalized in different rules. ONC is proposing to instead maintain a single set of ''ONC Certification Criteria for Health IT,'' which would be updated in an incremental fashion in closer alignment to standards development cycles and regular health information technology (IT) development timelines (88 FR 23750). As further discussed in section III.R. of this proposed rule, we are proposing to modify the definition of CEHRT for purposes of the Quality Payment Program at § 414.1305 to no longer refer to year-specific editions, and to incorporate any changes made by ONC to its definition of Base EHR and its certification criteria for health IT.

(d) Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians

i. Changes to the Query of Prescription Drug Monitoring Program Measure Under the Electronic Prescribing Objective

We previously adopted the Query of Prescription Drug Monitoring Program (PDMP) measure under the Electronic Prescribing (e-Prescribing) objective for the Promoting Interoperability performance category. For background on this measure, we refer readers to the CY 2019 PFS final rule (83 FR 59800 through 59803) and the CY 2020 PFS final rule (84 FR 62992 through 62994). In the CY 2021 PFS final rule (85 FR 84887 through 84888) and the CY 2022 PFS final rule (86 FR 65466 through 65467), we finalized that the Query of PDMP measure will remain optional and eligible for 10 bonus points for the CY 2021 and CY 2022 performance periods.

In the CY 2023 PFS final rule, we finalized our proposal to require the Query of PDMP measure beginning with the CY 2023 performance period, and that the measure will be worth 10 points (87 FR 70061 through 70067). In addition, along with other key specifications described in the CY 2023 PFS final rule, we removed the phrase ''except where prohibited in accordance with applicable law'' from the measure description, and established two exclusions beginning with the CY 2023 performance period: (1) Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period; and (2) Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period (87 FR 70061 through 70067). Finally, in the CY 2023 PFS final rule, we finalized a third exclusion for the Query of PDMP measure, but this exclusion was only available for the CY 2023 performance period/2025 MIPS payment year. (87 FR 70067)

The second exclusion is the same exclusion that we adopted for e-Prescribing measure in the CY 2018 PFS final rule (82 FR 53679). It has come to our attention that the second exclusion is problematic because it does not address situations where the MIPS eligible clinician does not electronically prescribe Schedule II opioids or Schedule III and IV drugs, in accordance with applicable law during the performance period, but does write more than 100 permissible prescriptions during the performance period. Therefore, we are proposing to modify the second exclusion criterion to state that any MIPS eligible clinician who does not electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period can claim the second exclusion.

We are inviting public comments on this proposal.

ii. Proposed Technical Update to the Electronic Prescribing Measure

The ONC 21st Century Cures Act final rule (85 FR 25660 through 25661) retired the ''drug-formulary and preferred drug list checks'' certification criterion at 45 CFR 170.315(a)(10), which was associated with measures under the Electronic Prescribing Objective for the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category (80 FR 62882 and 83 FR 59817). ONC retired this criterion after January 1, 2022, as provided in 45 CFR 170.550(m)(1) (85 FR 26661).

In the CY 2021 PFS final rule, we finalized that the ''drug-formulary and preferred drug list checks'' criterion will no longer be associated with measures under the Electronic Prescribing Objective and will no longer be required to meet the CEHRT definition for the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, beginning with CY 2021 EHR reporting and performance periods (85 FR 84815 through 84825).

In the CY 2023 PFS final rule, we inadvertently omitted a revision to TABLE 92: Objectives and Measures for the Medicare Promoting Interoperability Performance Category for the CY 2023 performance period to reflect this change (87 FR 70075). In an effort to

more clearly capture the previously established policy finalized in the CY 2021 PFS final rule with respect to the e-Prescribing measure, we are proposing to revise the measure description as shown in Table 45 to read ''At least one permissible prescription written by the MIPS eligible clinician is transmitted electronically using CEHRT'' and the numerator will be updated to read to indicate ''Number of prescriptions in the denominator generated and transmitted electronically using CEHRT'' to reflect the removal of the health IT certification criterion ''drug-formulary and preferred drug list checks.''

We are inviting public comments on this proposal.

iii. Changes to the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) Measure

A. Background

In the CY 2022 PFS final rule (86 FR 65475 through 65477), we adopted the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) measure under the Protect Patient Health Information Objective in the Promoting Interoperability performance category beginning with the CY 2022 performance period. ONC developed several SAFER Guides, including the High Priority Practices SAFER Guide, to help organizations at all levels conduct self-assessments which optimize the safety and use of EHRs. Under the SAFER Guides measure, MIPS eligible clinicians are currently required to attest to whether they have conducted an annual self-assessment using the High Priority Practices SAFER Guide (available at *https://www.healthit.gov/topic/safety/safer-guides*), at any point during the calendar year in which the performance period occurs, with one ''yes/no'' attestation statement. Beginning with the CY 2022 performance period, we required MIPS eligible clinicians to complete this attestation for this measure, though MIPS eligible clinicians are not scored based on their answer to the attestation or whether they fully complete the self-assessment. An attestation of ''yes'' or ''no'' is currently acceptable, and a MIPS eligible clinician can attest ''no'' without penalty. For additional information, please refer to our discussion of the SAFER Guides measure in the CY 2022 PFS final rule (86 FR 65475 through 65477).

B. Proposed Change to the SAFER Guides Measure

The SAFER Guides measure is intended to encourage MIPS eligible clinicians to use the High Priority Practices SAFER Guide, annually, to assess their progress and status on important facets of patient safety, including CEHRT implementation, safety and effectiveness, identifying vulnerabilities, and developing a ''culture of safety'' within their organization. For instance, the High Priority Practices SAFER Guide asks users to review and ensure that entries of allergies, problem lists, and diagnostic test results utilize standardized coding elements in their CEHRT (such as uniformly and consistently coding results as ''normal'' or ''high''). By ensuring their CEHRT consistently documents and codes health information, MIPS eligible clinicians confirm their CEHRT supports clear communication of a patient's health status, mitigating the risk of oversight, gaps, or potential safety risks introduced by the CEHRT, in the interoperable exchange of health information. By implementing the High Priority Practices SAFER Guide's recommended practices, MIPS eligible clinicians may be better positioned to operate CEHRT responsibly in care delivery, and to make improvements to the safe use of CEHRT as necessary over time.

Given our interest in promoting the safety and the safe use of CEHRT, we are proposing to amend the SAFER Guides measure to require MIPS eligible clinicians to conduct this self-assessment annually, and attest a ''yes'' response, accounting for completion of the self-assessment for the High Priority Practices SAFER Guide. The self-assessment should be completed between clinicians and staff members together, allowing MIPS eligible clinicians to see a snapshot of the status of the CEHRT used by their organization in terms of safety, and to identify areas needing improvement. Therefore, we are proposing to modify the SAFER Guides measure beginning with the CY 2024 performance period/2026 MIPS payment year such that only a ''yes'' response on the attestation will constitute completion of this measure, and a ''no'' response will result in a score of zero for the whole Promoting Interoperability performance category, indicating that the MIPS eligible clinician failed the requirements of the Promoting Interoperability performance category and is not a meaningful user of CEHRT. To reflect this proposal, we are proposing to modify our reporting requirements at § 414.1375 (b)(2)(ii)(C) to include ''For the 2024 MIPS payment year through the 2025 MIPS payment year'', and to add § 414.1375 (b)(2)(ii)(D), to say ''Beginning with the 2026 MIPS payment year, submit an affirmative attestation regarding the MIPS eligible clinician's completion of the annual self-assessment under the SAFER Guides measure during the year in which the performance period occurs.''

We believe this proposed modification is feasible for MIPS eligible clinicians to implement, as they have had time to grow familiar with the use of the SAFER Guides under this measure by attesting either ''yes'' or ''no'' to conducting the self-assessment. We also note the availability of resources to assist MIPS eligible clinicians with completing the self-assessment as required by the SAFER Guides measure. One example of such resources is the SAFER Guides authors' paper titled ''Guidelines for US Hospitals and Clinicians on Assessment of Electronic Health Record Safety Using SAFER Guides,'' available without charge to download or use at *https://jamanetwork.com/journals/jama/fullarticle/2788984.*

Therefore, we are proposing to modify our requirements for the SAFER Guides measure beginning with the CY 2024 performance period and subsequent years, to require MIPS eligible clinicians to conduct, and therefore attest ''yes,'' an annual self-assessment of their CEHRT using the High Priority Practices SAFER Guide (available at *https://www.healthit.gov/topic/safety/safer-guides*), at any point during the calendar year in which the performance period occurs. Under this proposal, although the SAFER Guides measure would continue to be required with no associated points, an attestation of ''no'' would result in the MIPS eligible clinician not meeting the measure's requirements and therefore not a meaningful user of CEHRT, warranting a score of zero for the Promoting Interoperability performance category.

If our proposal to modify the SAFER Guides measure is finalized, we are also proposing to modify our reporting requirements at § 414.1375(b)(2)(ii)(C), and to add § 414.1375(b)(2)(ii)(D). Specifically, at § 414.1375(b)(2)(ii)(C), we propose to end our current requirements for the SAFER Guides measure with the 2025 MIPS payment year. Then, at § 414.1375(b)(2)(ii)(D), we propose to require, beginning with the 2026 MIPS payment year, that a MIPS eligible clinician submit an affirmative attestation regarding the MIPS eligible clinician's completion of the annual self-assessment under the SAFER Guides measure during the year in which the performance period occurs.

As a reminder, under the SAFER Guides measure, we do not currently require, and do not propose to require, MIPS eligible clinicians to attest to whether they have implemented any best practices ''fully in all areas'' as described in the High Priority SAFER Guide, nor will a MIPS eligible clinician be scored on how many of the practices they have fully implemented (86 FR 65475). We refer readers to Table 45 in this proposed rule for a description of the measure, and to the CY 2022 PFS final rule for additional background information (86 FR 65475 through 65477). Upon review of our current regulation governing reporting of the current SAFER Guides measure at § 414.1375(b)(2)(ii)(C), we identified areas where our regulation is unclear regarding the requirements for reporting the SAFER Guides measure. We are therefore also proposing to amend the regulatory text at § 414.1375(b)(2)(ii)(C) to specify clearly that a MIPS eligible clinician must submit an attestation, with either an affirmative or negative response, with respect to whether the MIPS eligible clinician completed the annual self-assessment under the SAFER Guides measure during the year in which the performance period occurs. As previously discussed, if our proposal to modify the SAFER Guides measure is finalized, this proposed regulatory provision would only be applicable for the 2024 MIPS payment year through the 2025 MIPS payment year.

We are inviting public comments on these proposals.

(e) Requirements for the Promoting Interoperability Performance Category for the CY 2024 Performance Period

i. Objectives and Measures for the CY 2024 Performance Period

For ease of reference, Table 45 lists the objectives and measures for the Promoting Interoperability performance category for the CY 2024 performance period/2026 MIPS payment year as revised to reflect the policies proposed in this proposed rule.

TABLE 45: Objectives and Measures for the Promoting Interoperability Performance Category for the CY 2024 Performance Period

Objective	Measure	Numerator	Denominator	Exclusion
Electronic Prescribing: Generate and transmit permissible prescriptions electronically	e-Prescribing: At least one permissible prescription written by the MIPS eligible clinician is transmitted electronically using CEHRT.*	Number of prescriptions in the denominator generated and transmitted electronically using CEHRT.*	Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the performance period.	Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.
Electronic Prescribing	Query of PDMP: For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any MIPS eligible clinician who: 1. is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period; or 2. Any MIPS eligible clinician who does not electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period.*
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and reconciles summary of care information from other health care providers into their EHR using the functions of CEHRT	Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider (1) creates a summary of care using CEHRT; and (2) electronically exchanges the summary of care record.	Number of transitions of care and referrals in the denominator where the summary of care record was created using CEHRT and exchanged electronically	Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician	Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.
Health Information Exchange	Support Electronic Referral Loops by Receiving and Reconciling Health	Number of electronic summary of care records in the denominator for	Number of electronic summary of care records received using CEHRT for	Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which

Objective	Measure	Numerator	Denominator	Exclusion
	Information: For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, mediation allergy, and current problem list.	which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.	the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.
Health Information Exchange	HIE Bi-Directional Exchange: Statement 1: I participate in an HIE 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. Statement 2: 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 not engaging in exclusionary behavior when determining exchange partners. Statement 3: I use the functions of CEHRT to support bi-	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	directional exchange with an HIE.			
Health Information Exchange	Enabling Exchange Under TEFCA MIPS eligible clinicians would attest to the following: • Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC's website) in good standing (i.e. not suspended) and enabling secure, bi-directional exchange of information to occur, in production, 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. • Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A
Provider to Patient Exchange: The MIPS eligible clinician provides patients (or patient-authorized representative) with timely electronic access to their health information.	Provide Patients Electronic Access to Their Health Information: For at least one unique patient seen by the MIPS eligible clinician: 1. The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and 2. The MIPS	Number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications of the	Number of unique patients seen by the MIPS eligible clinician during the performance period.	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's CEHRT.	API in the MIPS eligible clinician's CEHRT.		
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Immunization Registry Reporting: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period; OR 2.operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange	Electronic Case Reporting: The MIPS eligible clinician is in active engagement with a public health agency to electronically submit case reporting of reportable conditions.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the performance period; OR 2.operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the

Objective	Measure	Numerator	Denominator	Exclusion
				start of the performance period; OR 3. operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the performance period:
Public Health and Clinical Data Exchange	Public Health Registry Reporting: (bonus) The MIPS eligible clinician is in active engagement with a public health agency to submit data to public health registries.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Public Health and Clinical Data Exchange	Clinical Data Registry Reporting: (bonus) The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting: (bonus) The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Protect Patient Health Information: Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.	Security Risk Assessment: Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data created or maintained by certified electronic health record technology (CEHRT) in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none

Objective	Measure	Numerator	Denominator	Exclusion
	security deficiencies as part of the MIPS eligible clinician's risk management process.			
Protect Patient Health Information	SAFER Guides High Priority Practices Guide: Conduct an annual assessment of the High Priority Practices Guide SAFER Guides*	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none

* Signifies a policy proposed in this proposed rule.

ii. Scoring Methodology for the CY 2024 Performance Period

Table 46 reflects the scoring methodology for the Promoting Interoperability performance category for the CY 2024 performance period.

TABLE 46: Scoring Methodology for the CY 2024 Performance Period

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of PDMP	10 points	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points	Required (MIPS eligible clinician's choice of one of the three reporting options)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points	
	-OR-		
	Enabling Exchange under TEFCA	30 points	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points	Required
Public Health and Clinical Data Exchange	Report the following two measures: • Immunization Registry Reporting • Electronic Case Reporting	25 points	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting	5 points (*bonus*)	Optional

Notes: The Security Risk Analysis measure and the SAFER Guides measure are required, but will not be scored. In addition, MIPS eligible clinicians must submit an attestation regarding ONC direct review, and attest to the actions to limit or restrict the compatibility or interoperability of CEHRT, as required by § 414.1375(b)(3).

iii. Exclusion Redistribution

Many required measures have exclusions associated with them as shown on Table 45. If a MIPS eligible clinician believes that an exclusion for a particular measure applies to them, they may claim it when they submit their data. The maximum points available in Table 46 do not include the points that will be redistributed in the event that a MIPS eligible clinician claims an exclusion. For ease of reference, Table 47 shows how points will be redistributed among the objectives and measures for the CY 2024 performance period in the event a MIPS eligible clinician claims an exclusion.

TABLE 47: Exclusion Redistribution for CY 2024 Performance Period

Objective	Measure	Redistribution if exclusion is claimed
Electronic Prescribing	e-Prescribing	10 points to HIE objective
	Query of PDMP	10 points to e-Prescribing measure
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points to Provide Patients Electronic Access to Their Health Information measure
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points to the Support Electronic Referral Loops by Sending Health Information measure
	-OR-	
	Health Information Exchange Bi-Directional Exchange	No exclusion
	-OR-	
	Enabling Exchange under TEFCA	No exclusion
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	No exclusion
Public Health and Clinical Data Exchange	Report the following two measures: • Electronic Case Reporting • Immunization Registry Reporting	If an exclusion is claimed for both measures, 25 points are redistributed to the Provide Patients Electronic Access to their Health Information measure

Notes: The Security Risk Analysis measure and the SAFER Guides measure are required, but will not be scored.
In addition, MIPS eligible clinicians must submit an attestation regarding ONC direct review, and attest to the actions to limit or restrict the compatibility or interoperability of CEHRT, as required by § 414.1375(b)(3).

iv. 2015 Edition Health IT Certification Criteria

For ease of reference, Table 48 lists the objectives and measures for the Promoting Interoperability performance category for the CY 2024 performance period and the associated 2015 Edition health IT certification criteria.

TABLE 48: Promoting Interoperability Performance Category Objectives and Measures and 2015 Edition Certification Criteria

Objective	Measure	2015 Edition (CY 2024 Performance Period)
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing
	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)	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)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Health Information Exchange (alternative)	Enabling Exchange under TEFCA	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)(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)(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)(6) 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.
Protect Patient Health Information	Security Risk Assessment	The requirements are a part of CEHRT specific to each certification criterion
	Safety Assurance Factors for EHR Resilience Guides (SAFER Guides)	No 2015 health IT certification criteria at this time.

*The ONC 21st Century Cures Act final rule made changes to the existing 2015 Edition Health IT Certification Criteria by introducing new criteria and revising and removing existing criteria (85 FR 25667 through 25668). These changes are required for certified health IT used by MIPS eligible clinicians beginning with the CY 2023 performance period.

(f) Clinical Social Workers

In the CY 2022 PFS final rule (86 FR 65387 through 65389), we added clinical social workers to the definition of a MIPS eligible clinician under § 414.1305, beginning with the CY 2022 performance period/2024 MIPS payment year. Prior to the CY 2022 performance period, this clinician type was not eligible to participate in the Medicare Promoting Interoperability Program to earn incentive payments for meaningful use of CEHRT or receive reduced Medicare payments for failing to meaningfully use CEHRT. Clinical social workers were also not eligible for Medicaid EHR incentive payments.

In the CY 2022 PFS final rule (86 FR 65489), we stated that clinical social workers therefore may lack experience with the adoption or use of CEHRT, and that we believed there may not be sufficient Promoting Interoperability performance category measures that are applicable and available to them. In the CY 2022 PFS final rule (86 FR 65489) and the CY 2023 PFS final rule (87 FR 70087), we established that we will apply to clinical social workers the same reweighting policy for the Promoting Interoperability performance category that we adopted previously for NPs, PAs, CNSs, CRNAs, and other types of MIPS eligible clinicians who are non-physician practitioners for the CY 2022 performance period/2024 MIPS payment year and the CY 2023 performance period/2025 MIPS payment year. Specifically, because we believed there may not be sufficient Promoting Interoperability performance category measures available and applicable to clinical social workers, pursuant to section 1848(q)(5)(F) of the Act, we assigned a weight of zero to the Promoting Interoperability performance category for clinical social workers. However, if a clinical social worker submits any data for any of the measures specified for the Promoting Interoperability performance category, then this category will not be reweighted to zero and we will score the clinical social worker on this category as part of their final composite performance score in accordance with § 414.1380(c)(1). This reweighting policy for clinical social workers is codified at § 414.1380(c)(2)(i)(A)(*4)(iii).*

Because CY 2022 was the first year that clinical social workers were included in our definition of MIPS eligible clinicians, we do not yet have any performance period data that we could use to evaluate whether the Promoting Interoperability performance category measures are applicable to this type of MIPS eligible clinician. In the CY 2023 PFS final rule (87 FR 70087), when we reweighted the Promoting Interoperability performance category for clinical social workers for the CY 2023 performance period/2025 MIPS payment year, we noted we would evaluate whether this reweighting policy should be continued for future years when we have performance period data available. Given that we do not have data from the CY 2022 performance period available to analyze at the time of this proposed rule, we are proposing to continue the existing policy of reweighting the Promoting Interoperability performance category for clinical social workers for the CY 2024 performance period/2026 MIPS payment year, and making the corresponding revisions to the regulatory text at § 414.1380(c)(2)(i)(A)(*4)(iii*).

We are inviting public comments on this proposal.

(5) APM Improvement Activities Performance Category Score

(a) Background

Section 1848(q)(5)(C) of the Act establishes specific scoring rules for the improvement activities performance category. Section 1848(q)(5)(C)(ii) of the Act provides that a MIPS eligible clinician who is in an Alternative Payment Model (APM), as defined in section 1833(z)(3)(C) of the Act, with respect to a performance period shall earn a minimum score of one half of the highest potential score for the improvement activities performance category. In accordance with section 1848(q)(5)(C)(ii) of the Act, we codified at § 414.1380(b)(3)(i) that individual MIPS eligible clinicians or groups who participate in an APM (as defined in section 1833(z)(3)(C) of the Act) for a performance period will earn at least 50 percent for the improvement activities performance category (81 FR 30132). With respect to MIPS eligible clinicians who participate in a MIPS APM for a performance period, we stated that they may receive an improvement activity score higher than 50 percent (81 FR 30132). Because we had identified all MIPS APMs as having met the improvement activity threshold score requirement, we noted that all MIPS APM participants will receive a score of 100 percent for the improvement activities performance category (85 FR 84865, 85031).

(b) Proposal

It has come to our attention that in the preamble of the CY 2021 PFS final rule (85 FR 84865) the terminology ''automatic'' was used in reference to the baseline score provided by section 1848(q)(5)(C)(ii) of the Act (85 FR 84865). This has led to an interpretation by some MIPS eligible clinicians that the baseline score represents ''credit'' that is ''automatically applied'' in all circumstances.[316] This is not how we intended this provision to function, and we wish to ensure that our rules do not automatically grant such ''credit''.[317] We are concerned that absent revisions the application of our current regulation may produce unintended or unexpected scoring outcomes for MIPS eligible clinicians and groups.

In order to prevent such scoring scenarios, we are proposing to amend § 414.1380 by revising paragraph (b)(3)(i) to require that, in order to initiate the baseline score for the improvement activities performance category, a MIPS eligible clinician or group with APM participation must have submitted data for two performance categories or attest to having completed an improvement activity. We are also proposing to amend § 414.1380 by adding paragraph (c)(2)(iv) to provide that we will not apply a baseline score if we have also approved a request for performance category reweighting or hardship exception affecting the improvement activities performance category, including MIPS EUC Exception applications under § 414.1380(c)(2)(i)(A)(*6*) or (C)(*2*), and automatic EUC events per § 414.1380(c)(2)(i)(A)(*8*) or (C)(*3*).

We believe that these proposals are necessary in part because § 414.1380(c)(2)(i)(A)(*6*) requires us to score any data submitted by a MIPS eligible clinician with an approved application-based hardship exception or who was identified as a clinician in a CMS-designated region affected by an automatic EUC event under §§ 414.1380(c)(2)(i)(A)(*6*), (A)(*8*), (C)(*2*), and (C)(*3*), regardless of whether that submission was for the purpose of MIPS final scoring. Based upon our current policies, a submission of data for the quality or Promoting Interoperability performance categories would initiate or prompt the calculation of a baseline

[316] For example, in the ''2022 Data Submission FAQs,'' available at *https://qpp.cms.gov/resources/resource-library*, we stated that MIPS eligible clinicians participating in APMs are eligible to receive ''automatic credit'' in the improvement activities performance category.

[317] Similarly, in the CY 2021 PFS final rule, we finalized a proposal to modify § 414.1380(b)(3)(ii) to make clear that the baseline score provided by section 1848(q)(5)(C)(i) of the Act for the improvement activities performance category is not automatically granted for clinicians participating in patient-centered medical homes and comparable specialty practices (83 FR 59868).

score for the improvement activities performance category, making the improvement activities category eligible for scoring. We believe that result is contrary to the purpose of hardship exceptions, such as the MIPS EUC Exception application provided by § 414.1380(c)(2)(i)(A)(*6*), which are designed to reweight the improvement activities performance category to zero percent.

We also believe this proposal would further our vision that ''the bedrock of the Quality Payment Program is high-quality, patient-centered care followed by useful feedback, in a continuous cycle of improvement'' (81 FR 77010). Generally speaking, through MIPS, we collect feedback based upon data and measures submitted for the quality, Promoting Interoperability, improvement activities, and cost performance categories. We need composite scores from at least two of those four performance categories in order for us to calculate a clinician's final score. There is no data submission requirement for the cost performance category—we use the Medicare claims data submitted by that clinician to calculate their cost-measure performance. Similarly, a MIPS eligible clinician is not required to submit detailed data for the improvement activities performance category; instead, a MIPS eligible clinician simply attests to having completed an activity or activities to report the performance category. We therefore believe that it is most appropriate for a MIPS eligible clinician to submit measurable data on the quality and Promoting Interoperability performance categories for the purpose of final scoring in order to be credited with the baseline score for the improvement activities performance category.[318]

We believe these proposals are timely in light of the proposal at section III.F.h.2. to require that Medicare Shared Savings Program (SSP) Accountable Care Organization (ACO) clinicians report the Promoting Interoperability performance category at the TIN level, as opposed to the APM Entity (that is, the, ACO) or individual level. If our existing policies are not amended, an SSP ACO clinician's submission of data to the Promoting Interoperability category will prompt the baseline score in the improvement activities performance category in every circumstance regardless of whether the clinician's group requested or otherwise qualified for reweighting of the performance categories. This proposal would allow us to conform to the general scoring expectation that, in the event the participant's request to reweight three or four performance categories to zero percent due to a hardship, per §§ 414.1380(c)(2)(i)(A)(*6*), (A)(*8*), (C)(*2*), and (C)(*3*), the participant would receive a final score equal to the performance threshold, resulting in a neutral payment adjustment, even if data are incidentally submitted for other performance categories.

In summary, we propose to amend § 414.1380 by revising paragraph (b)(3)(i) and adding paragraph (c)(2)(iv) to limit the application of baseline scores provided under section 1848(q)(5)(C)(ii) of the Act for the purpose of MIPS final scoring. We seek comment on these proposals.

g. MIPS Final Score Methodology

(1) Performance Category Scores

(a) Background

Sections 1848(q)(1)(A)(i) and (ii) and (5)(A) of the Act provide, in relevant part, that the Secretary shall develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards with respect to applicable measures and activities specified for the four performance categories for a performance period and use such methodology to provide for a composite performance score for each such clinician for each performance period.

For the CY 2024 performance period/2026 MIPS payment year, we intend to continue to build on the scoring methodology we have finalized for prior years. This scoring methodology allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians. In this proposed rule we are proposing to update our scoring policies consistent with this framework. Specifically, we propose to—

- Provide a technical update to § 414.1380(a)(1)(i) and (b)(1)(v)(A),
- Amend our criteria for assessing ICD–10 coding impacts under our scoring flexibilities policy; and
- Update our policies regarding Improvement scoring for the cost performance category.

We are not proposing changes to scoring policies for the Promoting Interoperability or improvement activities performance categories.

(b) Technical Updates

In the CY 2022 PFS final rule, we finalized proposals to remove measure bonus points for reporting additional high priority measures and using end to end electronic reporting beginning in the CY 2022 performance period/2024 MIPS payment year (86 FR 65504 through 65507). We updated corresponding regulation at § 414.1380(b)(1)(v)(B)(1)(iii) regarding the end to end measure bonus points, but not § 414.1380(a)(1)(i) regarding performance standards or § 414.1380(b)(1)(v)(A) regarding the high priority bonus points. Accordingly, we propose to revise § 414.1380(a)(1)(i) to provide that, measure bonus points for submitting high priority measures and using end-to-end reporting are available for performance periods and payment years prior to the CY 2023 performance period/2025 MIPS payment year. We also propose to revise § 414.1380(b)(1)(v)(A) to state that, beginning with the CY 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians will no longer receive these measure bonus points for submitting high priority measures.''

We refer readers to our regulation at § 414.1380 for our current policies on scoring. We request comments on these technical update proposals.

(c) Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

We refer readers to § 414.1380(b)(1) for our current policies regarding quality measure benchmarks, calculating total measure achievement and measure bonus points, calculating the quality performance category 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, 84 FR 63011 through 63018, 85 FR 84898 through 84913, 86 FR65490 through 65509, and 87 FR 70088 through 70091). In the CY 2023 PFS final rule, we finalized policies to score administrative claims measures in the quality performance category using benchmarks calculate from data submitted during the associated performance period and clarified the topped-out measure lifecycle (87 FR 70088 through 70091).

[318] There is no data submission requirement for the quality and cost performance categories for a MIPS eligible clinician assessed under the facility-based measurement scoring methodology described in § 414.1380(e). Therefore, we would require that such clinicians report data on the Promoting Interoperability performance category (or attest to having completed an improvement activity) in order to prompt the baseline score for the improvement activities performance category.

(i) Scoring Flexibility for Changes That Impact Quality Measures During the Performance Period

We refer readers to CY 2018, CY 2019, Quality Payment Program final rules and the CY 2021, and CY 2022 PFS final rules (82 FR 53714 through 53716, 83 FR 59845 through 59847, 85 FR 84898 through 84901, and 86 FR 65491 and 65492 respectively) and § 414.1380(b)(1)(vii)(A) for our previously establish scoring flexibilities policy.

In the CY 2018 Quality Payment Program final rule (82 FR 53714 through 53716), we finalized that, beginning with the CY 2018 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 stated that our determination as to whether a measure is significantly impacted by ICD–10 coding changes would include these factors: A more than 10 percent change in codes in the measure numerator, denominator, exclusions, and exceptions; clinical guideline changes or new products or procedures reflected in ICD–10 code changes; and feedback on a measure received from measure developers and stewards (82 FR 53714). We stated 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 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 CY 2020 performance period) (82 FR 53716).

In the CY 2019 Quality Payment Program final rule (83 FR 59845 through 59847), we finalized policies beginning with the CY 2019 performance period/ 2021 MIPS payment year to reduce the total available measure achievement points in 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 wanted the flexibility to respond to instances in which the clinical evidence and guidelines change and approved measures no longer reflect the most up-to- date clinical evidence and could even result in a practice that is harmful to patients. We finalized expanding the list of reasons that a quality measure may be impacted during the performance period in addition to revising when we will 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.

In the CY 2021 PFS final rule (85 FR 84898 through 84901), we finalized a consolidation of the CY 2018 and CY 2019 scoring flexibilities policies that allowed, beginning with the CY 2021 performance period/2023 MIPS payment year, truncation of the performance period or suppression of a quality measure respectively 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 will assess the measure on 9 months of data, and if 9 consecutive months of data are not available, we will 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 the CY 2022 PFS final rule (86 FR 65491), we finalized a policy to expand the situations in which the scoring flexibilities policies would be applied. This update revised § 414.1380(b)(1)(vii)(A) to change ''significant changes'' to ''significant changes or errors'' and to include the omission of codes or inclusion of inactive or inaccurate codes. Previous versions of the policy only included changes to codes (such as ICD–10, CPT, or HCPCS codes), clinical guidelines, or measure specification as impacts outside the control of the clinician and its agents and that CMS determines may result in patient harm or misleading results and trigger application of this policy.

In this year's rule, we are proposing two modifications to the criteria by which we assess the impacts of ICD–10 coding changes. Firstly, we are proposing to eliminate the 10 percent ICD–10 coding change factor established in the CY 2018 Quality Payment Program rule (82 FR 53714). The quality and cost performance categories rely on measures that use detailed specifications that include ICD–10 code sets. We annually issue new ICD–10 coding updates, which are effective from October 1 through September 30. As part of this update, codes are added and removed from the ICD–10 code sets. When we adopted this standard in the CY 2018 Quality Payment Program final rule (82 FR 53714), we were concerned that ICD–10 coding changes in the final quarter of the performance period may render a measure no longer comparable to its historical benchmark. However, we have found that a 10 percent change to ICD–10 codes does not necessarily reflect a meaningful impact to clinicians' ability to report and be fairly scored on a quality measure. In the CY 2018 Quality Payment Program proposed rule, we discussed an approach where we would consider any change in ICD–10 coding to impact performance on a measure and thus only rely on the first 9 months of the 12-month performance period for such measures; however, we stated that such an approach was too broad (overly inclusive of changes) and would truncate measurement for too many measures where performance may not be significantly affected (82 FR 30098). We maintain this perspective but have concluded that a 10 percent change in codes is similarly over inclusive as it leads to the suppression of measures that can still be scored using all 12 months of the performance period. In place of the 10 percent threshold we propose to assess the overall impact on a measure resulting from changes to ICD–10 codes. Rather than consider a flat 10 percent change as a factor for when ICD–10 coding changes affect a measure, we would instead assess how the coding changes affect the measure numerator, denominator, exclusions, and exceptions in ways that could lead to misleading or harmful results. We would assess whether resultant changes to the numerator, denominator, exceptions, exclusions, or other measure elements change the scope or intent of the measure.

Changes in measure scope or intent would be considered significant changes that affect the applicability of the historical benchmark. ICD–10 codes include information related to clinical diagnoses and eligible patient population. For example, ICD–10 codes in the denominator correspond to the total eligible patient population considered for a measure. If as a result of a clinical guideline change a code is changed from an exclusion to a code to be considered in the total patient population indicated in the denominator for a measure, this would meaningfully change the scope of the measure and could lead to misleading results in measurement. Additionally, instances in which coding changes change the designation of whether performance was met or not (numerator)

could similarly lead to misleading results. These changes would be considered significant and therefore trigger our scoring flexibilities policy.

Second, we are proposing to assess the impacts of coding changes and our associated course of action (suppression, truncation, or standard 12-month reporting) by measure collection type. Our scoring policy states that we calculate benchmarks by collection type (§ 414.1380(b)(1)(ii). As benchmarks are assessed by collection type, we must consider by collection type whether the changes or errors will result in patient harm or misleading results.

Each collection type has different technical limitations. For example, measure specifications for the MIPS CQMs and Medicare Part B claims collection types can be updated in the performance period immediately following the publication each October of changes to ICD–10 codes. If an ICD–10 coding change occurs in October of 2024, CMS can immediately update the specifications for the measure's MIPS CQMs and Medicare Part B claims collection types and the ICD–10 changes would not result in any misleading results for the measure for those collection types.

This differs from eCQM measure specifications, which are posted in the May the year before the measure specifications take effect and are valid for the 12-month reporting period. For the CY 2024 performance period/2026 MIPS payment year, eCQM measures specifications will be posted in May of 2023 and are valid for the applicable 12-month performance period in CY 2024. In the example given above, the measure's eCQM collection type would not be updated again until May 2025 for the CY 2026 performance period/2028 MIPS payment year, and clinicians would be left reporting pursuant to outdated specifications for the final quarter of the CY 2024 performance period. This could result in misleading results for the measure's eCQM collection type. As a result, it would be appropriate for CMS to assess the impact of changes to measures and implement the appropriate scoring flexibility by collection type.

Lastly, we are proposing that measure specifications for eCQMs include the capability to be truncated to a 9-month performance period. Current measure specifications for eCQMs provide exclusively for a 12-month reporting period. If a measure is significantly impacted by ICD–10 coding changes, it therefore cannot be reported for a truncated performance period of 9-month. In order to implement the scoring flexibilities policy as intended and protect our ability to score measures where 9 consecutive months of data is available, we propose to begin requiring measure specifications to include logic for a 9-month performance period in addition to the currently existing 12-month performance period.

These updates will help us to better provide scoring flexibilities to clinicians by being sensitive to the particular impacts to and capabilities of the particular quality measures collection types. We seek comment on our proposal to update the criteria by which be apply scoring flexibilities in response to ICD–10 coding changes.

(d) Cost Performance Category Score

(i) Improvement Scoring Methodology

(A) Background

Section 1848(q)(5)(D)(i) requires that, if sufficient data are available to measure a MIPS eligible clinician's improvement in the quality and cost performance categories, then our methodology for computing the final score must take into account such improvement. In the CY 2018 Quality Payment Program final rule (82 FR 53748 through 53752), we established policies related to measuring improvement in the cost performance category at the measure level, an improvement scoring methodology for the cost performance category, and a formula for calculating the cost performance category percent score to include achievement and improvement. These policies were to apply beginning with the CY 2018 performance period/2020 MIPS payment year. We codified these policies at 42 CFR 414.1380(b)(2)(iii) and (iv) (82 FR 53748 through 53752, 53957).

Subsequent to the publication of the CY 2018 Quality Payment Program final rule, the Bipartisan Budget Act of 2018 (BBA 18) (Pub. L. 115–123, February 9, 2018) was enacted. Section 51003(a)(1)(B) of the BBA 18 added a new clause at section 1848(q)(5)(D)(iii) of the Act which provided that the cost performance category score shall not take in to account the improvement of the MIPS eligible clinician for each of the second, third, fourth, and fifth years for which the MIPS applies to payments (the CY 2018 performance period/2020 MIPS payment year through the CY 2021 performance period/2023 MIPS payment year).

To implement these statutory changes, in the CY 2019 PFS final rule (83 FR 35956, 36080 through 36082), we established that the maximum cost improvement score for the CY 2018 performance period/2020 MIPS payment year through the CY 2021 performance period/2023 MIPS payment year is zero percentage points, which we codified at § 414.1380(a)(1)(ii) and (b)(2)(iv)(E). In the CY 2023 PFS final rule (87 FR 70091 through 70093, 70228), we stated that we would begin to implement cost improvement scoring in the CY 2022 performance period/2024 MIPS payment year and established that the maximum cost improvement score available would be 1 percentage point. We codified this policy at § 414.1380(b)(2)(iv)(E). In addition, under our authority at § 414.1380(c)(2)(i)(A)(8), we reweighted the cost performance category's score to zero percent of the final score for the CY 2019 performance period/2022 MIPS payment year through the CY 2021 performance period/2023 MIPS payment year due to the COVID–19 Public Health Emergency (PHE) (85 FR 19277 through 19278; See ''Extension to Data Submission Deadline'' on Quality Payment Program website at *https://qpp.cms.gov/*). On these bases, to date, we have not applied a cost improvement score to MIPS eligible clinicians' final scores in accordance with the policies we established in the CY 2018 Quality Payment Program final rule and our regulations at § 414.1380(b)(2)(iii) and (iv). (*https://qpp.cms.gov/*).

(B) Description of Previously Finalized Cost Improvement Scoring Methodology

As discussed previously in this section, we established several policies related to our calculation and application of cost improvement scores to MIPS eligible clinicians' final scores in the CY 2018 Quality Payment Program final rule (82 FR 53748 through 53752). First, we established that we would determine the cost improvement score at the individual measure level, instead of the performance category level, for the cost performance category (82 FR 53749 through 53750). Second, we established our methodology for calculating the cost improvement score, generally by comparing the number of cost measures with significant improvement in performance and the number of cost measures with significant declines in performance for a MIPS eligible clinician or group between two consecutive performance periods (82 FR 53750 through 53752). Specifically, we established that we would quantify the cost improvement score by subtracting the number of cost measures with a significant decline from the number of cost measures with a significant improvement, and then dividing the result by the number of cost measures for which the MIPS eligible clinician or group was scored

for two consecutive performance periods, and then multiply the resulting fraction by the maximum improvement score (82 FR 53750 through 53752). We further established that we would determine whether there was significant improvement or decline in performance between the two performance periods by applying a common standard statistical test to measure significance, the t-test, as used in the Shared Savings Program (82 FR 53750 through 53752). Finally, we established that the cost improvement score cannot be lower than zero percentage points (82 FR 53750 through 53752).

We codified our cost improvement scoring policies at § 414.1380(b)(2)(iv). These policies governing our cost improvement scoring methodology have not been modified since the CY 2018 Quality Payment Program final rule.

(C) Mathematical Feasibility Issue for Cost Improvement Scoring Methodology

In reviewing our cost improvement scoring methodology, we discovered that calculating cost improvement scoring based on comparing only cost measures with a statistically significant change, determined by using a t-test, is not congruent with the underlying data. A t-test compares how significant the differences are between group means, which are aggregate values, and cannot compare how significant the differences are between single values. However, our current cost improvement methodology set forth at § 414.1380(b)(2)(iv) requires comparing a MIPS eligible clinician's scores for an individual cost measure, which are single value points rather than group means. Further, the current methodology purports to compare those single value points between two consecutive performance periods to determine if there has been a statistically significant change (improvement or decline) in performance. Therefore, a t-test cannot be applied to the single cost measure score data points for consecutive time periods to determine if a statistically significant change has occurred, rendering our cost improvement scoring methodology mathematically infeasible.

When we initially developed the cost improvement scoring methodology for the cost performance category, there were only two population-based cost measures (total per capita cost and Medicare Spending per Beneficiary measures), and no episode-based measures. As of the CY 2023 performance period/2025 MIPS payment year, there are 23 episode-based cost measures in addition to the two population-based measures. We expect to add additional episode-based measures to the cost performance category in future years as MIPS matures.

We believe that the aggregated nature of the two population-based measures influenced our determination regarding the feasibility of establishing statistical significance, using a t-test, when we developed and established the cost improvement scoring methodology. However, although these population-based measures are aggregated measures, they are calculated as individual single values in time, and not aggregate values which the t-test requires, for a specific clinician for each of the two consecutive performance periods. Further, considering a method using statistical significance might have been an oversight because of the lack of episode-based measures when the cost improvement scoring method was developed.

Because we have not implemented cost improvement scoring since we finalized this methodology in the CY 2018 Quality Payment Program final rule as discussed in section (4)(a)(iv) of this proposed rule, we failed to identify that the currently established cost improvement scoring method is not mathematically feasible. We identified the mathematical infeasibility of the current cost improvement methodology in the process of implementing cost improvement scoring for the CY 2023 performance period/2025 MIPS payment year.

(D) Operational Feasibility Issues for Cost Improvement Scoring Methodology

In addition, in the process of implementing cost improvement scoring for the CY 2023 performance period/2025 MIPS payment year, we identified three issues with our current policy at § 414.1380(b)(2)(iv)(A) because we determine each MIPS eligible clinician's cost improvement score at the individual cost measure level, and not the category level, for the cost performance category. To address these three issues, further specified herein, we propose to revise this policy so that we will determine the cost improvement score at the category level, instead of the cost measure level, for the cost performance category.

- Measure level improvement scoring implementation issue: The growing number of cost measures brings into question if using the current methodology for cost improvement scoring introduces complexities to its implementation, which in turn brings into question operational feasibility. When the methodology was established, in the CY 2018 Quality Payment Program final rule (82 FR 53748 through 53752), there were only two cost measures. As of the CY 2023 performance period/2025 MIPS payment year, there are 25 cost measures; we expect to add additional measures to the cost performance category as MIPS matures. Maintaining measure level improvement scoring, for a performance category that will continue to see growth in the number of measures, would be resource intensive, complex to implement, and error prone. Specifically, every measure would need its own workflow and testing, which would increase the amount of work to ensure year-over-year comparisons are accurate and increase risk of calculation or data errors. Further, maintaining measure level cost improvement scoring would introduce the same operational complexities we see in benchmarking measures, particularly when a measure encounters significant change from one year to the next—a reality that might present in future MIPS performance years. These challenges support our proposal to changing improvement scoring from measure level to category level for the cost performance category.
- Performance category improvement scoring consistency: As set forth at § 414.1380(b)(1)(vi)(C), we calculate each MIPS eligible clinician's improvement score for the quality performance category in MIPS at the performance category level. Upon further evaluation, we found that using two different methods of improvement scoring for the quality and cost performance categories would increase the implementation cost and operational complexity described above—as well as confuse MIPS eligible clinicians and call into question why we use two different methodologies. As such, we concluded that using category level assessment for cost improvement scoring would establish consistency across MIPS and allow effective communication with MIPS eligible clinicians, while reducing implementation cost and operational complexity.
- Fairness of improvement scoring: The episode-based measures for the cost performance category are specific to certain clinical conditions and/or care settings. Some MIPS eligible clinicians might not have the sufficient volume threshold for any or all of the episode-based measures for two consecutive performance periods, making year over year improvement scoring at the measure level less viable. Measure level improvement scoring might negatively impact these clinicians' overall cost performance category scoring because of the inclusion of episode-based measures outside of their scope of practice.

Further in the CY 2018 Quality Payment Program final rule (82 FR 53750) we received comments in favor of category level assessment for cost improvement scoring because of concerns with the inclusion of episode-based measures and their potential growth for the cost performance category. Specifically, the concerns highlighted that determining improvement scoring at the measure level might be unfair; it would be difficult for all MIPS eligible clinicians to demonstrate improvement across all measures. A category level assessment provides an equitable cost improvement scoring for MIPS eligible clinicians with different scopes of practice because it would only reflect measures that are applicable to them.

(E) Proposed Modifications for Cost Improvement Scoring Methodology Beginning With the CY 2023 Performance Period/2025 MIPS Payment Year

In light of both the mathematical and operational feasibility issues with our current cost improvement scoring methodology, we are proposing two modifications beginning with the CY 2023 performance period/2025 MIPS payment year.

First, we propose to determine each MIPS eligible clinician's cost improvement score at the category level, instead of the current measure level, beginning with the CY 2023 performance period/2025 MIPS payment year. We propose this modification based on the operational feasibility considerations previously discussed. We also propose that, if this proposal is finalized, § 414.1380(b)(2)(iv)(A) and (C) would be amended to reflect that the cost improvement score will be determined at the category level for the cost performance category. In addition, we propose that, if this proposal is finalized, § 414.1380(b)(2)(iv)(B) would be amended to reflect that we would determine whether sufficient data are available to measure improvement to calculate the cost improvement score based on whether a MIPS eligible clinician or group participates in MIPS using the same identifier in 2 consecutive performance periods and is scored on the cost performance category for 2 consecutive performance periods.

Second, we propose to modify the cost improvement scoring methodology to remove the requirement that we compare measures with a ''statistically significant change (improvement or decline) in performance'' as determined based on application of a t-test beginning with the CY 2023 performance period/2025 MIPS payment year. As previously discussed in section IV.A.4.g.(1)(d)(i)(C) of this proposed rule, determining cost improvement scoring based on statistical significance, using a t-test, is not congruent with our underlying data and is mathematically infeasible.

As such, we are proposing to remove the statistical significance requirement and update the calculation on how we quantify cost improvement scoring accordingly. Specifically, at § 414.1380(b)(2)(iv)(C), we are proposing to determine the cost improvement score at the category level by subtracting the cost performance category score from the previous performance period (for example, CY 2022 performance period/2024 MIPS payment year) from the cost performance category score from the current performance period (for example, CY 2023 performance period/2025 MIPS payment year), and then by dividing the difference by the cost performance category score from the previous performance period (for example, CY 2022 performance period/2024 MIPS payment year), and by dividing by 100.

In our current and established policy set forth at § 414.1380(b)(2)(iii), the overall cost performance category score for the current year with the improvement assessment is based on the following calculation: Cost Performance Category Score = Current Year Performance Score + Improvement Score. We do not propose any changes to this established policy.

The following is an example to illustrate how the cost improvement score will be calculated if our two proposals to modify our cost improvement scoring policies are adopted. An individual clinician, using the same identifier (TIN A/NPI 1) for two consecutive performance periods, has a cost performance category score of 52.00 percent from the previous year, and 63.71 percent in the current year. Using our proposed change, at § 414.1380(b)(2)(iv)(C), to determine the cost improvement score at the category-level, without using statistical significance, the first step is to quantify the change between current performance period score and the previous performance period score. This is 63.71 percent − 52.00 percent, which equals 11.71 percent. Then, the cost improvement score is determined as follows: ((change between current and previous year performance scores/previous year performance score))/100. This is ((11.71 percent/52 percent)/100). Therefore, the cost improvement score for the current year is 0.23 percentage points.

TABLE 49: Example of Assessing Improvement in the Cost Performance Category

Performance Year	Clinician	Performance Score	Change between Current and Previous Years	Improvement Score
Previous Year	TINA/NPI 1	52.00%	-	-
Current Year	TINA/NPI 1	63.71%	11.71%	0.23 pp

*pp = percentage point

Based on our current and established policy, set forth at § 414.1380(b)(2)(iii), the overall cost performance category score for current performance period is current year performance score + improvement score. This is 63.71 percent + 0.23 percentage point, which equals 63.94 percent.

Lastly, to determine how many points the cost performance category contributes to the final score as set forth in § 414.1380(c)(1), the current year cost performance category score (63.94 percent) is multiplied by the weight of the cost performance category (30 percent of the final score) and by 100 to determine the points to the final score. The individual clinician would have 63.94 percent × 30 percent × 100 = 19.18 points cost performance category contribution to the final score.

We are proposing that these two modifications to our cost improvement scoring policy would be effective

beginning with the CY 2023 performance period/2025 MIPS payment year. As discussed previously in section IV.A.4.g.(1)(d)(i)(A) of this proposed rule, section 1848(q)(5)(D)(i) of the Act requires that we account for a MIPS eligible clinician's improvement in the cost performance category if we have sufficient data available to measure improvement. Because we have not implemented cost improvement scoring to date, we did not have sufficient data available to measure year-over-year improvement scoring for the cost performance category until the CY 2023 performance period/2025 MIPS payment year. However, we do have such sufficient data available beginning with the CY 2023 performance period/2025 MIPS payment year. Further, section 1848(q)(5)(D)(iii) of the Act, requiring that we delay our implementation of cost improvement scoring through the CY 2021 performance period/2023 MIPS payment year, no longer applies. Therefore, we are proposing to implement cost improvement scoring, with these two proposed modifications, beginning with the CY 2023 performance period/2025 MIPS payment year.

On this basis, we are proposing to amend § 414.1380(b)(2)(iv)(E) to state that the maximum cost improvement score for the 2020, 2021, 2022, 2023, and 2024 MIPS payment years is zero percentage points and that the maximum cost improvement score beginning with the CY 2025 MIPS payment year is 1 percentage point. In addition, we are proposing to amend § 414.1380(a)(1)(ii) to state that improvement scoring is available in the cost performance category starting with the 2025 MIPS payment year, instead of the 2024 MIPS payment year. The remainder of the language currently at § 414.1380(a)(1)(ii) will remain the same.

We are soliciting public comment on these proposals.

f. MIPS Payment Adjustments

(1) Background

Section 1848(q)(6)(A) of the Act requires that we specify a MIPS payment adjustment factor for each MIPS eligible clinician for a year. This MIPS payment adjustment factor is a percentage determined by comparing the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with section 1848(q)(6)(D) of the Act. The MIPS payment adjustment factors specified for a year must result in differential payments such that MIPS eligible clinicians with final scores above the performance threshold receive a positive MIPS payment adjustment factor, those with final scores at the performance threshold receive a neutral MIPS payment adjustment factor, and those with final scores below the performance threshold receive a negative MIPS payment adjustment factor.

For previously established policies regarding our determination and application of MIPS payment adjustment factors to each MIPS eligible clinician, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77329 through 77343), CY 2018 Quality Payment Program final rule (82 FR 53785 through 53799), CY 2019 PFS final rule (83 FR 59878 through 59894), CY 2020 PFS final rule (84 FR 63031 through 63045), CY 2021 PFS final rule (85 FR 84917 through 84926), CY 2022 PFS final rule (86 FR 65527 through 65537), and CY 2023 PFS final rule (87 FR 70096 through 70102).

In the CY 2023 PFS final rule (87 FR 70096 through 70102), we established the performance threshold for the CY 2023 performance period/2025 MIPS payment year by calculating the mean of the final scores for all MIPS eligible clinicians using CY 2017 performance period/2019 MIPS payment year data. In addition, we included information about our timing for providing MIPS performance feedback to MIPS eligible clinicians for the CY performance period in accordance with section 1848(q)(12) of the Act.

(2) Establishing the Performance Threshold

(a) Statutory Background and Authority

As discussed above, in order to determine a MIPS payment adjustment factor for each MIPS eligible clinician for a year, we must compare the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with Section 1848(q)(6)(D) of the Act. Section 1848(q)(6)(D)(i) of the Act requires that we compute the performance threshold such that it is the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a ''prior period'' specified by the Secretary. Section 1848(q)(6)(D)(i) of the Act also provides that the Secretary may reassess the selection of the mean or median every 3 years.

Sections 1848(q)(6)(D)(ii) through (iv) of the Act provided special rules, applicable only for certain initial years of MIPS, for our computation and application of the performance threshold for our determination of MIPS payment adjustment factors. Specifically, for the CY 2017 performance period/2019 MIPS payment year through CY 2022 performance period/2024 MIPS payment year, section 1848(q)(6)(D)(ii) of the Act required that we establish an additional performance threshold for determining additional positive MIPS payment adjustment factors applicable to MIPS eligible clinicians with exceptional performance. Then, for the CY 2017 performance period/2019 MIPS payment year through CY 2021 performance period/2023 MIPS payment year, section 1848(q)(6)(D)(iii) required that we establish a performance threshold based on a period prior to such performance periods and take into account available data with respect to performance on measures and activities that we may use under the four MIPS performance categories and other factors determined appropriate by the Secretary. Specifically, section 1848(q)(6)(D)(iii) of the Act addressed how we would establish a performance threshold for MIPS in its initial years prior to having final score data available from prior periods of MIPS. Finally, for the CY 2019 performance period/CY 2021 MIPS payment year through CY 2021 performance period/2023 MIPS payment year, section 1848(q)(6)(D)(iv) of the Act required that we methodically increase the performance threshold each year to ''ensure a gradual and incremental transition'' to the performance threshold we estimated would be applicable in the CY 2022 performance period/2024 MIPS payment year. Although sections 1848(q)(6)(D)(ii) through (iv) of the Act are no longer applicable for establishing the performance threshold for the CY 2024 performance period/2026 MIPS payment year, these previously applicable statutory requirements explain our prior computations of the performance threshold that impact our policy considerations for establishing the performance threshold for MIPS going forward.

In the CY 2022 PFS final rule (86 FR 65527 through 65532), we selected the mean as the methodology for determining the performance threshold for the CY 2022 through 2024 performance periods/2024 through 2026 MIPS payment years. We also established in our regulation at 42 CFR 414.1405(g) that, for the CY 2022 performance period/2024 MIPS payment year through the CY 2024 performance period/2026 MIPS

payment year, the performance threshold would be the mean of the final scores for all MIPS eligible clinicians from a prior period. For CY 2022 through CY 2023 performance periods/2024 through 2025 MIPS payment years, we selected a single performance period when selecting a prior period to compute the mean of the final scores and establish the performance threshold. However, as discussed under paragraph (b) of this section, we propose to modify and refine our policy for selecting a ''prior period'' to establish the performance threshold under paragraph (b) of this section.

For further information on our current performance threshold policies, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77333 through 77338), CY 2018 Quality Payment Program final rule (82 FR 53787 through 53792), CY 2019 PFS final rule (83 FR 59879 through 59883), CY 2020 PFS final rule (84 FR 63031 through 63037), CY 2021 PFS final rule (85 FR 84919 through 84923), CY 2022 PFS final rule (86 FR 65527 through 65532), and CY 2023 PFS final rule (87 FR 70096 through 70100).

We codified the performance thresholds for each of the first 7 years of MIPS at § 414.1405(b)(4) through (9). These performance thresholds are shown in Table 50.

TABLE 50: Performance Thresholds for the CY 2017 through CY 2023 Performance Periods/2019 through 2025 MIPS Payment Years

MIPS Performance Period	2017 MIPS Performance Period	2018 MIPS Performance Period	2019 MIPS Performance Period	2020 MIPS Performance Period	2021 MIPS Performance Period	2022 MIPS Performance Period	2023 MIPS Performance Period
Year of MIPS	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**
Performance Threshold	3 points	15 points	30 points	45 points	60 points	75 points	75 Points
Change from prior year	N/A	12 points	15 points	15 points	15 points	15 points	0 points

(b) Proposal To Modify Our Policy for Establishing the Performance Threshold Beginning With the CY 2024 Performance Period/2026 MIPS Payment Year

In previous years, we selected a single performance period when selecting a prior period. In this proposed rule, we are reassessing our previous interpretation of ''prior period'' as described at section 1848(q)(6)(D)(i) of the Act.

Section 1848(q)(6)(D)(i) states that the performance threshold for a year shall be the mean or median (as selected by the Secretary) of the composite performance scores for all MIPS eligible professionals with respect to a ''prior period'' specified by the Secretary. The use of ''prior period'' in section 1848(q)(6)(D)(i) of the Act differs from other provisions in the statute which specifically refer to ''a year'' or ''performance period.'' For example, section 1848(q)(6)(A) of the Act specifies application of a MIPS adjustment factor for ''a year.'' Meanwhile, section 1848(q)(4) of the Act specifically defines the term ''performance period'' for MIPS, requiring that the Secretary shall establish ''a performance period (or periods) for a year (beginning with 2019)'' and such ''performance period (or periods)'' shall begin and end prior to the beginning of such ''year and be as close as possible to such year.'' These statutory provisions governing MIPS clearly distinguish the terms ''performance period'' and ''year'' from ''prior period'' used in section 1848(q)(6)(D)(i) of the Act. If the ''prior period'' we use to determine the mean or median of all MIPS eligible clinicians' final scores to establish the performance threshold under section 1848(q)(6)(D)(i) of the Act was intended to be limited to a single year or performance period, we believe the statute would have been more specific on that point rather than using the unique term, ''prior period.''

Because section 1848(q)(6)(D)(i) of the Act does not specifically refer to ''a performance period'' or ''year'' to establish the performance threshold, we believe that the term ''prior period'' can refer to a time span other than a single year or performance period as long as that ''prior period'' is specified by the Secretary. More specifically, given our interpretation that ''prior period'' does not require CMS to select a single performance year as the period, we propose to add § 414.1405(g)(2) to specify that, beginning with CY 2024 performance period/2026 MIPS payment year, a ''prior period'' for purposes of establishing a performance threshold as identified in § 414.1405(b) is a time span of 3 performance periods. Subsequently, we also propose to redesignate language at § 414.1405(g) which states that, for each of the 2024, 2025, and 2026 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under paragraph (b) of this section, as § 414.1405(g)(1).

Recognizing the flexibility of the term, ''prior period,'' we reviewed the data we have available from prior MIPS performance periods, and believe it would be appropriate to specify a ''prior period'' as three performance periods. Using three performance periods as the prior period would prevent the performance threshold from being dependent on a single potentially anomalous performance period, or on two performance periods, whose mean or median final score may be an outlier compared to other performance periods. The mean or median of final scores over 36 months is less likely to be impacted by unusual fluctuations in performance specific to a shorter time frame, is more likely to reflect clinician performance, and therefore, more appropriate to set the performance threshold. Using the mean or median of final scores of three performance periods would allow us to include more scores in the computation of the mean or median, and therefore, mitigate the impact of outliers. Further, using three performance periods would also smooth out year-to-year fluctuations in the performance threshold, developing greater consistency and stability in MIPS, and providing more predictability for MIPS eligible clinicians who may wish to set MIPS performance goals. Additionally, as more data become available, we will consider whether a longer time span than three performance periods may be

appropriate to mitigate outliers and better reflect clinician performance trends.

In the CY 2022 PFS final rule (86 FR 65531 through 65532), we stated that, under our interpretation of section 1848(q)(6)(D)(i) of the Act at that time, choosing the mean or median from a ''prior period'' does not allow us to balance scores from multiple years. However, on further reflection, the presence of distinctions in the statute between ''prior period'' and ''performance period'' and ''year'' has prompted us to reevaluate the appropriateness of limiting our establishment of the performance threshold based on a single prior performance period.

We request comments on our proposal to use three performance periods as the ''prior period'' we use to establish a performance threshold and codify the policy at § 414.1405(g)(2).

(c) Performance Threshold for the CY 2024 Performance Period/2026 MIPS Payment Year

While we chose to use the mean in our methodology for determining the performance threshold for the CY 2022 through 2024 performance periods/2024 through 2026 MIPS payment years, we have not specified which prior period's mean final score we would use for the CY 2024 performance period/2026 MIPS payment year's performance threshold. From our review of the data available to us, we identified the mean final scores for each of the CY 2017 through 2021 performance periods/2019 through 2023 MIPS payment years individually, as well as the mean of the final scores for CY 2017 through CY 2019 performance periods/2019 through 2021 MIPS payment years combined, as shown in Table 51. Based on our proposed definition of ''prior period,'' we included means of final scores for MIPS eligible clinicians spanning over three performance periods within Table 51 in addition to a single year performance period. These six values represent the mean final scores for all MIPS eligible clinicians from prior periods that are available for consideration for the CY 2024 performance period/2026 MIPS payment year performance threshold.

We are not considering the means of the final scores for certain prior periods because of issues with the underlying data. First, for the CY 2020 through 2021 performance periods/2022 through 2023 MIPS payment years for the purpose of establishing the performance threshold because we extensively applied our extreme and uncontrollable circumstances policies described under § 414.1380(c)(2)(i) to MIPS eligible clinicians nationwide due to the COVID–19 PHE, which we believe resulted in skewing the final scores from those years such that they are not an appropriate indicator for future clinician performance. We announced on April 6, 2020, the application of extreme and uncontrollable circumstances policies described under § 414.1380(c)(2)(i) to MIPS eligible clinicians nationwide due to the COVID–19 PHE for the CY 2019 performance period/2021 MIPS payment year (85 FR 19277 through 19278). However, given the timing of the COVID–19 PHE and this announcement, the data was likely minimally impacted because many MIPS eligible clinicians had already submitted the data. Second, the final scores for the CY 2022 performance period/2024 MIPS payment year were not finalized in time for this proposed rule and, therefore, the mean final score for the CY 2022 performance period/2024 MIPS payment year is not included for consideration as a potential performance threshold value for the CY 2024 performance period/2026 MIPS payment year.

TABLE 51: Possible Values for the CY 2024 Performance Period/2026 MIPS Payment Year Performance Threshold

2017 Performance Period	2018 Performance Period	2019 Performance Period	2020 Performance Period	2021 Performance Period	2017-2019 MIPS Performance Periods
74.65 Points	87.00 Points	85.63 Points	89.47 Points	89.22 Points	82.06 Points

As shown in Table 51, the mean final scores available for consideration for the CY 2024 performance period/2026 MIPS payment year performance threshold cover a range of values from 74.65 points to 89.47 points (rounded to 75 points and 89 points, respectively). We propose to use the CY 2017 through CY 2019 performance periods/2019 through 2021 MIPS payment years (mean of 82 points, rounded down from 82.06 points) as the prior period for the purpose of establishing the performance threshold for the CY 2024 performance period/2026 MIPS payment year for several reasons.

First, as stated above in section IV.A.4.h.(2)(b) of this proposed rule, we believe using the mean or median of final scores across three performance periods would smooth out year-to-year fluctuations in the performance threshold, developing greater consistency and stability in MIPS, and providing more predictability for MIPS eligible clinicians who may wish to set MIPS performance goals. This would also allow us to include more scores in the computation of the mean or median, and therefore mitigate the impact of unusual fluctuations in performance specific to a 24-month or a 12-month timeframe. For example, since we applied extreme and uncontrollable circumstances policies described under § 414.1380(c)(2)(i) (85 FR 19277 through 19278) for the CY 2019 performance period/2021 MIPS payment year, we believe using the additional 24 months of data from the CY 2017 and 2018 performance periods/2019 and 2020 MIPS payment years will allow us to mitigate any potential impact of outliers in computing the mean to establish the performance threshold.

Second, we also believe continuing a gradual and incremental increase in the performance threshold by establishing the performance threshold for the CY 2024 performance period/2026 MIPS payment year at 82 will provide stability to MIPS eligible clinicians. This proposed performance threshold value would be an increase of nearly 7 points from the CY 2023 performance period/2025 MIPS payment year performance threshold of 75 points. This increase would be smaller than the 12-to-15-point increases in previous years, apart from the CY 2023 performance period/2025 MIPS payment year, during which the performance threshold remained the same as the previous year. We note that

the incremental and gradual increase is no longer required by section 1848(q)(6)(D)(iv) of the Act. However, we still believe that in the long term, the program is served by incremental and gradual changes, such as an increase in the performance threshold to best reflect MIPS eligible clinicians' recent performance by using data from later years. We also believe an incremental and gradual change in the performance threshold for the CY 2024 performance period/2026 MIPS payment year is appropriate as the PHE for COVID–19 concludes.

Finally, we also believe the performance threshold of 82 strikes an appropriate balance of using more robust data and yet accounting for clinician practices that are still recovering from the impacts of the COVID–19 PHE. If we were to use more recent data from CY 2018 performance period/2020 MIPS payment year or CY 2019 performance period/2021 MIPS payment year means, the increase would be more substantial than the incremental increase to 82.

The CY 2023 performance period/2025 MIPS payment year is the only year for which we did not increase the performance threshold from the prior year due to reasons noted in the CY 2023 PFS final rule (87 FR 70096 through 70100). First, we acknowledged that we removed transition policies, such as quality bonus points which had been established for scoring the quality performance category for the CY 2018 through 2020 performance periods/2020 through 2022 MIPS payment years (86 FR 65491 through 65507). Second, we stated that, for the CY 2019 through 2021 performance periods/2021 through 2023 MIPS payment years, we applied certain extreme and uncontrollable circumstances policies described under § 414.1380(c)(2)(i) to MIPS eligible clinicians nationwide due to the COVID–19 PHE, which resulted in the reweighting of some performance categories if data were not submitted for a MIPS eligible clinician. Given the elimination of those transition policies, as well as the possibility the performance categories will not be reweighted for as many MIPS eligible clinicians for the CY 2023 performance period/2025 MIPS payment year, we expected the mean final score for CY 2023 performance period/2025 MIPS payment year to be lower than the mean final scores from the CY 2018 through 2020 performance periods/2020 through 2022 MIPS payment years. On these bases, we established the performance threshold at 75 for the CY 2023 performance period/2025 MIPS payment year, without any change from the prior year (87 FR 70096 through 70100).

However, for the CY 2024 performance period/2026 MIPS payment year, we no longer need to account for those reasons stated in CY 2023 PFS final rule (87 FR 70096 through 70100) and explained above, and therefore, believe it is appropriate to increase the performance threshold. For example, the COVID–19 PHE expired on May 11, 2023, emphasizing the less unpredictable impact of the COVID–19 PHE on health systems' expenditures and resources.[319] In addition, we no longer believe we need to consider MIPS transition policies because they are no longer in effect and clinicians have now had several years of experience in reporting within MIPS, which has been in effect for seven years. Finally, we believe that, as clinicians gain more experience within the MIPS program and as more recent data are available, we should incorporate more recent data in determining the performance threshold. We believe our proposal to use the mean of the final scores for the CY 2017 through 2019 performance periods/2019 through 2021 MIPS payment years as the prior period for the purpose of determining the performance threshold for the CY 2024 performance period/2026 MIPS payment year achieves an appropriate balance.

Under this proposal, and pursuant to the methodology we established previously at § 414.1405(g), the performance threshold for the CY 2024 performance period/2026 MIPS payment year would be the mean of the final scores for all MIPS eligible clinicians for the CY 2017 through 2019 performance periods/2019 through 2021 MIPS payment years, which is 82 points (rounded from 82.06 points). We are proposing corresponding changes to § 414.1405(b)(9) to reflect this proposal.

Alternatively, as an effort to use more recent data, we considered using the single 2019 performance period/2021 MIPS payment year, with a mean of 86 (rounded from 85.63) to establish the performance threshold for the CY 2024 performance period/2027 MIPS payment year. However, in efforts to use more robust data from a longer period of time, we are proposing using the CY 2017 through 2019 performance period/2019 through 2021 MIPS payment year as the prior period, with its mean of 82 points, to set the performance threshold for the CY 2024 performance period/2026 MIPS payment year. We also believe the performance threshold of 82 instead of 86 would be more appropriate for clinician practices that are still recovering from the impacts of the COVID–19 PHE.

In the Regulatory Impact Analysis (RIA) in section VII.E.23.d.(4) of this proposed rule, we estimate that approximately 46 percent of MIPS eligible clinicians would receive a negative payment adjustment for the CY 2024 performance period/2026 MIPS payment year if the policies proposed in this proposed rule are finalized and the performance threshold is equal to 82 points. We refer readers to the alternatives considered in the RIA in section VII.F.4 of this proposed rule where we present the impact of using data from alternative years to determine the performance threshold for the CY 2024 performance period/2026 MIPS payment year.

We are requesting comments on this proposal, as well as whether we should use means of final scores from alternative years to set the performance threshold for the CY 2024 performance period/2026 MIPS payment year, which we considered and discussed in the RIA in section VII.F.4 of this proposed rule.

(3) Example of Adjustment Factors

Figure 1 provides an illustrative example of how various final scores will be converted to a MIPS payment adjustment factor using the statutory formula and based on our proposed policies for the CY 2024 performance period/2026 MIPS payment year. In Figure 1, the performance threshold is set at 82 points, as we have proposed in section IV.A.4.h.(2)(c) of the proposed rule.

For purposes of determining the maximum and minimum range of potential MIPS payment adjustment factors, section 1848(q)(6)(B) of the Act defines the applicable percentage as 9 percent for the CY 2024 performance period/2026 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 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, as specified in section 1848(q)(6)(A)(iv)(II) of the Act, there is an exception for a final score between zero and one-fourth of the performance threshold (zero and

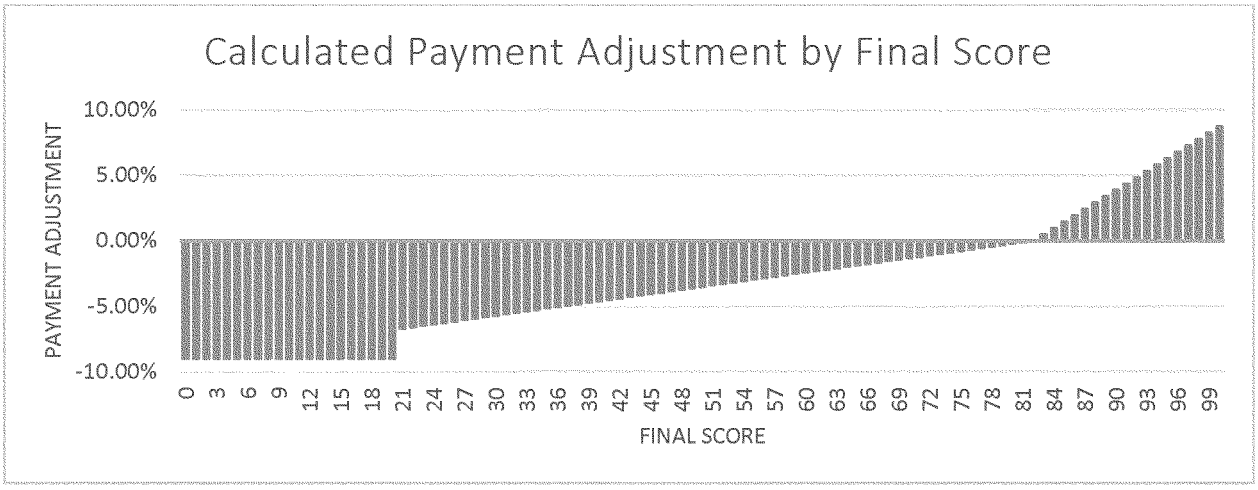
[319] *https://aspr.hhs.gov/legal/PHE/Pages/covid19-11Jan23.aspx; https://www.nytimes.com/2023/01/30/us/politics/biden-covid-public-health-emergency.html.*

20.5 points based on the performance threshold of 82 points for the CY 2024 performance period/2026 MIPS payment year). All MIPS eligible clinicians with a final score in this range will receive a negative MIPS payment adjustment factor equal to 9 percent (the applicable percentage). Second, the linear sliding scale for the positive MIPS payment adjustment factor is adjusted by the scaling factor, which cannot be higher than 3.0, as required by section 1848(q)(6)(F)(i) of the Act.

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 will be less than or equal to 9 percent (the applicable percentage). 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 will be greater than 9 percent. Only those MIPS eligible clinicians with a final score equal to 82 points (the proposed performance threshold for the CY 2024 performance period/2026 MIPS payment year) would receive a neutral MIPS payment adjustment.

Beginning with the CY 2023 performance period/2025 MIPS payment year, the additional MIPS payment adjustment for exceptional performance described in section 1848(q)(6)(C) of the Act is no longer available. For this reason, Figure 1 does not illustrate an additional adjustment factor for MIPS eligible clinicians with final scores at or above the additional performance threshold described in section 1848(q)(6)(D)(ii) of the Act.

FIGURE 1: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold for the CY 2024 performance period/2026 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustrative. For MIPS eligible clinicians with a final score of 100, the adjustment factor will be 9 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is intended to ensure budget neutrality (BN) but cannot be higher than 3.0. This example is illustrative as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

Table 52 illustrates the changes in payment adjustment based on the final policies from the CY 2023 PFS final rule (87 FR 70096 through 70103) for the CY 2023 performance period/2025 MIPS payment year and the proposed policies for the CY 2024 performance period/2026 MIPS payment year, as well as the applicable percent required by section 1848(q)(6)(B) of the Act.

TABLE 52: Illustration of Point System and Associated Adjustments Comparison between the CY 2023 Performance Period/2025 MIPS Payment Year and the Proposed CY 2024 Performance Period/2026 MIPS Payment Year

2023 Performance Period		2024 Performance Period	
Final Score Points	MIPS Adjustment	Final Score Points	MIPS Adjustment
0.0-18.75	Negative 9%	0.0-20.5	Negative 9%
18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale	20.51-81.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale
75.0	0% adjustment	82.0	0% adjustment
75.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 75.00 to 100.00 This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.	82.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 86.00 to 100.00 This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.

g. 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 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.

We made performance feedback available for the CY 2019 performance period/2021 MIPS payment year on August 5, 2020; for the CY 2020 performance period/2022 MIPS payment year on August 2 and September 27, 2021; and for the CY 2021 performance period/2023 MIPS payment year on August 22, 2022. Although we aim to provide feedback for the CY 2022 performance period/2024 MIPS payment year on or around July 1, 2023, it is possible the release date could be later depending on circumstances. We direct readers to *qpp.cms.gov* for more information.

K. Targeted Review

a. Background

Section 1848(q)(13)(A) of the Act requires that the Secretary establish a process under which a MIPS eligible clinician may seek an informal review of the calculation of the MIPS adjustment factor (or factors) applicable to the MIPS eligible clinician. In the CY 2017 Quality Payment Program final rule (81 FR 77353 through 77358), we finalized a targeted review process and related requirements under MIPS wherein a MIPS eligible clinician or group may request a review of the calculation of the MIPS payment adjustment factor and, as applicable, the calculation of the additional MIPS payment adjustment factor applicable to such MIPS eligible clinician or group for a year. Currently, MIPS eligible clinicians, groups, and Alternative Payment Model (APM) entities may request and receive targeted review of our calculation of their MIPS payment adjustment factor(s) under our established process and related requirements. In the CY 2017 Quality Payment Program final rule (81 FR 77546), we codified the MIPS targeted review process and related requirements at § 414.1385(a).

In the CY 2020 PFS final rule (84 FR 63045 through 63049), we revised the MIPS targeted review process and related requirements to address persons eligible to request targeted review, timeline for submission of targeted review requests, denial of targeted review requests, our requests for additional information, notification of targeted review decisions, and scoring recalculations. We codified these revisions to the targeted review process and related requirements at § 414.1385(a) (84 FR 63197 through 63198).

Currently, as specified at § 414.1385(a)(2), we provide that all requests for targeted review must be submitted within a 60-day period, beginning on the day that we make available the MIPS payment adjustment factors for the MIPS payment year applicable to each MIPS eligible clinician. In addition, § 414.1385(a)(2) provides that we may extend the targeted review request submission period. However, this current submission period for MIPS targeted review presents significant challenges to CMS as we seek to implement application of a differentially higher PFS conversion factor for eligible clinicians who are Qualifying APM Participants (QPs) for a year beginning with the CY 2024 QP Performance period/2026 payment year, as required by section 1848(d)(1)(A) of the Act.

Specifically, to ensure application of the alternative conversion factor for eligible clinicians who are QPs, we must submit the final list of QPs to our Medicare Administrative Contractors no later than October 1st of the preceding year. However, under our current

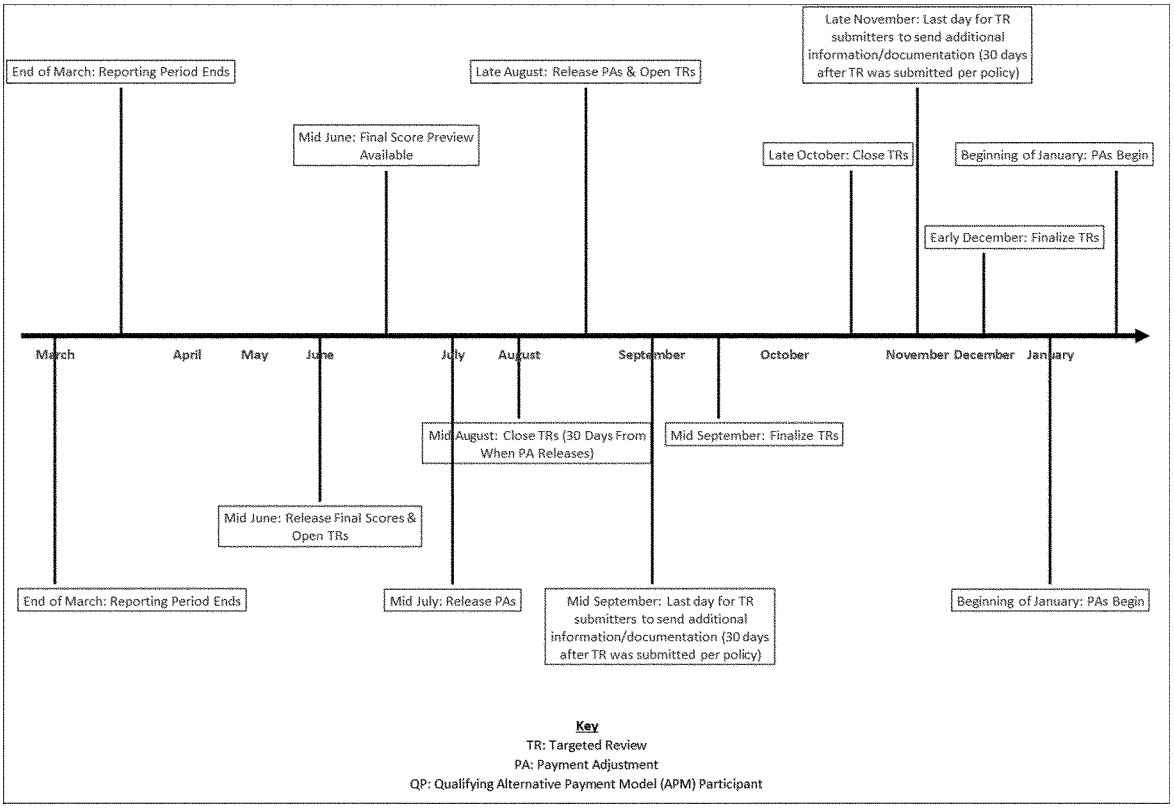
targeted review timeline for MIPS, this information would not be available until the first week of December. This is because the targeted review request submission period begins upon notification of the MIPS payment adjustment factors, which takes place sometime in August, and ends 60 days later, sometime in November. While QPs are excluded from MIPS reporting and any MIPS payment adjustment, we have received and addressed several requests for targeted review based on a clinician disputing whether they should be designated as a QP or a MIPS eligible clinician for purposes of payment under the Quality Payment Program. Based on our experience, we have found that more often than not a MIPS eligible clinician was initially identified as a QP but did not in fact participate in an Advanced APM and, conversely, a MIPS eligible clinician who believes they had achieved QP status was not identified as such. The targeted review process allows for clinicians to bring these issues to our attention. Accordingly, the targeted review process is essential to compiling an accurate list of QPs, which is necessary for purposes of determining who receives the application of the higher PFS conversion factor (also known as ''qualifying APM conversion factor'') of 0.75 percent (versus non-QPs, who receive 0.25 percent).

Section 1848(q)(13)(A) of the Act does not specify a timeframe for targeted review, broadly requiring that we ''establish a process'' for informal review of our calculation of the MIPS adjustment factor. Section 1848(q)(13)(A) of the Act only requires that the targeted review process permit a MIPS eligible clinician to seek ''informal review of the calculation of the MIPS adjustment factor (or factors)'' applicable to the MIPS eligible clinician for a MIPS payment year. We believe this broad authority for establishing this targeted review process, and lack of specificity as to any timeframe required for such process, permits CMS to determine a reasonable time period for submission of a request for targeted review so long as a MIPS eligible clinician can submit a request after we have informed them of our calculation of their MIPS adjustment factor(s).

Therefore, we are proposing to permit submission of a request for targeted review beginning on the day we make available the MIPS final score and ending 30 days after publication of the MIPS payment adjustment factors for the MIPS payment year. This proposal will allow for a total of approximately 60 days for the targeted review submission period (approximately 30 days before publication of the MIPS payment adjustments factors and 30 days thereafter). We believe this proposal will provide us with the necessary time to adjudicate the targeted reviews and finalize the QP status list by October 1st. If finalized, we are proposing to codify this proposed modification to this policy at § 414.1385(a)(2).

In Figure 2, we illustrate our proposed change to the timeline of the targeted review. The text above the timeline reflects the current process for targeted review while the text below the timeline reflects the proposed process in Figure 2.

FIGURE 2: Current and Proposed Targeted Review Process



To further shorten the timeline of the targeted review process for the reasons discussed above, we also are proposing to amend § 414.1385(a)(5). Specifically, we are proposing to require that, if CMS requests additional information under the targeted review process, that that additional information must be provided to and received by CMS

within 15 days of receipt of such request. This proposal would modify the current timeline to respond to CMS' request set forth at § 414.1385(a)(5), which is within 30 days of receipt.

In the CY 2017 Quality Payment Program final rule (81 FR 77353 through 77358), we implemented a virtual groups participation option under MIPS. Since virtual groups are eligible to submit data to the MIPS program, we are proposing to add virtual groups as being eligible to submit a request for targeted review. Finally, as discussed in section IV.A.4.d (4) of this proposed rule, we are also proposing to add subgroups as being eligible to submit a request for targeted review. We are proposing to codify these additions at § 414.1385(a).

We invite public comment on these proposals.

k. Third Party Intermediaries General Requirements

(1) Codification of Previously Finalized Policy From Preamble

A third party intermediary is an entity that CMS has approved under § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity for one or more of the quality, improvement activities, and Promoting Interoperability performance categories (§ 414.1305). Many of the policies that apply to third party intermediaries were finalized through prior rulemaking but not codified in the CFR. Among other things, this has made it challenging for third party intermediaries to track certain program requirements and has caused confusion for MIPS participants and third party intermediaries.

We have reviewed the previously finalized language and identified policies that we believe should be codified for these reasons. We describe these proposals and provide background throughout this section.

(2) General Requirements

(a) Background

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), the May 8th COVID–19 IFC (85 FR 27594 and 27595), the CY 2021 PFS final rule (85 FR 84926 through 84947), the CY 2022 PFS final rule (86 FR 65538 through 65550), and the CY 2023 PFS final rule (87 70102 FR through 70109) for our previously established policies regarding third party intermediaries. Where we are proposing to codify existing final policy, we incorporate the rationale described in these prior rules by reference.

In this proposed rule, in addition to codifying previously finalized policies and making technical updates for clarity, we propose to: (1) Add requirements for third party intermediaries to obtain documentation; (2) Specify the use of a simplified self-nomination process for existing qualified clinical data registries (QCDRs) and qualified registries; (3) Add requirements for QCDRs and qualified registries to provide measure numbers and identifiers for performance categories; (4) Add a requirement for QCDRs and qualified registries to attest that information on the qualified posting is correct; (5) Modify requirements for QCDRs and qualified registries to support MVP reporting; (6) Specify requirements for a transition plan for QCDRs and qualified registries; (7) Specify requirements for data validation audits; (8) Add additional criteria for rejecting QCDR measures; (9) Add a requirement for QCDR measure specifications to be displayed throughout the performance period and data submission period; (10) Eliminate the Health IT vendor category; (11) Add failure to maintain updated contact information as criteria for remedial action; (12) Revise corrective action plan requirements; (13) Specify the process for publicly posting remedial action; and (14) Specify the criteria for audits.

(b) Requirement To Obtain Documentation

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 and 77385), we established requirements that QCDRs and qualified registries obtain signed documentation from clinicians and groups regarding their authority to handle and submit data on the clinician and group's behalf. We established that QCDRs and qualified registries must enter into appropriate Business Associate Agreements with MIPS eligible clinicians. QCDRs and qualified registries must obtain signed documentation that each holder of a national provider identifier (NPI) has authorized the third party intermediary to submit ''quality measure results, improvement activities measure and activity results, advancing care information objective results and numerator and denominator data or patient-specific data on Medicare and non-Medicare beneficiaries to CMS for the purpose of MIPS participation.'' The documentation should be annually obtained at the time the clinician or group enters into an agreement with the QCDR or qualified registry for the submission of MIPS data to the QCDR or qualified registry. A group, subgroup, Virtual Group, or APM Entity may have their authorized representative give permission to the third party intermediary to submit their data. Additionally, in the CY 2018 Quality Payment Program final rule (82 FR 53812), we clarified that Business Associate Agreements must comply with the HIPAA Privacy and Security Rules. Records of the authorization must be maintained for 6 years after the performance period ends (81 FR 77370). We propose to codify these requirements at § 414.1400(b)(3)(xii) and (xiii).

We invite comments on this proposal.

(c) Requirement To Report in Form and Manner Specified

(i) Criteria for Data Submission

At § 414.1400(a)(2)(C), we require that all data submitted by a third party intermediary must be submitted in the form and manner specified by CMS. We are specifying that these requirements include the obligation for a third party intermediary to: (1) report the number of eligible instances (reporting denominator); (2) report the number of instances a quality service is performed (performance numerator); (3) report the number of performance exclusions, meaning the quality action was not performed for a valid reason as defined by the measure specification; (4) comply with a CMS-specified secure method for data submission, such as submitting the QCDR's data in an XML file; (5) be able to calculate and submit measure-level reporting rates or the data elements needed to calculate the reporting and performance rates by taxpayer identification number (TIN)/NPI and/or TIN; (6) be able to calculate and submit a performance rate (that is the percentage of a defined population who receive a particular process of care or achieves a particular outcome based on a calculation of the measures' numerator and denominator specifications) for each measure on which the TIN/NPI or TIN reports; (7) provide the performance period start date the QCDR will cover; (8) provide the performance period end date the QCDR will cover; (9) report the number of reported instances, performance not met, meaning the quality actions was not performed for no valid reason as defined by the measure specification; and (10) submit quality, advancing care information, or improvement activities data and results

to us in the applicable MIPS performance categories for which the QCDR is providing data (81 FR 77367 through 77369 and 77384 through 77385). These criteria for data submission are technical requirements of functioning QCDRs and qualified registries.

(ii) Reporting on All Patients, Including Non-Medicare Patients

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 through 77385), we established that QCDRs and qualified registries are required to submit data on all patients, not just Medicare patients. In section IV.A.4.f.(1)(b) of this rule, we propose a revision to the definition of the term collection type to allow Shared Saving Program ACOs meeting the reporting requirements under the APP to report on a subset of patients that is partially defined by having the payer of Medicare. We propose to codify our previously established requirement that data submitted by third party intermediaries must include data on all of the MIPS eligible clinician's patients regardless of payer, with the addition of the phrase ''unless otherwise specified by the collection type'' at § 414.1400(a)(3)(ii)(A). We invite comments on this proposal.

(3) Requirements for QCDRs and Qualified Registries

(a) Background

As described at § 414.1305, a QCDR is an entity that demonstrates clinical expertise in medicine and quality measurement development experience and collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. Section 1848(q)(5)(B)(ii) of the Act provides that the Secretary shall encourage MIPS eligible professionals to report on applicable measures through the use of certified EHR technology (CEHRT) and qualified clinical data registries.

We refer readers to § 414.1400(b)(4), the CY 2017 Quality Payment Program final rule (81 FR 77374 and 77375), the CY 2018 Quality Payment Program final rule (82 FR 53813 and 53814), the CY 2019 PFS final rule (83 FR 59900 through 59906), the CY 2020 PFS final rule (84 FR 63058 through 63074), the May 8th COVID–19 IFC (85 FR 27594 and 27595), the CY 2021 PFS final rule (85 FR 84937 through 84944), the CY 2022 PFS final rule (86 FR 65540 through 65550) and the CY 2023 PFS final rule (87 FR 70103 through 70106) for previously finalized standards and criteria for QCDRs and QCDR measure requirements.

As described at § 414.1305, a qualified registry is a medical registry, a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties or other data intermediary that, with respect to a particular performance period, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the MIPS qualification requirements specified by CMS for that performance period. The registry must have the requisite legal authority to submit MIPS data (as specified by CMS) on behalf of a MIPS eligible clinician or group to CMS.

We refer readers to § 414.1400(b), the CY 2017 Quality Payment Program final rule (81 FR 77382 and 77386), the CY 2018 Quality Payment Program final rule (82 FR 53815 and 53818), the CY 2019 PFS final rule (83 FR 59906), the CY 2020 PFS final rule (84 FR 63074 through 63077), the CY 2021 PFS final rule (85 FR 84944 through 84947), and the CY 2022 PFS final rule (86 FR 65539 through 65548) for previously finalized standards and criteria for qualified registries.

(b) Self-Nomination and Program Requirements

(i) Subgroup Reporting

In the CY 2022 Quality Payment Program final rule (86 FR 65544), we established the requirement that third party intermediaries must support subgroup reporting beginning with the CY 2023 performance period/2025 MIPS payment year. This requirement that third party intermediaries support subgroup reporting was finalized because it would allow for clinicians to meaningfully report MIPS Value Pathways (MVPs) given that subgroups will be implemented concurrently with MVPs. We propose to add new language to codify this policy. We propose to revise § 414.1400(b)(1)(iii) that beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs and qualified registries must support subgroup reporting.

We invite comments on this proposal.

(ii) Simplified Self-Nomination Process for Existing QCDRs and Qualified Registries in MIPS, That Are in Good Standing

In the CY 2018 Quality Payment Program final rule (82 FR 53811 through 53812 and 53817 through 53818), we established that beginning with the CY 2019 performance period/2021 MIPS payment year, QCDRs and qualified registries in good standing (that is, QCDRs and qualified registries that are not on probation or disqualified) (81 FR 77386 through 77389) that ''wish to self-nominate using the simplified process can attest, in whole or in part, that their previously approved form is still accurate and applicable'' (see also § 414.1400(b)(2)). When this is the case, third party intermediaries may use the simplified process. The goal of the simplified self-nomination form is to reduce the self-nomination burden for third party intermediaries in good standing by allowing them to self-nominate with a mostly pre-populated self-nomination form. The policy allows third party intermediaries to attest that sections of their application have no changes even if there are minimal changes or substantive changes in other parts of their application. An example of a minimal change is adding or removing MIPS quality measures. An example of a substantive change is new QCDR measures for consideration. For sections of an application that do require changes, the requirements are the same as those for the normal self-nomination process (82 FR 53808).

In the course of implementing this policy, we have learned that the text of § 414.1400(b)(2) has confused some third party intermediaries such that they have attested that their previously approved self-nomination form is still accurate and have not submitted self-nomination forms because they thought they did not need to do so if they had no changes. We are proposing to revise § 414.1400(b)(2) to reflect that QCDRs and qualified registries are still required to submit their self-nomination form even if they utilize the simplified self-nomination process. Even if a third party intermediary has no change to make to its form from the previous year, there may be new sections to fill out and they need to respond to attestations within the course of the application. We propose to revise the last sentence of § 414.1400(b)(2) from ''For the CY 2019 performance period/2021 MIPS payment year and future years, existing QCDRs and qualified registries that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period'' to state, ''For the CY 2019 performance period/2021 MIPS payment year and future years, an existing QCDR or qualified registry that is in good standing may use the simplified self-nomination process during the self-nomination period, from

July 1 and September 1 of the CY preceding the applicable performance period.'' This proposal would ensure that third party intermediaries that have previously participated in MIPS and are in good standing can use the process to reduce the burden of self-nomination.

We invite comments on this proposal.

(iii) Measure Numbers and Identifiers and Titles for the Improvement Activity Performance Category, the Promoting Interoperability Performance Category, and MVPs

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 through 77385), we established that QCDRs and qualified registries must provide the measure numbers for the MIPS quality measures on which the QCDR and qualified registry is reporting. We propose to codify this previously finalized provision at § 414.1400(b)(3)(ix). For completion and consistency, we also need to receive identifiers for improvement activities, Promoting Interoperability, and titles for MVPs. This information is used to track which quality measures, improvement activities, Promoting Interoperability performance category measures and MVPs QCDRs and qualified registries support in a performance period. This information is available on the qualified postings that are published on the QPP Resource Library. We propose that § 414.1400(b)(3)(ix) would additionally require QCDRs and qualified registries to submit to CMS the identifiers for the improvement activity performance category, the Promoting Interoperability performance category measures, and titles for MVPs.

We invite comments on this proposal.

(iv) Quality Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 through 77385), we established that one criterion for data submission for QCDRs and qualified registries is that they must be able to submit results to CMS for at least six individual quality measures with at least one outcome measure during self-nomination. If an outcome measure is not available, a QCDR or qualified registry must be able to submit to CMS results for at least one other high priority measure. We propose to codify this previously finalized provision at § 414.1400(b)(3)(x).

We invite comments on this proposal.

(v) Qualified Posting Attestation

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 through 77385), we established that QCDRs and qualified registries must sign a document that verifies their ''name, contact information, cost for MIPS eligible clinicians or groups to use the qualified registry, services provided, and the specialty-specific measure sets the qualified registry intends to report.'' As technology has progressed, we no longer need third party intermediaries to sign a document and instead require an attestation. We became aware that this requirement is not consistent with our established policy in describing the manner in which the QCDR or qualified registry documents this information. In order to align with current processes, we propose to add § 414.1400(b)(3)(xiv), which would require that QCDRs and qualified registries attest that the information listed on the qualified posting is accurate. The qualified posting contains information to help clinicians, groups, subgroups, virtual groups, APM Entities determine the services, cost, reporting options, measures/activities, etc. that a CMS-approved intermediary supports. We publish it every performance period and update it, as needed. While we have used the term qualified posting since the inception of the Quality Payment Program, we have not previously defined this term, and therefore, we propose to define qualified posting as the document made available by CMS that lists QCDRs or qualified registries available for use by MIPS eligible clinicians, groups, subgroups, virtual groups, and APM Entities at § 414.1305.

We invite comments on these proposals.

(vi) Data Access Capabilities

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 through 77385), we established that QCDRs and qualified registries must comply with any request by CMS to review data submitted by a third party intermediary for purposes of MIPS. We propose to codify this previously finalized provision at § 414.1400(b)(3)(xv).

We invite comments on this proposal.

(vii) Attestation of Data Access Capabilities

As was previously described, the CY 2017 Quality Payment Program rule finalized the requirement for third party intermediaries to comply with any request by CMS to review data submitted by a third party intermediary for purposes of MIPS reporting requirements (81 FR 77367 through 77369 and 77384 through 77385). However, it did not require third party intermediaries to attest to their capabilities. Attestation during the self-nomination period emphasizes the importance of this capability for third party intermediaries even if the capability is not ultimately utilized later. We propose to add § 414.1400(b)(3)(xvi)(A) to require that a QCDR or a qualified registry attest that it has required each MIPS eligible clinician on whose behalf it reports to provide the QCDR or qualified registry with all documentation necessary to verify the accuracy of the data on quality measures that the eligible clinician submitted to the QCDR or qualified registry. We also propose to add § 414.1400(b)(3)(xvi)(B) to require that a QCDR or a qualified registry must attest that it has required each MIPS eligible clinician to permit the QCDR or qualified registry to provide the information described in § 414.1400(b)(3)(xvi)(A) to CMS upon request to ensure that data can be accessed by the third party intermediary for auditing purposes as we have heard from some third party intermediaries that they do not have access to the data and depend on clinicians do the audit.

We invite comments on this proposal.

(viii) Third Party Intermediary Support of MVPs

In the CY 2022 PFS final rule (86 FR 65543), we finalized a new requirement at § 414.1400(b)(1)(ii) that, beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. QCDRs and qualified registries may also support the APP. This proposal was finalized because MVPs are beginning to be implemented in the CY 2023 performance period/2025 MIPS payment year, and third party intermediaries have the necessary experience reporting data to support MVP reporting.

To further clarify this finalized policy, we responded to a comment in the CY 2022 PFS final rule (86 FR 65543) by explaining that third party intermediaries who support MVPs are required to ''support all measures and activities available in the MVP across the quality, improvement activities, and Promoting Interoperability performance categories. The exceptions to this requirement are the cost measures and population health measures . . . [and] QCDR measures, which are only reportable through a QCDR. In instances where QCDR measures are included in an MVP, a qualified registry or health IT vendor will be expected to support all other quality measures included within the MVP.'' Some interested parties have

expressed concern regarding this requirement as many MVPs include measures that may be reported by clinicians across multiple specialties, some of whom might be outside their intended customer base. We are concerned that continuing this strict requirement for MVP support could undermine adoption during the time in which MVP submission is an option under MIPS. Given that many third party intermediaries may not support measures for clinicians in all specialty areas that might report a MVP, we are proposing to add a sentence at the end of § 414.1400(b)(1)(ii) that a QCDR or a qualified registry is required to support MVPs pertinent to the specialties they support. The proposed addition states that a QCDRs or a qualified registry must support all measures and improvement activities available in the MVP with two exceptions. The first proposed exception to this requirement at § 414.1400(b)(1)(ii)(A) is that if an MVP includes several specialties, then a QCDR or a qualified registry is only expected to support the measures that are pertinent to the specialty of their clinicians. For example, if an orthopedic care MVP includes both surgery and physical therapy measures, and the third party intermediary caters specifically to physical therapists, they are not required to support the surgical measures. The second proposed exception at § 414.1400(b)(1)(ii)(B) is that QCDR measures are only required to be reported by the QCDR measure owner. In instances where a QCDR does not own the QCDR measures in the MVP, the QCDR may only support the QCDR measures if they have the appropriate permissions.

We invite comments on these proposals.

(ix) Readiness To Accept Data

In the CY 2019 PFS final rule (83 FR 59761), we established that a QCDR or a qualified registry must be up and running by January 1st of the performance period so that they can accept and retain clinician data starting on January 1st. We propose to codify at § 414.1400(b)(3)(xvii) the requirement that a QCDR or a qualified registry must be able to accept and retain data by January 1 of the applicable performance period.

We invite comments on this proposal.

(x) Duration of Services Provided

In the CY 2020 PFS final rule (84 FR 63053), we finalized a new requirement at § 414.1400(a)(2)(i)(E) that the organization must provide services throughout the entire performance period and applicable data submission period. In section IV.A.4.k.(3)(b)(xi) of this rule, we discuss the requirements for a transition plan for cases in which organizations are not able to provide services throughout the entire year. While we recognize and allow for cases in which organizations may find themselves unable to provide services throughout the course of an entire year, we would require that they indicate their intent to do so as part of program requirements. We propose to modify this requirement to state the organization must certify it intends to provide services throughout the entire performance period and applicable data submission period. We propose to make this change at § 414.1400(a)(2)(i)(C) as a result of our proposal to divide requirements for self-nomination from programmatic requirements as discussed in section IV.A.4.k.(7) of this rule.

We invite comments on these proposals.

(xi) Transition Plan Requirements

In the CY 2020 PFS final rule (84 FR 63052 through 63053), we finalized a new requirement at § 414.1400(a)(2)(i)(F) that prior to discontinuing services to any MIPS eligible clinician, group, virtual group, subgroup, or APM Entity during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, virtual group, subgroup, or APM Entity 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. As part of an overall effort to divide self-nomination requirements from program requirements as discussed in section IV.A.4.k.(7) of this rule, at § 414.1400, we propose to redesignate and revise paragraph (a)(2)(i)(F) to paragraph (a)(3)(iv) that, prior to discontinuing services to any MIPS eligible clinician, group, virtual group, subgroup, or APM Entity during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, virtual group, subgroup, or APM Entity 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 transition plan by a date specified by CMS. The transition plan must address the following issues, unless different or additional information is specified by CMS. We propose to specify the contents required in the transition plan in paragraphs (a)(3)(iv)(A) through (E). Therefore, we propose to add § 414.1400(a)(3)(iv)(A) to require that the transition plan state the issues that contributed to the withdrawal mid-performance period or discontinuation of services mid-performance period. We also propose to add § 414.1400(a)(3)(iv)(B), which would require that the transition plan state the number of clinicians, groups, virtual groups, subgroups or APM entities inclusive of MIPS eligible, opt-in and voluntary participants that would need to find another way to report and as applicable, and identify any QCDRs that were granted licenses to QCDR measures which would no longer be available for reporting due to the transition. We further propose to add paragraph (a)(3)(iv)(C) to state the steps the third party intermediary will take to ensure that the clinicians, groups, virtual groups, subgroups, or APM Entities identified in § 414.1400(a)(3)(iv)(B)(*1*) are notified of the transition in a timely manner and successfully transitioned to an alternate third party intermediary, submitter type, or, for any measure or activity on which data has been collected, collection type, as applicable. At paragraph (a)(3)(iv)(D), we propose to require that the transition plan include a detailed timeline of when the third party intermediary will take the steps identified in paragraph (a)(3)(iv)(C), including notification of affected clinicians, groups, virtual groups, subgroups, or APM Entities, the start of the transition, and the completion of the transition. Finally, we propose to add at paragraph (a)(3)(iv)(E) that the third party intermediary must communicate to CMS that the transition was completed by the date included in the detailed timeline. The proposals would enable CMS to have documentation of the steps, actions, tasks, and timeline for completion of the transition of clients.

We invite comments on these proposals.

(c) Submission Requirements

(i) Risk-Adjusted Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77384 through 77385), we established that qualified registries ''submitting MIPS quality measures that are risk-adjusted . . . must submit the risk-adjusted measure results to CMS when submitting the data for these measures.'' We propose to codify this previously finalized provision at § 414.1400(b)(3)(xi).

We invite comments on this proposal.

(ii) Data Validation Audit Requirements

Section 414.1400(b)(3)(v) outlines the requirements for third party intermediary's annual data validation audits. As specified at paragraph (b)(3)(v)(E), the QCDR or qualified registry must 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 or qualified registry will submit data to CMS, except that if a 3 percent sample size would result in fewer than 10 TIN/NPIs, the QCDR or 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 QCDR or 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. We finalized this policy (81 FR 77366 through 77367) to reflect the number of reporting entities, which may be individuals, as represented by TIN/NPIs, but are often compositions of TIN/NPIs as represented by groups, subgroups, or APM entities. Since these compositions represent a single unit of measurement, we believe that they should be considered as a single unit.

We have received questions about the required sampling methodology from interested parties who are confused by the references to TIN/NPI in the context of sample size and how they map to individual MIPS eligible clinicians, groups, virtual groups, subgroups or APM Entities. To reduce confusion among third party intermediaries regarding the data validation audit sample, we propose to revise § 414.1400(b)(3)(v)(E)(*1*) and (*2*) to replace references to TIN/NPI with ''a combination of individual MIPS eligible clinicians, groups, virtual groups, subgroups and APM Entities.'' The new text would state: (1) Uses a sample size of at least 3 percent of a combination of individual clinicians, groups, virtual groups, subgroups and APM Entities for which the QCDR or qualified registry will submit data to CMS, except that if the sample size may be no fewer than a combination of 10 individual clinicians, groups, virtual groups, subgroups and APM Entities, and no more than a combination of 50 individual clinicians, groups, virtual groups, subgroups and APM Entities, the QCDR or qualified registry may use a sample size of a combination of 50 individual clinicians, groups, virtual groups, subgroups and APM Entities; and (2) Uses a sample that includes at least 25 percent of the patients of each individual clinician, group, virtual group, subgroup or APM Entity in the sample, except that the sample for each individual clinician, group, virtual group, subgroup or APM Entity must include a minimum of 5 patients and need not include more than 50 patients.

We invite comments on this proposal.

(4) Requirements Specific to QCDRs

(a) Background

As described at § 414.1305, a QCDR is an entity that demonstrates clinical expertise in medicine and quality measurement development experience and collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. Section 1848(q)(5)(ii)(B) of the Act provides that the Secretary shall encourage MIPS eligible professionals to report on applicable measures through the use of CEHRT and qualified clinical data registries.

We refer readers to § 414.1400(b)(4), the CY 2017 Quality Payment Program final rule (81 FR 77374 and 77375), the CY 2018 Quality Payment Program final rule (82 FR 53813 and 53814), the CY 2019 PFS final rule (83 FR 59900 through 59906), the CY 2020 PFS final rule (84 FR 63058 through 63074), the May 8th COVID–19 IFC (85 FR 27594 and 27595), the CY 2021 PFS final rule (85 FR 84937 through 84944), the CY 2022 PFS final rule (86 FR 65540 through 65550) and the CY 2023 PFS final rule (87 FR 70103 through 70106) for previously finalized standards and criteria for QCDRs and QCDR measure requirements.

(b) QCDR Measure Self-Nomination Requirements

(i) New QCDR Measures May Not Be Submitted After Self-Nomination

In the CY 2017 Quality Payment Program final rule (81 FR 77375 through 77377), we established that QCDRs could submit measures that are not on the annual list of MIPS quality measures as part of the self-nomination process for an entity to become a QCDR. In the CY 2018 Quality Payment Program final rule (82 FR 53808), we established a process by which existing QCDRs that are in good standing could attest that certain aspects of their previous year's approved self-nomination have not changed. We intended for the self-nomination document to be comprehensive in terms of which QCDR measures would be submitted for consideration. However, we have received requests to add measures following the completion of the QCDR self-nomination process for the performance year. Our review process requires consideration of a complete self-nomination with all measures, so we propose to add that the measure was submitted after self-nomination to our list of reasons for rejecting a QCDR measure at § 414.1400(b)(4)(iv)(O).

We invite comments on this proposal.

(ii) Limitations on Number of QCDR Measures Submitted for Self-Nomination

In the CY 2017 Quality Payment Program final rule, we established at § 414.1400(b)(4)(i) that QCDRs must submit certain specifications for QCDR measures that would be considered for approval by CMS (81 FR 77374 through 77378). These measures would then be considered for approval or rejection under the requirements of § 414.1400(b)(4)(iii) and (iv). CMS reviews these measures carefully and each additional measure takes considerable time and effort to review. We have had experiences in which a single QCDR has submitted a large number of QCDR measures for consideration. While we are mindful that there may be a number of valid measure concepts, we are generally trying to focus measurement within the Quality Payment Program. In an effort to optimize resource allocation and encourage QCDRs to focus their submitted measures on those that have the highest value, we are proposing to add at § 414.1400(b)(4)(iv)(P) that a QCDR measure may be rejected if the QCDR submits more than 30 quality measures not in the annual list of MIPS quality measures for CMS consideration. We considered a lower limit given that clinicians in traditional MIPS are only required to report on 6 quality measures and clinicians reporting via MVPs may report even fewer. However, we recognize that some QCDRs serve more diverse clinical populations and could conceivably wish to submit this many as part of self-nominations. We note that we would continue to evaluate individual measures on their merits as specified in our requirements at § 414.1400(b)(4)(iii) and (iv).

We invite comments on this proposal.

(iii) Requirements for Previous Data on QCDR Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77368), we established a requirement that for non-MIPS measures the QCDR must provide us, if available, data from years prior to the start of the performance period. We

propose to codify this previously finalized provision at § 414.1400(b)(4)(i)(C).

We invite comments on this proposal.

(iv) Requirement for QCDR Measure Specifications To Remain Published Through the Performance Period and Data Submission Period

In the CY 2017 Quality Payment Program final rule (81 FR 77375 through 77376), we established at § 414.1400(b)(4)(i)(B) that no later than 15 calendar days following CMS posting of all approved specifications for a QCDR measure, the QDCR must publicly post the CMS-approved measure specifications for the QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted. While we established when this posting was required, we did not establish a standard for the duration of this posting. We have become aware of situations in which QCDR measure owners have removed this documentation during the course of the performance period or before the closure of the submission period. We propose to revise § 414.1400(b)(4)(i)(B) to add a provision that the approved QCDR measure specifications must remain published through the performance period and data submission period. Although it was not previously specified, it was our intention that this information be made available for the entirety of the time that the measure could be considered and reported by clinicians or groups as part of the Quality Payment Program. Measure specifications must be available throughout the duration of measure use for interested parties to understand the target population of the measure, how the measure is built and calculated, and to identify existing measure gaps. Clinicians may elect to begin collecting data at various times in the year and even if data collection has started, may need to consult specifications throughout the performance period to confirm that data collection is in concordance with the specifications. We believe this addition will prevent QCDRs from removing specifications following the initial required posting and increase transparency for participants. We also propose to make a technical update to the language removing the reference to providing the NQF number due to changes in the contractor that CMS uses for measure endorsement.

We invite comments on this proposal.

(5) Health IT Vendors

(a) Background

In the CY 2017 Quality Payment Program final rule (81 FR 77377 through 77382), we established the category of health IT vendor in the Quality Payment Program, along with requirements for data submission. In the CY 2019 PFS final rule, we codified the definition of a health IT vendor as an entity that supports the health IT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician's CEHRT) (83 FR 59907). In the CY 2022 PFS final rule (86 FR 65541), we finalized a reorganization of the regulatory text governing the third party intermediary section to improve clarity and readability. In that revised text, we established general requirements at § 414.1400(a), additional requirements for QCDRs and qualified registries at § 414.1400(b), and additional requirements for health IT vendors at § 414.1400(c).

(b) Proposal To Remove Health IT Vendor Category

In the CY 2021 PFS final rule, we established additional program safeguards regarding data validation audit and targeted audit requirements that would apply specifically to QCDRs and qualified registries. We noted (85 FR 84928 and 84929) that while we did not propose these additional requirements for health IT vendors, we had become aware of situations in which health IT vendors have submitted data that are inaccurate and unusable and that could result in improper payments or otherwise undercut the integrity of the MIPS program. In our review of comments in response to our solicitation on the future application of such requirements on health IT vendors, we observed that several commenters supported requirements for health IT vendors to perform data validation to align requirements with QCDRs and qualified registries and improve data integrity. We also observed that several commenters opposed additional data validation requirements for health IT vendors due to the associated cost, and that such a requirement would be duplicative of requirements of health IT vendors under the ONC regulatory framework.

Since the publication of the CY 2021 PFS final rule, we continue to have experiences with third party intermediaries submitting data that is inaccurate and unusable. We believe this necessitates a reconsideration of the lack of data validation requirements for health IT vendors in contrast to those requirements for QCDRs and qualified registries.

In the CY 2019 PFS final rule (83 FR 59747 through 59749), we established the definition of collection type, submitter type, and submission type. These definitions are intended to more precisely describe how data is collected and submitted for the Quality Payment Program. For the quality, Promoting Interoperability, and improvement activity performance categories, an approved third party intermediary may submit directly to the submissions application programming interface (API), or upload files via *qpp.cms.gov*. Historically, third party intermediaries are able to receive tokens by virtue of successful self-nomination as a QCDR or qualified registry or, for those technologies that use CEHRT, through a request to CMS.

In examining the different requirements for QCDRs and qualified registries and health IT vendors, we note that the primary difference is the requirement for self-nomination at § 414.1400(b)(2) and requirements primarily related to data validation audits at § 414.1400(b)(3). We considered whether we should add a self-nomination requirement for health IT vendors or require data validation audits for health IT vendors or both. However, we believe that adding a self-nomination requirement or data validation audit requirements would essentially eliminate the difference between a health IT vendor and a qualified registry. We observe today that many vendors serve in capacities as qualified registries, QCDRs or health IT vendors with similar technology. Rather than establish identical or nearly identical requirements for different categories of vendors, we instead propose to eliminate the health IT vendor category beginning with the CY 2025 performance period and by revising § 414.1400(a)(1)(iii). Absent a self-nomination process for Health IT vendors, we do not believe we can establish a meaningful enforcement mechanism to ensure that the vendors are meeting the requirements as we have laid out.

Removing Health IT vendors from the definition of third party intermediary will not preclude the vendors from assisting MIPS eligible clinicians with reporting under the program. Instead, the vendors may still provide their technology for clinicians to directly report under MIPS. We believe that eliminating the category of Health IT vendor as a distinct type of third party intermediary will create a clearer distinction between those vendors that are submitting data to us for the

purposes of MIPS and must meet the requirements of a qualified registry or QCDR and those vendors that work with clinicians through the sale and support of health IT that permits the clinician or group to submit the data.

We invite comments on this proposal.

(6) Remedial Action and Termination of Third Party Intermediaries

(a) Background

We refer readers to § 414.1400(e), the CY 2017 Quality Payment Program final rule (81 FR 77386 through 77389), the CY 2019 PFS final rule (83 FR 59908 through 59910), the CY 2020 PFS final rule (84 FR 63077 through 63080), the CY 2021 PFS final rule (85 FR 84947), the CY 2022 PFS final rule (86 FR 65542 and 65550) and the CY 2023 PFS final rule (87 FR 70106 through 70109) for previously finalized policies for remedial action and termination of third party intermediaries.

(b) Additional Basis for Remedial Action

(i) Failure To Maintain Correct Contact Information

In the CY 2017 Quality Payment Program final rule, we established the process for self-nomination for QCDRs (81 FR 77364 through 77367) and qualified registries (81 FR 77383 through 77384). We also established the process for corrective action plans in the CY 2017 Quality Payment Program final rule (81 FR 77389). In our work with QCDRs and qualified registries, we experienced times when the QCDR or qualified registry did not respond to certain requests in a timely manner, thereby delaying program operations. In some cases, we had further correspondence with the QCDR or qualified registry and those organizations suggested that the contact information (generally an email address) submitted as part of the self-nomination was not correct, so the request was never received. While we understand that personnel can change over time in an organization, such a change does not relieve the QCDR or qualified registry of its obligations under these rules. Therefore, we propose an additional provision at § 414.1400(e)(2)(iv) to allow us to immediately or with advance notice terminate a third party intermediary that has not maintained current contact information for correspondence.

We invite comments on this proposal.

(ii) Consecutive Years on Remedial Action

In the CY 2017 Quality Payment Program final rule, we established a process for placing third party intermediaries on probation for not meeting requirements (81 FR 77387). Specifically, if a third party intermediary did not meet requirements for qualification, they could be placed on probation for the current performance period and/or the following performance period. We also established that after two years on probation, a third party intermediary would be disqualified for the subsequent performance year (81 FR 77387 through 77389). In the CY 2019 PFS final rule, policies relating to probation and disqualification were renamed and reorganized under remedial action and termination of third party intermediaries (83 FR 59908 through 59910). Additionally, we finalized reasons for terminating third party intermediaries including being placed on remedial action, not submitting a corrective action plan, and not promptly correcting data errors (83 FR 59908 through 59910). At that time, we did not propose any actions related to third party intermediaries on remedial action for multiple years, as had been established under our initial probation policy.

We continue to experience issues with third party intermediaries that require corrective action plans in multiple years. We believe that third party intermediaries that consistently require corrective action plans, whether for the same or unrelated issues, do not further the goals of the Quality Payment Program, which are to improve quality of care while limiting administrative burden. We believe allowing third party intermediaries that have consistently demonstrated failure to comply with CMS requirements such that they required corrective action plans undermine clinicians' and groups' efforts to improve quality and could result in increased administrative burden for those clinicians and groups. For this reason, we propose to add at § 414.1400(e)(2)(v) that CMS may terminate third party intermediaries that are on remedial action for 2 consecutive years. This proposal will minimize risk within the Quality Payment Program by terminating third party intermediaries that are consistently deemed as non-compliant.

We invite comments on this proposal.

(c) Revised Corrective Action Plan Requirements

As described in § 414.1400(e)(1)(i), among the remedial actions that CMS may take against a non-compliant third party intermediary is a corrective action plan (CAP). Under paragraphs (e)(1)(i)(A) through (D), unless different or additional information is specified by CMS, the CAP must address the following issues: (A) the issues that contributed to the non-compliance; (B) the impact to individual clinicians, groups, virtual groups, subgroups, or APM Entities, regardless of whether they are participating in the program because they are MIPS eligible, voluntarily 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; and (D) a detailed timeline for achieving compliance with the applicable requirements. In the CY 2023 PFS final rule, we finalized a policy at § 414.1400(e)(1)(i)(E) to require third party intermediaries to provide a communication plan for communicating the impact to the parties identified within the corrective action plan (87 FR 70107).

Based on our experience with corrective action plans from third party intermediaries through the years, we have identified a gap in our ability to determine if certain elements of the corrective action plan have been completed in the time and manner specified within the action plan. Therefore, we propose to add at § 414.1400(e)(1)(i)(F) an additional requirement for a third party intermediary under a corrective action plan to communicate the final resolution to CMS once the resolution is complete, and to provide an update, if any, to the monitoring plan provided under § 414.1400(e)(1)(i)(C). We believe this additional step will ensure that third party intermediaries complete the required actions within the corrective action plan.

We invite comments on this proposal.

(d) Public Posting of Deficiencies

In the CY 2017 Quality Payment Program final rule (81 FR 77386 through 77388), we established a remedial action that, in the event that a QCDR or qualified registry had data inaccuracies that affected more than 3 percent but less than 5 percent of the total number of MIPS eligible clinicians, we would have this information identified on the CMS public posting. We modified this requirement in the CY 2019 PFS final rule (83 FR 59909) that the data error rate would be publicly disclosed until the data error rate falls below 3 percent.

We are proposing to modify this requirement. While we previously determined that a single, objective measure (that is, a 3 percent error rate) would support our goals of public

notice, we believe that the precise metric is not a meaningful indicator. Specifically, some errors may be minor in nature yet affect a large number of clinicians for whom the QCDR or qualified registry has reported data. Other errors, however, may be materially significant but may not affect 3 percent of the MIPS eligible clinicians due to the unique nature of the data point at issue.

We believe that there is significant value in informing the public and potential customers which QCDRs and qualified registries are under remedial action or are terminated. Therefore, we propose to add a new provision at § 414.1400(e)(1)(ii)(B) that CMS may, beginning with the CY 2025 performance period/2027 MIPS payment year, publicly disclose on the CMS website that CMS took remedial action against or terminated the third party intermediary. We note that this public disclosure would be limited to the presence of the corrective action plan and would not include any proprietary information from the QCDR or qualified registry. We also propose to modify § 414.1400(e)(1)(ii) by redesignating it as § 414.1400(e)(1)(ii)(A) and ending this policy after the CY 2025 performance period/2027 MIPS payment year. We are proposing to remove this policy because we believe it would be superseded by the proposal included in § 414.1400(e)(1)(ii)(B).

We invite comments on these proposals.

(e) Considering Past Performance in Approving Third Party Intermediaries

In the CY 2017 Quality Payment Program final rule, we established that third party intermediaries would be placed on probation status if they had not met criteria for qualification following self-nomination (81 FR 77386 through 77389). Under the terms of the probation policy, a corrective action plan could be required to address any deficiencies or prevent them from recurring. In addition, a third party intermediary that was on probation status for 2 years would be disqualified for the subsequent performance period. In the CY 2019 PFS final rule (83 FR 59909), we consolidated the corrective actions that we would take in the event of a deficiency or error on the part of a third party intermediary. This included the elimination of a policy of probation for third party intermediaries and the establishment of a policy of remedial action for third party intermediaries. We did not change the factors made to determine a remedial action or probation.

We have continued to experience issues related to data errors from third party intermediaries and these errors often extend over multiple years. We are concerned that some third party intermediaries fail to address deficiencies with regularity, and are required to perform remedial actions as defined in corrective action plans over the course of many years. This suggests that these organizations are not able to properly adhere to the criteria for qualification for third party intermediaries. While we have established criteria for approval of third party intermediary at § 414.1400(a)(2)(ii)(A) which state that our determination to approve a third party intermediary may take into account whether the entity failed to comply with the requirements for a previous MIPS payment year, we wish to clarify that the consideration of past compliance can also include remedial actions. While we already have the ability to consider whether the entity failed to comply with certain requirements, we do not believe that the existing requirements are explicit enough for third party intermediaries to understand that a history of remedial actions, even if addressed such that the third party intermediary was not terminated could result in CMS not approving future approval.

We invite comment on this proposal.

(f) Terms of Audits

In the CY 2017 Quality Payment Program final rule (81 FR 77389 through 77390), we finalized that third party intermediaries submitting MIPS data must comply with auditing procedures as a condition to participate in MIPS. In this rule, we did not establish the reasons we have for auditing a particular third party intermediary. We note that we perform both random and targeted compliance audits based on a number of reasons and we wish to document those reasons for transparency to the public. Therefore, we propose at § 414.1400(f) that third party intermediaries may be randomly selected for compliance evaluation or may be selected at the suggestion of CMS if there is an area of concern regarding the third party intermediary. For example, areas of concern could include but are not limited to: high data errors, support call absences, delinquent deliverables, remedial action status, clinician concerns regarding the third party intermediary, a continuing pattern of Quality Payment Program Service Center inquiries or support call questions, and/or CMS concerns regarding the third party intermediary. We also propose to redesignate the existing section § 414.1400(f) (which includes paragraphs (f)(1), (2), and (3)) as paragraph (a)(3)(v) with minor changes in the text for clarity. We note that this section refers to program requirements, which we believe is a more appropriate characterization of these requirements.

We invite comments on these proposals.

(7) Technical Changes

In the course of reviewing the regulation for third party intermediaries, we identified areas in which certain language was used that is not as consistent or clear as it could be. We propose to make the following changes to § 414.1400 to improve clarity as denoted below:

- At paragraph (a)(2), to clarify that an organization may only become a third party intermediary for the purposes of MIPS by meeting the approval criteria by replacing the term ''third party intermediary'' with ''organization''.
- Redesignate paragraph (a)(3) to delineate third party intermediary approval criteria from requirements for third party intermediaries as they participate in the Quality Payment Program. We propose the following redesignations:
- § 414.1400(a)(3) redesignated as § 414.1400(a)(3)(i);
- § 414.1400(a)(2)(i)(C) redesignated as § 414.1400(a)(3)(ii);
- § 414.1400(a)(2)(i)(D) redesignated as § 414.1400(a)(3)(iii);
- § 414.1400(a)(2)(i)(F) redesignated as § 414.1400(a)(3)(iv); and
- § 414.1400 (a)(2)(iii) redesignated as § 414.1400(a)(3)(vi).

These reorganized sections also include minor changes to the text. Please note that we discuss new proposals related to these requirements in section IV.A.4.k.(3) of this proposed rule. There is also a conforming change to reference this section at § 414.1400(e)(1).

- At § 414.1400(e)(3) to remove the word ''total'' from the phrase ''total clinicians'' as this word was included in error.
- At § 414.1400(e)(4) to improve clarity and remove a paragraph.

We invite comments on these proposals.

l. Public Reporting on Compare Tool

Section 10331(a)(1) of the Affordable Care Act provides for the development of a Physician Compare internet website (''Physician Compare'') with information on physicians and other eligible professionals enrolled in Medicare who participate in the

Physician Quality Reporting Initiative (PQRI). Section 1848(q)(9) of the Act, as added by section 101(c) of MACRA, aligned Physician Compare with the newly established Merit-Based Incentive Payment System (MIPS) by requiring the public reporting of MIPS performance information for MIPS eligible professionals through Physician Compare.

For previous discussions of public reporting of physician and clinician performance and information, we refer readers to the CY 2016 Physician Fee Schedule (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), the CY 2022 PFS final rule (86 FR 65550 through 65554), the CY 2023 PFS final rule (87 FR 70109 through 70113) and the Care Compare: Doctors and Clinicians Initiative web page at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/care-compare-dac-initiative*. We also note that as finalized at § 414.1305 ''Physician Compare'' is defined as the Physician Compare internet website of CMS (or a successor website). As discussed in prior rulemaking, we note the current website is the Compare Tools hosted by the U.S. Department of Health and Human Services (HHS), referred to as the ''Compare tool'' throughout prior rulemaking and this proposed rule (86 FR 39466). (*https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/care-compare-dac-initiative*.)We also note that as finalized at § 414.1305 ''Physician Compare'' is defined as the Physician Compare internet website of CMS (or a successor website). As discussed in prior rulemaking, we note the current website is the Compare Tools hosted by the U.S. Department of Health and Human Services (HHS), referred to as the ''Compare tool'' throughout prior rulemaking and this proposed rule (86 FR 39466).

(1) Telehealth Indicator

In the CY 2023 PFS final rule, we finalized the addition of an indicator to the profile pages of clinicians who furnish telehealth services (87 FR 70109 through 70111) to established processes and coding policies to identify such clinicians (*id.*). Among the originally proposed policies, we proposed using Place of Service (POS) code 02 (indicating telehealth) on paid physician and ancillary service (that is, carrier) claims or modifier 95 appended on paid claims (87 FR 46330). During the CY 2023 PFS proposed rule public comment period, we received unanimous support for adding a telehealth indicator. One of the commenters also brought to our attention a POS coding update, and we subsequently finalized a policy of using both POS 02 and POS 10, as well as modifier 95 to identify clinicians that furnish telehealth services.

At the time of the CY 2023 PFS proposed rule, we were not aware of an update in process for POS Code 02 revising the description from ''telehealth'' to ''telehealth provided other than in patient's home'' for locations in which telehealth services were furnished. In connection with this change to POS Code 02, Medicare also adopted the then newly added POS Code 10, ''telehealth provided in patient's home.'' Since many telehealth visits occur in patients' homes it was appropriate and consistent with the intent of our proposal to include POS 10 in addition to POS 02 and claims modifier 95 to identify clinicians providing telehealth services in our final policy.

The POS Code 10 comment, described earlier in this section, received in response to our proposal in the CY 2023 PFS proposed rule, inferred the need to stay current with all types of coding changes that occur throughout the year, outside of the annual PFS rulemaking cycle. Under our current policy, we would already be using the most current CPT codes for each telehealth indicator update; however, we would need to use annual rulemaking to update the POS and claims modifier codes used for telehealth indicator public reporting purposes. Depending on how frequently codes are updated, there could be the unintended consequence of using the annual rulemaking cycle to adopt updated codes that could otherwise be avoided through establishing a coding flexibility policy. If we are limited to the codes specifically finalized via rulemaking, the codes used to inform the telehealth indicator may be incomplete or outdated when we refresh the telehealth indicator on clinician profile pages throughout the year, resulting in users of the Compare tool receiving incorrect information.

Adding coding flexibility for other codes, such as POS and claims modifiers, would both help avoid future regulatory burden and allow for more real-time accuracy of the telehealth information provided on Care Compare. This is particularly important since consumer testing and 1–800–MEDICARE inquiries have shown that patients and caregivers are actively looking for telehealth services, as well as for health equity purposes since telehealth is critical to those who live in rural areas, lack transportation, or have other limitations.

For these reasons, we are proposing to update our policy for identifying clinicians furnishing telehealth services, such that we remain current with CMS coding changes, without proposing and finalizing such coding changes via rulemaking. Specifically, instead of only using POS code 02, 10, or modifier 95 to identify telehealth services furnished for the telehealth indicator, we would use the most recent codes at the time the data are refreshed that identify a clinician as furnishing services via telehealth. This flexibility is consistent with how we use the most current CPT codes, some of which are time-limited, to identify clinicians furnishing telehealth services. We are proposing that at the time of such a data refresh we would publish the details of which codes are used for the telehealth indicator through education and outreach, such as via a fact sheet, listserv, and information posted on the Care Compare: Doctors and Clinicians Initiative page, available at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/care-compare-dac-initiative*. We are seeking comment on this proposal.

(2) Publicly Reporting Utilization Data on Profile Pages

Section 104(a) of MACRA provides that, beginning with 2015, the Secretary shall make publicly available on an annual basis, in an easily understandable format, information with respect to physicians and, as appropriate, other eligible professionals, on items and services furnished to Medicare beneficiaries. The information made available must be similar to the physician and other supplier utilization data we have historically made available through the Medicare Provider Utilization and Payment Data: Physician and Other Supplier Public Use File (''PUF'') and shall include information on the number of services furnished by the physician or other eligible professional under Medicare, which may include information on the most frequently furnished services or groupings of services. Section 104(e) of the MACRA requires that we integrate this data into the Compare tool. We finalized a policy to report the most recent available utilization data in downloadable format beginning in late 2017 (80 FR 71130). This information

continues to be available today in the Medicare Provider Data Catalog (PDC) available at *https://data.cms.gov/provider-data/topics/doctors-clinicians*. Separately, we have reported on the Compare tool clinician training information as well as a clinician's primary and secondary specialties.

In the CY 2023 PFS final rule, we established a policy for publicly reporting procedure information on clinician profile pages to provide patients more information in their clinician searches in an understandable format, beginning no earlier than CY 2023 (87 FR 70111 through 70113). Until that time, we had gathered utilization data for procedures from physician/supplier Medicare Part B non-institutional claims on certain services and procedures and published it in the Physician and Other Supplier Data PUF. Although these data are useful to the healthcare industry, healthcare researchers, and other interested parties, this information was presented in a technical manner that was not easily accessible or usable by patients, who do not frequently visit *https://data.cms.gov* or understand medical procedure coding.

We also established that priority procedures selected for utilization data public reporting will meet one or more of the following criteria:

- Have evidence of a positive relationship between volume and quality in the published peer reviewed clinical research;
- Are affiliated with existing MIPS measures indicating importance to CMS;
- Represent care that a patient might shop for a clinician to provide; and/or
- Are an HHS priority.

We finalized that this data would be based on a 12-month lookback period, with data refreshes updated bi-monthly, as technically feasible, and we would not initially prioritize complex, rare procedures. We noted that the utilization data shown on profile pages would only reflect Medicare Fee-for-Service (FFS) claims data and would not include procedures performed for patients who have other types of insurance. To meaningfully categorize procedures, we finalized the policy of using the Restructured Berenson-Eggers Type of Service (BETOS) Codes Classification System to collapse Healthcare Common Procedure Coding System (HCPCS) data into procedural categories, and when no Restructured BETOS categories are available, procedure code sources used in MIPS, such as the procedure categories already defined for MIPS cost or quality measures. Restructured BETOS is a taxonomy that allows for the grouping of procedure codes into clinically meaningful categories and subcategories. Additional Restructured BETOS information is available at *https://data.cms.gov/provider-summary-by-type-of-service/provider-service-classifications/restructured-betos-classification-system*. These category sources, as finalized, allow us to publicly report procedural utilization data in a meaningful way to patients and caregivers rather than showing thousands of rows of individual HCPCS data, as we do for the research community in the PDC. For example, applying categories enables us to list that a clinician performs knee arthroplasties. Using plain language, we would simplify the procedure category name to ''knee replacements'' for understandability instead of listing each of nine unique procedure codes indicating the specifics of exactly which bones and which implants were involved.

Since the publication of the CY 2023 PFS final rule, we conducted additional consumer testing and data analysis to prepare and select certain procedure-related utilization data for publication. Consumer testing showed that publicly reporting utilization data on patient-facing clinician profile pages and using plain language, is helpful for patients and caregivers to make informed healthcare decisions, since it allows them to find clinicians who have performed specific types of procedures. Consumer testing results showed that patients and caregivers understand this language, would not select a health care provider based on this information alone, and find the information helpful but would like the procedure volume to also reflect patients with other insurance if possible. Our data analyses have confirmed the availability of Medicare Advantage (MA) data increasing the representativeness of the procedure (that is, utilization) data, as discussed later in this section.

We are targeting to release procedure data based on FFS claims on clinician profile pages later this year, beginning with 13 priority procedure categories identified for public reporting. Details on the utilization data publicly reported on clinician profile pages will be available on the Care Compare: Doctors and Clinicians Initiative page, available at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/care-compare-dac-initiative* and on the PDC at *https://data.cms.gov/provider-data/dataset/eedd-4c6c*.

(a) Updating the Provider Data Catalog (PDC) Utilization Data Policy

As discussed earlier in this section, we historically have published a PDC file that is a subset of the most commonly performed procedures in the PUF. With the upcoming release of the initial procedural utilization data, we will publish a second utilization file in the PDC that will reflect the procedure category information on clinician profile pages. That is, consistent with what will be publicly reported on profile pages, the second PDC file will aggregate like procedures and include an indication of low volume counts, in accordance with the CMS small cell size policy, in which counts below 11 cannot be publicly reported, to protect patient privacy.

It would be of greater use for the PDC to only have one utilization downloadable file that reflects the same subset of data, in the same format, as what will be publicly reported on clinician profile pages. Doing so aligns the criteria for selecting utilization data in the PDC to reflect the same criteria for selection on clinician profile pages and will assist researchers in analyses of utilization data on clinician profile pages. Moreover, the researcher and clinician communities, who are the primary users of the PDC, would appreciate having the single downloadable dataset that reflects the same procedure utilization data that would appear on clinician profile pages. It would also be more efficient to focus resources on maintaining one file reflective of clinician profile page utilization data rather than both produce that file and duplicate some of the PUF information on the PDC. The full CMS PUF of FFS data is still available on *https://data.cms.gov* for researchers and clinicians who are interested in the full set of Medicare procedure information at the individual procedure code level. To direct researchers to the PUF of Medicare FFS information, we currently communicate where to locate the original PUF and the details of the updated PDC file through education and outreach, such as via a fact sheet, listserv, and information posted on the Care Compare: Doctors and Clinicians Initiative page, available at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/care-compare-dac-initiative*.

Therefore, we propose revising the policy to publicly report a subset of the Medicare PUF on the PDC to instead provide a single downloadable dataset including the procedure utilization data that would appear on clinician profile pages. If this proposal is finalized, we

would remove the PUF subset file from the PDC and only keep the utilization data file that reflects the information on clinician profile pages in the PDC.

We seek comment on all aspects of this proposal, including any concerns about technical feasibility; our proposed approach to aligning the criteria for selecting utilization data in the PDC to reflect the same criteria for selection on clinician profile pages; ways in which we inform researchers on the location of the full CMS PUF for continued use; and any other considerations. The proposals discussed later in sections IV.A.4.l.(2)(b) and (2)(c) would also be reflected in the new downloadable utilization data file in the PDC if the other proposals are finalized as proposed.

(b) Procedure Grouping Policy for Publicly Reporting Utilization Data

As mentioned earlier in this section, in the CY 2023 PFS final rule, we finalized using Restructured BETOS and procedure code sources used in MIPS when no Restructured BETOS categories are available, such as the procedure categories already defined for MIPS measures to meaningfully categorize procedures for public reporting (87 FR 70111). However, since finalizing this policy, we identified some commonly sought procedures, such as hysterectomy, that do not have a procedure category specified in the Restructured BETOS categorization system or a relevant code set in any MIPS quality or cost measures. We anticipate this issue could occur for additional procedures as we continue to identify additional priority procedures for public reporting.

We received a few comments on the CY 2023 PFS proposed rule that stated that some of the Restructured BETOS categories may be too broad and acknowledged that there is no other existing standard, systematic way to group procedures by HCPCS codes (87 FR 70111 and 70112). However, we did not receive any suggestions for alternative sources for the purpose of grouping procedures during the CY 2023 PFS proposed rule public comment period.

We now propose to define meaningful categories using subject matter expert (for example clinician) input in instances where a procedure category is unavailable under the Restructured BETOS or MIPS measures, if a code category exists but is not suitable for public reporting, or in instances where a procedure category does not exist, to create new, clinically meaningful, and well-understood procedure categories as needed. Added flexibility in grouping HCPCS codes to create procedure categories meaningful to patients and caregivers would allow users of the Compare tool to better assess a clinician's volume and scope of experience with a particular procedure and inform healthcare decision making.

To implement this, we are proposing to modify the existing policy such that, in addition to the two previously finalized sources (Restructured BETOS categorization system and code sources used in MIPS), we may use alternate sources to create clinically meaningful and appropriate procedural categories, particularly when no relevant grouping exists. If we develop new procedure categories for publicly reporting utilization data on clinician profile pages, we propose to engage subject matter experts and interested parties through periodic requests for feedback using methods outside of rulemaking, such as listserv emails, listening sessions, and focus groups to solicit feedback on bespoke procedure categories planned for future releases of utilization data, as appropriate and technically feasible.

We are seeking comment on all aspects of our proposal to modify existing procedural categorization policy to use alternate sources to create clinically meaningful and appropriate procedural categories and our proposed approach to engaging with subject matter experts in developing procedure categories, as appropriate and technically feasible.

(c) Incorporating Medicare Advantage (MA) Data Into Public Reporting

Between the time of the CY 2023 PFS proposed and final rules, our Medicare FFS claims data analyses showed that for the initial 13 priority procedures identified, approximately 50 percent of clinician-procedure combinations fall into the low volume category, which meant that, based on Medicare physician and ancillary service (carrier) claims in the past 12 months, we could only publish an indicator that a clinician has experience with the procedure rather than specific counts. Under the small cell size policy, we prohibit the use of specific procedure or patient counts in cases where the count is below ten. The high number of clinicians with a low volume indicator is partly due to not including data for patients with other coverage, such as MA plans or other payers, for whom a given clinician has also performed such procedures. As such, we are currently limited in our ability to contextualize low volume clinician experience with procedures in a way that is useful and easily understandable for patients and caregivers who may be looking for a clinician with experience performing a specific procedure.

As we identify more priority procedures for public reporting, more procedures may be subject to the small cell size policy using Medicare FFS data alone, which would prevent us from publicly reporting health care provider experience with such procedures for patients and caregivers to use in their healthcare decisions. Based on public comments and consumer testing, including other payer data would help prevent this issue. Specifically, we received several comments on the CY 2023 PFS proposed rule from the clinician community who had expressed concern about the understandability of the data and that limiting procedure data counts to Medicare FFS claims only does not reflect the full scope of clinician practice (87 FR 70112). Consumer testing findings have also shown that patients and caregivers would like procedure information to reflect all procedures performed, since it better represents clinicians' experience.

While we agreed with comments received on the CY 2023 PFS proposed rule, we were unable to finalize the possibility of using other payer data as appropriate and technically feasible at that time. However, we have subsequently determined through analysis of MA encounter data submitted to CMS that it would be technically feasible to integrate MA encounter data into procedure category counts and that adding such data adds to the representation of some clinicians' scope of care. For example, adding MA encounter data to the initial set of publicly reported procedure categories would reduce the low volume clinician-procedure counts by approximately 12 percent. An additional 10,689 unique clinicians would have information on their profile pages, since they do not have this information based on FFS data alone. These unique clinicians account for furnishing 9 percent (10,869/114,243) of the combined FFS and MA patient populations from July 1, 2021 to June 30, 2022.

Therefore, we are proposing to publicly report aggregated counts of procedures performed by providers based on MA encounter data in addition to Medicare FFS utilization data, given that we have determined it is appropriate and technically feasible. Section 104(a) and (b) of MACRA provides for the public reporting of items and services furnished to Medicare beneficiaries under title XVIII of the Act, including, at a minimum, information on the most frequent

services or groupings of services furnished by physicians or other eligible professionals under part B of title XVIII of the Act. This provision authorizes the publication of information on the items and services furnished to ''Medicare beneficiaries under Medicare by physicians and certain other professionals.'' Notably, the statute authorizes the disclosure of information on all items and services furnished to Medicare beneficiaries under the Medicare Act; that is, the statute does not limit the disclosure to a particular subset of Medicare services. Indeed, section 104(c)(1) of MACRA provides that the information made available must include ''at a minimum'' certain information on Part B services. This does not limit the disclosure authorized by section 104(a) of MACRA to information on Part B items and services; instead, it specifies the minimum information that CMS must disclose, leaving additional disclosures under section 104(a) of MACRA to CMS' discretion. MA plans cover Part A and Part B benefits (excluding hospice services, acquisition costs for kidneys used for transplants, and, for a limited period, certain services under new National Coverage Determinations and changes in legislation) for Medicare beneficiaries that elect to enroll in an MA plan; this coverage is also under Title XVIII of the Act. Section 104(a) of MACRA thus authorizes the disclosure of certain information about items and services provided as benefits under an MA plan and furnished by a physician or other eligible professional.

Separately, section 10331(b)(4) of the Affordable Care Act provides for the Secretary to, in developing and implementing his plan to make information as determined appropriate by the Secretary available on Physician Compare, include data that reflects the care provided to all patients seen by physicians, under both the Medicare program and, to the extent practicable, other payers, to the extent such information would provide a more accurate portrayal of physician performance. Thus, the inclusion of MA encounter data is consistent with the relevant statutory provisions regarding the disclosures on the Care Compare website.

Per section 1853(a)(3)(B) of the Act, CMS has required MA organizations to submit the data necessary to characterize the context and purposes of each item and service provided to a Medicare beneficiary enrolled in an MA plan to use for risk adjusting payments by CMS to MA plans. Per the MA regulation at § 422.310(f)(1)(vii), CMS may use this risk adjustment data, which includes MA encounter data, for activities to support administration of the Medicare program and for purposes authorized by other applicable law. The MA regulation at § 422.310(f)(2) allows CMS to release encounter data for any of the purposes specified in § 422.310(f)(1) in accordance with applicable Federal laws and CMS data sharing procedures, subject to protections of beneficiary confidentiality and commercially sensitive data. Finally, § 422.310(f)(3) imposes restrictions on when the data is available for release. We propose to rely on § 422.310(f), as well as section 104 of the MACRA and section 10331 of the Affordable Care Act, for using and releasing the MA encounter data as part of the Care Compare website. To accomplish this, we are also proposing to amend § 422.310(f)(3) to permit the release of the MA encounter data on the timeframe(s) used for disclosure and release of the data on the Care Compare website. This proposal would ensure that there is no confusion about our ability to use and release the MA encounter data for the Care Compare website and downloadable files and permit release of MA when necessary and appropriate to support activities or authorized uses under paragraph (f)(1)(vii) of this section.

Using and analyzing MA encounter data as part of the aggregated information disclosed through the Care Compare website will more completely fulfill the public reporting required by section 104 of the MACRA and section 10331 of the ACA and using the MA encounter data in implementing these statutory provision supports administration of the Medicare program. In addition, it is also consistent with administering the Medicare program overall to provide appropriate and helpful information to beneficiaries in selecting a provider. Thus, the use and disclosure of the MA encounter data here are within the scope of § 422.310(f)(1)(vii).

The aggregated utilization data we propose to include in the Compare tool meets the additional requirements to protect beneficiary and commercially sensitive information at § 422.310(f)(2) because only identifying information about healthcare providers and types of procedures performed within a specific time period would be disclosed on the website and available for release in the PDC downloadable files. The disclosure and release of these portions of the MA encounter data are consistent with CMS data sharing procedures, which are applied to the Medicare FFS data already displayed and available for download on the Care Compare website. However, when releasing the MA encounter data under § 422.310(f)(2), the timing limitations at § 422.310(f)(3) prohibit releasing encounter data before the applicable payment year's reconciliation has been completed except for in specified circumstances. Neither of the exceptions applies here. Because we propose to use information from the MA encounter data, in combination with FFS claims data, over a 12-month rolling period, but risk adjustment reconciliation occurs no sooner than 13 months after the end of the year that services were provided, the timing of the proposed release of the MA encounter data is not within the scope of the timing requirements in § 422.310(f)(3).

MA organizations submit encounter data continuously, but do not have the same timeliness requirements for submission that FFS providers have for submitting claims. In the August 22, 2014 final rule entitled, ''Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Hospitals and Certain Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program'' (79 FR 49854), CMS adopted § 422.310(f)(3) to address concerns that the need to update or correct MA encounter data prior to the final submission deadline could mean that the MA encounter data was not sufficiently complete or fully reliable for public release. However, since that time, which was during the first few years of submission of MA encounter data to CMS, submissions of MA encounter data have improved. In particular, the provider identifying information and procedure codes required for the Compare tool are well reported. Because the Compare tool is reporting aggregated counts of procedures, and not at the beneficiary level, releasing this data before final reconciliation is appropriate to support the administration of the Medicare program. Furthermore, including utilization and limited provider-identifying data from MA encounters prior to the data being reconciled by the MA organization would substantially improve the Compare tool and, thereby, the administration of the Medicare program overall by providing patients and

caregivers with more useful and easily understandable information about procedures performed by providers in their search for a clinician. We therefore propose to amend § 422.310(f)(3) to include an additional exception at (f)(3)(iv) that permits CMS to release aggregated risk adjustment data before the reconciliation for the applicable payment year has been completed if CMS determines that releasing aggregated data is necessary and appropriate for the purposes specified in § 422.310(f)(1)(vii).

Based on our analyses, the inclusion of data about utilization in the MA program would reduce the low volume procedure counts subject to the small cell size policy, in which precise counts less than ten procedures or patients cannot be publicly reported. This would allow us to more accurately report the types of services that Medicare clinicians provide. Based on the public comments in our prior rulemakings about the Care Compare website and consumer feedback, aggregating utilization data from the Medicare FFS and MA program would also enhance patient use of the information. Although the initial release of publicly reported utilization data on the Compare tool is limited to clinicians' Medicare FFS claims, publicly reporting utilization data that includes Medicare FFS and MA would also be more consistent with MIPS quality information submitted via health IT vendors or registries that include other payer data. Lastly, adding MA data to the counts in the existing Medicare FFS utilization data file will mitigate interested party concerns by ensuring the data is more reflective of the physician's/clinician's scope of practice.

We seek comment on all aspects this proposal.

(3) Request for Information: Publicly Reporting Cost Measures

Section 1848(q)(9)(A)(i) of the Act requires us to publicly report MIPS eligible clinicians' final scores and performance category scores and authorizes, but does not require, us to publicly report MIPS eligible clinicians' performance with respect to each measure or activity. In the CY 2017 Quality Payment Program final rule (81 FR 77390 through 77399), we finalized our policies for publicly reporting MIPS eligible clinicians' and groups' final scores, performance category scores, and measure-level scores in an easily understandable format. Currently, we publicly report certain MIPS performance information that meet public reporting standards on clinician, group, and Accountable Care Organization (ACO) profile pages of the Compare tool (available at *https://www.medicare.gov/care-compare/*) so Medicare patients and caregivers can use it when making healthcare decisions. In addition to publicly reporting final scores and performance category scores in the PDC, we established a policy to publicly report performance on measures, activities, and attestations, from the MIPS quality, cost, Promoting Interoperability (previously called Advancing Care Information), and improvement activities performance categories that meet established public reporting standards (81 FR 77395). We codified these public reporting standards in our regulations at § 414.1395(b), requiring that performance data be statistically valid, reliable, accurate, and comparable across collection types, to be included in the PDC, available at *https://data.cms.gov/provider-data/topics/doctors-clinicians.* The data must also resonate with patients and caregivers as determined by user testing to be included on the Compare tool profile pages.

As of the time of this proposed rule, data from the CY 2021 performance period/2023 MIPS payment year regarding MIPS eligible clinicians' performance in the quality, improvement activities, and Promoting Interoperability performance categories that meet public reporting standards are publicly available on Compare tool profile pages and in the PDC. However, we have not publicly reported any cost measure information from the cost performance category since the inception of MIPS for two primary reasons.

First, in the CY 2019 PFS final rule (83 FR 59910 through 59912), we established a policy to delay publicly reporting any new quality and cost measures for the first two years they are in MIPS to allow MIPS eligible clinicians and groups to gain experience with the new measures. We codified this policy in our regulation at § 414.1395(c). After this period, we would reevaluate the measures to determine when and if they are suitable for public reporting (83 FR 59910 through 59912). Second, we have not had cost measures available for public reporting because of the COVID–19 Public Health Emergency (PHE), during which we reweighted the cost performance category to zero percent for MIPS eligible clinicians' final scores in the CY 2019 performance period/2021 MIPS payment year, as discussed at *https://qpp.cms.gov/resources/covid19?py=2019,* the CY 2020 performance period/2022 MIPS payment year, as discussed at *https://qpp.cms.gov/resources/covid19?py=2020,* and the CY 2021 performance period/2023 MIPS payment year, as discussed at *https://qpp.cms.gov/resources/covid19?py=2021.* That is, for several years, we provided cost measure scores to clinicians for informational purposes only and did not publicly report MIPS eligible clinicians' performance in the cost measure category.

However, given the number of cost measures we have adopted in MIPS for at least two years and the PHE ending, we are evaluating ways to publicly report performance on cost measures on clinician and group profile pages beginning with data from the 2024 performance period/2026 MIPS payment year being publicly reported in 2026. Public reporting of these data would assist patients and caregivers in making healthcare decisions. In section IV.A.4.f.(2) of this proposed rule, we are proposing, beginning with the CY 2024 performance period/2026 MIPS payment year, adoption of five new episode-based cost measures and removal of one episode-based cost measure. If our proposal is finalized, there would be a total of 25 cost measures—23 Episode-Based Cost Measures (EBCMs), Medicare Spending Per Beneficiary (MSPB), and Total Per Capita Cost (TPCC)—available for public reporting in CY 2026, provided they meet public reporting standards as set forth in our regulation at § 414.1395. In the CY 2019 PFS final rule (83 FR 59910 through 59912), we finalized a policy to delay publicly reporting any new quality and cost measures for the first 2 years they are in MIPS at § 414.1395(c). There are currently 25 cost measures available for public reporting at the time of this Request for Information, and the 5 cost measures proposed for inclusion in section IV.A.4.f.(2) of this rule would not be eligible for public reporting until the CY 2026 performance period/2028 MIPS payment year. Additionally, by publicly reporting cost measures, we would further our goals of transparency, encouraging MIPS eligible clinicians to prioritize cost efficiency, and enabling patients and caregivers to make informed decisions about clinicians who consider costs as part of their care.

Research suggests that patients and caregivers are interested in comparative cost information.[320] An Agency for

[320] Greene, J., & Sacks, R.M. (2018). Presenting Cost and Efficiency Measures That Support Consumers to Make High-Value Health Care Choices. Health services research, 53 Suppl 1(Suppl 1), 2662–2681. *https://doi.org/10.1111/1475-6773.12839.*

Healthcare Research and Quality (AHRQ) environmental scan and systematic review of all payer claims databases (APCDs) in 2017 found there is a need for standardized and transparent cost measures reporting, as well as user-friendly interfaces that help patients and caregivers make informed healthcare decisions.[321] Several sources highlight the importance of presenting cost information in the context of quality metrics to improve healthcare consumers' ability to interpret cost data.[322] [323] Although there is limited research in this area, there is evidence that consumers can make high-value choices using cost in combination with other performance data.[324]

During a recent consumer testing session with patients, the majority of whom were Medicare beneficiaries and included two retired clinicians, several participants noted that they find cost information valuable and would use it in conjunction with other information when making healthcare decisions. This early finding suggests that this type of information is valued by healthcare consumers; additional consumer testing with patients and caregivers and input from clinical subject matter experts would be beneficial for gathering feedback from the population who use the website and ensure that publicly reported MIPS cost measures are interpreted correctly and useful to website users. Further consumer testing with patients and caregivers would also help determine which aspects of cost performance information resonate most with them, as well as how to best display and plain language cost measure information on clinician and group profile pages.

We intend to propose in future rulemaking to publicly report MIPS cost measures beginning with data from the CY 2024 performance period/2026 MIPS payment year in CY 2026 on Compare tool clinician and group profile pages and in the PDC in 2026. In this Request for Information (RFI), we are seeking comment on a number of aspects of how to best establish publicly reporting cost measures, as discussed below.

- Potential approaches to reporting MIPS cost measures, including whether it is more meaningful to only report aggregated episodes or include component-level cost information for the EBCMs. Cost measure components are specified in the measure construction for each episode type based on input from clinical expert engagement activities during the development process and can include services related to either clinical treatments or adverse events (for example, clinically related diagnostic care, the need to receive post-acute care following the initial procedure or hospitalization, and the need to visit an emergency room or be readmitted for additional inpatient care following the initial procedure or hospitalization). With this context, patients would have additional information enabling them to make informed healthcare decisions.

To provide actionable cost measure data, we will test the consumer perceptions of the components of cost measures in addition to the overall cost measure scores to determine whether they resonate with users. We expect that component costs will provide context for patients and caregivers to understand the extent to which costs are driven by what may be perceived as high-quality care (for example, post-discharge follow-up visits) or low-quality care (for example, procedure re-do). For example, when comparing clinicians, consumers could assess frequency or severity (for example, as measured by above average costs associated with clinically related complications).

- Benchmarking and possible comparators as well as how to best present this information to provide frames of reference for the cost performance information. Cost measures present a unique challenge to public reporting as their interpretation is not intuitive to consumers. While higher than expected costs may be driven by adverse outcomes, overall cost is comprised of care components that consumers could perceive as higher quality (for example, follow-up visits) as well as lower quality (for example, clinically related emergency department visits and re-hospitalizations). As a result, overall costs alone do not provide sufficient context about the drivers of those costs and may cause consumers more confusion in making a choice about where to seek care. Publishing overall costs could also be misleading, as previous consumer testing showed that some patients and caregivers interpret higher costs as a reflection of higher quality, when in fact testing during cost measure development has consistently demonstrated that clinicians with higher shares of costly adverse events, such as hospital readmission, tend to have worse scores.

One mechanism of contextualizing cost measure performance is through displaying cost measures alongside clinically relevant quality measures, resulting in a reflection of value. However, there are two main reasons the current structure of MIPS does not consistently support this preferred display. First, under the self-selection policy for quality measures, MIPS eligible clinicians may select measures on which they expect to score best, rather than those that are most clinically relevant to their practice. This can result in a clinician profile with quality measures that are clinically unrelated to the clinician's core practice activities and, therefore, the clinician's cost measures. Second, MIPS eligible clinicians have a choice between reporting their performance on quality measures as individuals or as part of a group. Group-reported quality measure performance cannot be disaggregated to the clinician level. Because we calculate cost measures independently for all eligible clinicians and groups using Medicare claims, performance information is available at both levels. When reporting cost measure performance at the clinician level (because patients and caregivers using the Compare tool prefer measure performance at the most granular level available), we could have cost measures on a MIPS eligible clinician's profile page with no accompanying quality measures. Given these realities inherent to MIPS, there may not always be relevant quality measure information available to display alongside cost for a value concept. MIPS Value Pathways (MVPs) may mitigate some of these issues, since clinicians would have a smaller set of quality measures, some of which could be more related to their specialty, for selection, but clinician versus group level performance reporting discrepancies would persist.

Therefore, we have considered several approaches to presenting cost measure performance information without assuming related quality measures would be available for adjacent display, including reporting the ratio of cost to the national average cost and the dollar cost per episode. These approaches may result in challenges to interpreting meaningful differences in costs. The

[321] Agency for Healthcare Research and Quality, All-Payer Claims Databases Measurement of Care: Systematic Review and Environmental Scan of Current Practices and Evidence (2017) *https://www.ahrq.gov/data/apcd/envscan/findings.html.*

[322] Greene, J., & Sacks, R.M. (2018). Presenting Cost and Efficiency Measures That Support Consumers to Make High-Value Health Care Choices. Health services research, 53 (Suppl 1), 2662–2681. *https://doi.org/10.1111/1475-6773.12839.*

[323] Commonwealth Fund, Hospital Price Transparency: Making It Useful for Patients, (2019), available at *https://www.commonwealthfund.org/blog/2019/hospital-price-transparency-making-it-useful-patients.*

[324] Greene, J., & Sacks, R.M. (2018). Presenting Cost and Efficiency Measures That Support Consumers to Make High-Value Health Care Choices. Health services research, 53 (Suppl 1), 2662–2681. *https://doi.org/10.1111/1475-6773.12839.*

Achievable Benchmark of Care (ABC™) methodology we currently use to star rate performance on publicly reported MIPS quality and Promoting Interoperability measures would not be appropriate for cost measures, because this method is used for measures in which a single direction of performance (for example, higher) is universally desirable, which, as discussed previously, is not always the case with cost performance. We have also considered an approach to display the MIPS eligible clinician's or group's relative position in the distribution of the cost measure performance compared to the national average we calculate from MIPS cost measures using three levels. Doing so, we could determine whether each clinician or group performance on each scored cost measure is ''greater than,'' ''less than,'' or ''no different'' compared to the national average cost.

We are inviting comment on this possible approach to publicly reporting individual MIPS eligible clinician's or group's performance on individual EBCMs, MSPB, and TPCC compared to the average performance of all MIPS eligible clinicians nationally. We are also seeking comment on considerations for these comparators or benchmarks discussed above, particularly whether they would be useful to present or if there are any alternatives we have not yet considered.

To summarize the aspects discussed above in which we request additional information, we are seeking comment on the following topics related to public reporting of MIPS cost measures on the Compare tool:

- How can we present MIPS cost measures information in a way that reflects meaningful outcomes to patients and their caregivers and the value of care, rather than cost alone?
- What are the considerations for publicly reporting the total episodic cost, component-level costs, or both? Do the component costs provide adequate context for patients and their caregivers to make informed healthcare decision? What other specific information about MIPS cost measures, including the context of quality measures and MVPs, should we consider including on the Compare tool?
- What are the considerations for publicly reporting the national average cost, ratio of cost to the national average cost, and/or the dollar cost per episode as possible benchmarks for comparison discussed above in this section? What other benchmarks or comparator approaches should we consider?
- Are there any considerations for evaluating cost measures for public reporting beginning with cost measure data from CY 2024 performance period/2026 MIPS payment year in the CY 2026?
- What other factors, such as those related to health equity, should be taken into consideration?
- We request comment on additional information that we may not have considered or discussed above about publicly reporting MIPS cost measures, as well as any unintended impacts and/or positive outcomes that could result from making this information publicly available on the Compare tool.

n. Overview of QP Determinations and the APM Incentive

(1) Overview

The Quality Payment Program provides incentives for eligible clinicians to engage in value-based, patient-centered care under Medicare Part B via MIPS and Advanced APMs. The structure of the Quality Payment Program enables us to advance accountability and encourage improvements in care. The Secretary has also adopted the closely related goal of having all people with Traditional Medicare in an accountable care relationship with their health care provider by 2030, where their needs are holistically assessed and their care is coordinated within a broader total cost of care system. Our vision for increased participation among clinicians in Advanced APMs is driven by a belief that integrating individuals' clinical needs across a spectrum of providers and settings will improve patient care and population health.

As we continue to improve the Quality Payment Program, we seek to develop, propose, and implement policies that encourage broad clinician participation in Advanced APMs. For example, in this section, we are proposing to calculate QP determinations at the individual level for each unique NPI associated with an eligible clinician participating in an Advanced APM. As discussed further in the proposal, we believe that this change will provide a more accurate measure of the actual engagement of individual clinicians participating in Advanced APMs. This accuracy is important for administration of the Quality Payment Program incentives and also could help us better identify and understand the motivating factors and indicators of clinician readiness for greater adoption of Advanced APMs.

In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77445), we finalized our policy at § 414.1425(b) for Qualifying APM Participant (QP) determinations. For the purposes of making QP determinations, an eligible clinician must be present on the Participation List of an APM Entity in an Advanced APM on one of the ''snapshot dates'' (March 31, June 30, or August 31) for the QP Performance Period. An eligible clinician included on a Participation List on any one of such dates is included in the APM Entity group even if that eligible clinician is not included on that Participation List at one of the prior- or later-listed dates. We perform QP determinations for the eligible clinicians in an APM Entity group three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP snapshot dates. An eligible clinician can be determined to be a QP only if the eligible clinician appears on the Participation List on a snapshot date that we use to determine the APM Entity group and to make QP determinations at the APM Entity group level based on participation in the Advanced APM. For eligible clinicians who appear on a Participation List for more than one APM Entity, but do not to achieve QP status based on any APM Entity-level determinations, we make QP determinations at the individual level as described in § 414.1425(c)(4). Likewise, for eligible clinicians on an Affiliated Practitioner list for an Advanced APM, we make QP determinations at the individual level three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination snapshot dates as described in § 414.1425(b)(2).

(2) Individual QP Determination

Under the current policy at § 414.1425(b), most eligible clinicians participating in Advanced APMs receive their QP determinations at the APM Entity level. In the CY 2017 Quality Payment Program proposed rule (81 FR 28319), we contemplated that ''as with any group assessment, there will be some situations in which individual Threshold Scores would differ from group Threshold Scores if assessed separately. This could lead to some eligible clinicians becoming QPs when they would not have met the QP Threshold individually (a 'free-rider' scenario) or, conversely, some eligible clinicians not becoming QPs within an Advanced APM Entity when they might have qualified individually (a dilution scenario).'' At that time, we believed that the benefits of performing QP determinations for the APM Entity as a group outweighed these potential

scenarios. However, as we previously indicated in a Request for Information in the CY 2023 PFS proposed rule (87 FR 46337 through 46339), we have come to believe that the effects of these types of scenarios, including effects that we had not intended or foreseen in the 2017 rule, have come to outweigh the benefits of performing QP determinations at the APM Entity level.

First, it has been brought to our attention that our policy to conduct most QP determinations at the APM Entity level may have inadvertently discouraged some APM Entities from including certain types of eligible clinicians, particularly in multi-specialty APM entities such as ACOs, leading those clinicians to be excluded from participation in Advanced APMs. Because the APM Entity Threshold Scores (using the payment amount and patient count methods) that are used to make APM Entity-level QP determinations are based on an aggregate calculation across all eligible clinicians participating in the APM Entity group, eligible clinicians in the APM Entity group who furnish proportionally fewer services that lead to attribution of patients or payment amounts to the APM Entity are likely to lower the APM Entity's Threshold Score. Many Advanced APMs attribute patients to APM Entity groups based in part on the provision of primary care services, but not all eligible clinicians typically furnish primary care services. For example, primary care physicians may furnish proportionally more evaluation and management (E/M) (office visit) services, which, as we explain more in the next section, are frequently the basis for attribution of patients and payment amounts to the numerator of the APM Entity's Threshold Score, whereas specialist physicians may furnish proportionally more diagnostic tests and surgical procedures, which are not usually part of the attribution basis to the APM Entity.

We have received reports from Advanced APM participants and specialty societies that some APM Entities have taken steps to exclude from their APM Entity groups (and consequently from their Participation Lists) eligible clinicians who furnish proportionally fewer services that lead to the attribution of patients or payment amounts for purposes of calculating Threshold Scores for APM Entity-level QP determinations. For reasons stated above, this action typically would lead to the exclusion of certain specialists from the APM Entity. There are important reasons that it is not beneficial for an APM Entity to exclude specialists and other eligible clinicians who furnish relatively fewer services that lead to attribution. In both the Medicare Shared Savings Program and in models tested by the Innovation Center that the meet the criteria to be Advanced APMs, CMS seeks to promote patient-centered care that is integrated across the continuum of care. The inclusion of specialists in APM Entities is essential for achieving this goal. For example, a comprehensive network that includes a range of specialists is central to the success of an ACO in the Medicare Shared Savings Program for its intended purpose in patient-centered care that coordinates items and services for Medicare FFS beneficiaries, a key aim of value-based care and practice transformation.[325] The methodology used in beneficiary assignment for the Shared Savings Program is deliberately constructed such that assignment is largely based on primary care, rather than specialty care, which results in specialists contributing proportionately less in terms of payment amounts and patient counts to the numerator of the ACO's Threshold Score calculation used for APM Entity-level QP determinations. Similarly, it was not our intent to create a policy whereby eligible clinicians who are seeing most or all of their Medicare patients through an Advanced APM may remain unable to achieve QP status because the APM Entity with which they participate in the Advanced APM includes eligible clinicians who furnish very few services through the Advanced APM. It has always been one of the goals of the APM track of the Quality Payment Program for the availability of QP status to incentivize eligible clinicians to join Advanced APMs. But under our current policy to make most QP determinations at the APM Entity level, there is the potential that eligible clinicians who are fully engaged in an Advanced APM may still be unable to earn QP status. We carefully considered our policy to make most QP determinations at the APM Entity level, and believed it was the best approach at the time. However, we did not intend for the policy to create potentially conflicting incentives for APM Entities between the goal for their eligible clinicians to achieve QP status under the Quality Payment Program, and their full participation in an Advanced APM with a group of eligible clinicians that can deliver a full spectrum of care.

In the CY 2017 Quality Payment Program proposed rule (81 FR 28319), we stated that ''the statute consistently refers to an eligible clinician throughout section 1833(z) of the Act and clearly identifies that the QP determinations are to be made for an eligible clinician,'' then noted that ''in section 1833(z)(3)(B) of the Act, the definition of an eligible clinician includes a group of such professionals.'' While the statutory scheme provides for the flexibility to establish policies that apply for groups of eligible clinicians, it does not require that approach. When we proposed the policy to calculate Threshold Scores at the APM Entity level, we based this policy in part on ''a premise that positive change occurs when entire organizations commit to participating in an Advanced APM and focusing on its cost and quality goals as a whole.'' While we continue to believe in this premise, we also recognize that, if APM Entities are removing or otherwise not including eligible clinicians who may technically contribute less to the APM Entity-level Threshold Score, such actions may impede other worthy goals of the Advanced APM (such as increased care coordination directly among providers caring for a patient), in which case that larger positive change we were seeking to foster is not being achieved.

Conversely, we are concerned that, under our current policy to make most QP determinations at the APM Entity level, in situations where an APM Entity does attain QP status, some eligible clinicians who furnish relatively fewer of their services through that APM Entity may receive a disproportionate financial benefit because their QP status was achieved as a result of the care furnished by other eligible clinicians in the APM Entity while their APM Incentive Payment is calculated based on all of the covered professional services that the individual eligible clinician furnishes during the base year, including services that were not furnished through an Advanced APM. Our policy to make most QP determinations at the APM Entity level allows these windfall financial rewards because we calculate the Threshold Scores using the aggregate of payment amounts or patient counts for attributed patients based on Medicare Part B covered professional services furnished by all the eligible clinicians in the APM Entity, whether an individual eligible clinician furnished a few or many such services. Once an eligible clinician receives QP status for a year, the APM Incentive Payment is calculated based on paid claims for the individual QP's covered professional services across all their TINs in the base year. This can allow an eligible clinician with minimal Advanced APM participation to receive

[325] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/about.*

a disproportionately large APM Incentive Payment, which we do not believe aligns with the intent of the Quality Payment Program.

As a result, we have reconsidered our current policy to make most QP determinations at the APM Entity level. Instead, we propose to amend § 414.1425(b) so that, beginning with the QP Performance Period for CY 2024, we would make all QP determinations at the individual level. We note that under §§ 414.1425(b)(2) and 414.1425(c)(4) we currently calculate Threshold Scores at the individual level when the Advanced APM includes eligible clinicians only on an Affiliated Practitioner List, and further, under § 414.1425(c)(4) we also calculate QP determinations individually when the eligible clinician participates in multiple Advanced APMs and does not achieve QP status at the APM Entity level. The proposal would not change our policy for these determinations, but would change the way we make QP determinations for all other eligible clinicians. Under the proposal, we would calculate Threshold Scores for QP determinations at the individual level for each unique NPI associated with an eligible clinician participating in an Advanced APM. We would calculate a Threshold Score for each NPI based on all covered professional services furnished across all Tax Identification Numbers (TINs) to which the eligible clinician has reassigned their billing rights. This individual Threshold Score would provide a more specific measurement of each eligible clinician's participation in an Advanced APM. This proposed methodology would ensure that those eligible clinicians who individually meet a QP threshold would receive QP status and its commensurate financial and other benefits. At the same time, it would remove the incentive for APM Entities to exclude certain types of eligible clinicians from their Participation Lists, because the success or failure of the APM Entity's eligible clinicians to reach QP status no longer would be collective. Because each eligible clinician on the APM Entity's Participation List would be evaluated individually at the NPI level, eligible clinicians with lower proportions of payments and payments through the Advanced APM Entity would not affect the QP status of other eligible clinicians on the APM Entity's Participation List.

(3) Payment Amount and Patient Count Methods

In the CY 2017 Quality Payment Program final rule (81 FR 77450 through 77457) we finalized the payment amount method and patient count method for calculation of Threshold Scores used for QP determinations under the Medicare option, and codified these methods at § 414.1435(a) and (b), respectively. The payment amount method is based on payments for Medicare Part B covered professional services, including certain supplemental service payments, while the patient count method is based on numbers of patients. Both methods use the ratio of ''Attributed beneficiaries'' to ''Attribution-eligible beneficiaries, as defined at § 415.1305.[326]

Attributed beneficiaries are those who are attributed to the APM Entity under the terms of the Advanced APM as indicated on the most recent available list of Attributed beneficiaries at the time of a QP determination. Attribution-eligible beneficiaries generally are those who, during the QP Performance Period, meet six criteria specified in the definition of that term at § 414.1305 and described in section IV.A.4.m.(3) of this proposed rule.

When making QP determinations at the APM Entity or individual eligible clinician level, we begin by calculating Threshold Scores using the payment amount and patient count methods. These Threshold Scores are percentages based on the ratio of the payment amounts or patient counts for Attributed beneficiaries to the payment amounts or patient counts for Attribution-eligible beneficiaries during the QP performance period. If the Threshold Score (using either the payment amount or patient count method) for the eligible clinician or APM Entity, as applicable, meets or exceeds the relevant QP threshold described at § 414.1430(a), the relevant eligible clinicians (either the individual eligible clinician or all those on the APM Entity's Participation List) attain QP status for such year.

FIGURE 3: QP Determination Calculation

$$\frac{\text{Attributed beneficiaries}}{\text{Attribution-eligible benefices}}$$

The regulation at § 414.1435(b)(3) provides 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. In the CY 2021 PFS final rule (85 FR 84951 through 84952), we amended § 414.1435(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. This means that beneficiaries who have been attributed to one APM Entity and are thus barred under the terms of an Advanced APM from attribution to another APM Entity are removed from the denominator of the payment amount method and patient count method in QP Threshold Score calculations for the APM Entity to which they cannot be attributed (in other words, we do not penalize an APM Entity in the QP Threshold Score calculation by including a beneficiary in its

[326] For technical information on the QP calculation methodology, see the ''QP Methodology Fact Sheet'' that we publish annually, which can be found as part of the ''2023 Learning Resources for QP Status and APM Incentive Payment'' materials on the Quality Payment Program Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1509/2023%20Learning%20Resources%20for%20QP%20Status%20and%20APM%20Incentive%20Payment.zip*.

denominator when the terms of an Advanced APM do not permit such beneficiary to be attributed to such APM Entity).

(a) Attributed Beneficiary

An Attributed beneficiary is a beneficiary attributed to the APM Entity under the terms of the Advanced APM as indicated on the most recent available list of attributed beneficiaries at the time of a QP determination. There may be beneficiaries on the most recent available list who do not meet the criteria to be Attribution-eligible beneficiaries because the QP performance period does not coincide with the Advanced APM's performance period or attribution period, or for other reasons. There may be cases where a beneficiary's status changes, for example by enrolling in a Medicare Advantage Plan. We exclude these beneficiaries from our Threshold Score calculations because they do not meet criteria to be Attribution-eligible beneficiaries. Although APMs may have reconciliation processes in place to address changes in beneficiary status at various intervals, those processes do not necessarily coincide with the timeframe of QP determinations. Therefore, when calculating Threshold Scores for QP determinations, we exclude from the list of Attributed beneficiaries any beneficiaries who do not meet the criteria to be Attribution-eligible beneficiaries at that point in time.

(b) Attribution-Eligible Beneficiary

An Attribution-eligible beneficiary is a beneficiary who:

- Is not enrolled in Medicare Advantage or a Medicare cost plan;
- Does not have Medicare as a secondary payer;
- Is enrolled in both Medicare Parts A and B;
- Is at least 18 years of age;
- Is a United States resident; and
- Has a minimum of one claim for E/M services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period or, for an Advanced APM that does not base attribution on E/M services and for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to have at least one claim for E/M services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period, the attribution basis determined by CMS based upon the methodology the Advanced APM uses for attribution, which may include a combination of E/M and/or other services.

Our stated intent when we finalized the definition of Attribution-eligible beneficiary (81 FR 77451 through 77452) was to have a definition that would, for the purposes of QP determinations, allow us to be consistent across Advanced APMs in how we consider the population of beneficiaries served by an APM Entity. The criteria we used to define Attribution-eligible beneficiary were aligned with the attribution methodologies and rules for our contemporaneous Advanced APMs. The first five criteria are conditions that are required for a beneficiary to be attributed to any Advanced APM. The sixth criterion identifies beneficiaries who have received certain services from an eligible clinician who is associated with an APM Entity for any period during the QP Performance Period. For Most Advanced APMs, we chose to refer to E/M services because many Advanced APMs use E/M services to attribute beneficiaries to their participant APM Entities. Over time we have updated the list of services that are considered to be E/M services for purposes of identifying Attribution-eligible beneficiaries and have published this list as part of the ''2023 Learning Resources for QP Status and APM Incentive Payment'' materials on the Quality Payment Program Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1509/2023%20Learning%20Resources%20for%20QP%20Status%20and%20APM%20Incentive%20Payment.zip.*

We also included an exception in this sixth criterion to allow an alternative approach for Advanced APMs that do not base attribution exclusively on E/M services, and thus for which Attributed beneficiaries are not a subset of the Attribution-eligible beneficiary population based on the requirement to have at least one claim for E/M service. To date we have implemented this alternative approach for four Advanced APMs:

- Bundled Payments for Care Improvement Advanced Model.
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track).
- Comprehensive ESRD Care Model (LDO arrangement and Non LDO Two Sided Risk Arrangement).
- Maryland Total Cost of Care Model (Care Redesign Program).

We have published links to the methodologies we use to identify Attribution-eligible beneficiaries for these Advanced APMs in the ''2023 Learning Resources for QP Status and APM Incentive Payment'' materials on the Quality Payment Program Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1509/2023%20Learning%20Resources%20for%20QP%20Status%20and%20APM%20Incentive%20Payment.zip.*

We adopted the general rule with flexibility to apply alternative methods for this criterion to ensure that, for the Advanced APMs for which attribution is based on services other than E/M services, the Attributed beneficiary population is truly a subset of such Advanced APMs' attribution-eligible populations and, ultimately, so that our way of identifying beneficiaries for purposes of Threshold Score calculations for QP determinations is appropriate for such Advanced APMs. That said, our thinking at the time that we developed these approaches was shaped by the form and nature of the Advanced APMs that existed at that time. A key lesson we have learned over time as we have implemented the APM track of the Quality Payment Program is that, by affording sufficient flexibility within the program, we can both foster innovation in Advanced APMs and simplify our execution of the program. By having a more narrowly-defined default approach to beneficiary attribution (relying on E/M services), we frequently needed to exercise the flexibility to determine an appropriate attribution methodology for an Advanced APM that falls into the exception, which meant that we identified several individually-tailored ways of performing the attribution methodology for each specific Advanced APM. As such, we have come to believe that application of our current regulations may result in increased complexity over time if, as we anticipate, Advanced APMs continue to evolve and use novel approaches to value-based care that may emphasize a broad range of covered professional services.

Further, as we noted in our discussion of the proposal to calculate QP status at the individual NPI level, primary care practitioners generally furnish a higher proportion of E/M services to beneficiaries than do specialists, and as for the Threshold Score calculations described previously, the emphasis on E/M services in our beneficiary attribution policy may have inadvertently encouraged APM Entities to exclude specialists from their Participation Lists. Under our current policy, if one or more eligible clinicians on the APM Entity's Participation List are furnishing covered professional services to a beneficiary but none of those services are among the E/M

services we use for attribution, that beneficiary would not be Attribution-eligible, and therefore, would not be included in our QP determination calculation at all, even though they actually are receiving covered professional services from an eligible clinician on the APM Entity's Participation List.

We are proposing to change the definition of ''Attribution-eligible beneficiary'' at § 414.1305 so that a single definition using covered professional services will be applied regardless of the Advanced APMs in which the eligible clinician participates. We believe that this complements our proposal to no longer conduct APM Entity group-level QP determinations and switch to making QP determinations at the individual eligible clinician level. We are also concerned that retention of the current policy under which E/M services are the default basis for attribution and special processes are required for Advanced APMs that use a different attribution basis could result in a complex set of unique attribution approaches for Advanced APMs.

In order to create a uniform basis for beneficiary attribution across all Advanced APMs, we are proposing to modify the sixth criterion of the definition of ''attribution-eligible beneficiary'' at § 414.1305 to include any beneficiary who has received a covered professional service furnished by the eligible clinician (NPI) for whom we are making the QP determination. By no longer specifying E/M services as the default attribution basis in the sixth criterion, we also eliminate the need for flexibility to use a different attribution basis that ties attribution-eligibility to a specific Advanced APM's attribution methodology. This would simplify and streamline the attribution methodology by making attribution based on covered professional services across all Advanced APMs.

The proposal to base attribution eligibility on the receipt of a covered professional service also would address the issue discussed earlier in this section whereby, under our current policy, beneficiary attribution for purposes of QP determinations is contingent upon the beneficiary receiving an E/M services, and as a result beneficiaries who are actually being provided covered professional services by eligible clinicians on an APM Entity's Participation List are not Attribution-eligible if none of the services provided are E/M services. Under our proposal, because we would consider all covered professional services for attribution, and not solely E/M services, we would be able to include as Attributed beneficiaries those who are receiving only other (non-E/M) covered professional services through the Advanced APM. We believe this proposal would result in a QP calculation that, by including beneficiaries receiving any covered professional service, more accurately reflects eligible clinicians' actual participation in Advanced APMs.

We note that the proposal would not change the dates of service used for purposes of QP determinations. As such, QP determinations at any given snapshot date (March 31, June 30, and August 31, respectively) would be made by including all covered professional services furnished during the QP Performance Period for January 1 through the applicable snapshot date.

We believe that this change would more appropriately recognize the Advanced APM participation of the eligible clinicians for whom these determinations are being made, particularly when considered in conjunction with the proposal to make QP determinations at the individual eligible clinician level. We further believe that this proposal would simplify and streamline QP determinations, and address the challenges to Advanced APM participation reportedly faced by specialists who are less likely than primary care practitioners to provide E/M services.

We seek comment on this proposal to modify the sixth criterion in the definition of ''Attribution-eligible beneficiary'' at § 414.1305 to include a beneficiary who has a minimum of one claim for a covered professional service furnished by an eligible clinician who is on the Participation List for the APM Entity at any determination date during the QP Performance Period.

(4) QP Thresholds and Partial QP Thresholds

Section 1833(z)(2) of the Act specifies the thresholds for the level of participation in Advanced APMs required for an eligible clinician to become a QP for a year. The Medicare Option, based on Part B payments for covered professional services or counts of patients furnished covered professional services under Part B, has been applicable since payment year 2019 (performance year 2017). The All-Payer Combination Option, through which QP status is calculated using the Medicare Option as well as an eligible clinician's participation in Other Payer Advanced APMs, has been applicable since payment year 2021 (performance year 2019). In the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77439), we finalized our policy for QP and Partial QP Thresholds for the Medicare Option as codified at § 414.1430(a) and for the All-Payer Combination Option at § 414.1430(b).

Section 4111(a)(2) of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328, December 29, 2022) amended section 1833(z)(2) of the Act by extending for payment years 2024 and 2025 (performance years 2022 and 2023) the applicable payment amount and patient count thresholds for an eligible clinician to achieve QP status. Specifically, section 4111(a)(2) of the CAA, 2023, amended section 1833(z)(2) of the Act to continue the QP payment amount thresholds that applied in payment year 2024 (performance year 2022) to payment year 2025 (performance year 2023). Additionally, section 4111(a)(2) of the CAA, 2023, amended section 1833(z)(2) of the Act to require that, for payment year 2025, the Secretary use the same percentage criteria for the QP patient count threshold that applied in payment year 2022. As such, the Medicare Option QP thresholds for payment year 2025 will remain at 50 percent for the payment amount method and 35 percent for the patient count method. The CAA, 2023, also amended section 1848(q)(1)(C)(iii) of the Act to extend through payment year 2025 the Partial QP thresholds that were established since payment year 2021 under the Medicare Option. Therefore, the Partial QP thresholds for payment year 2025 (performance year 2023) will remain at 40 percent for the payment amount method and 25 percent for the patient count method.

Under the All-Payer Combination Option, the QP thresholds for payment year 2025 (performance year 2023) will be 50 percent for the payment amount method and 35 percent for the patient count method. The Partial QP thresholds for payment year 2025 will be 40 percent for the payment amount method and 25 percent for the patient count method. In order to become a QP through the All-Payer Combination Option, eligible clinicians must first meet certain minimum threshold percentages under the Medicare Option. For payment year 2025 (performance year 2023), the minimum Medicare Option threshold an eligible clinician must meet for the All-Payer Combination Option to become a QP is 25 percent for the payment amount method or 20 percent under the patient count method. For Partial QP status, the minimum Medicare Option threshold an eligible clinician must meet for the All-Payer Combination Option is 20 percent

for the payment amount method or 10 percent under the patient count method.

To conform our regulation with the amendments made by the CAA, 2023, we propose to amend § 414.1430 by revising paragraphs (a) and (b) to reflect the statutory QP and Partial QP threshold percentages for both the payment amount and patient count under the Medicare Option and the All-Payer Option with respect to payment year 2025 (performance year 2023) in accordance with the CAA, 2023 amendments.

The proposed revisions to § 414.1430(a) and (b) for the Medicare Option and All-Payer Combination Option QP and Partial QP thresholds are as follows:

- Paragraph (a)(1)(iv) to state that for 2025 the amount is 50 percent, and paragraph (a)(1)(v) to state that for 2026 and later, the amount is 75 percent.
- Paragraph (a)(2)(iv) to state that for 2025 the amount is 40 percent, and paragraph (a)(2)(v) to state that for 2026 and later, the amount is 50 percent.
- Paragraph (a)(3)(iv) to state that for 2025 the amount is 35 percent, and paragraph (a)(3)(v) to state that for 2026 and later, the amount is 50 percent.
- Paragraph (a)(4)(iv) to state that for 2025 the amount is 25 percent, and paragraph (a)(4)(v) to state that for 2026 and later, the amount is 35 percent.
- Paragraph (b)(1)(i)(A) to state that for 2021 through 2025 the amount is 50 percent, and paragraph (b)(1)(i)(B) to state that for 2026 and later, the amount is 75 percent.
- Paragraph (b)(2)(i)(A) to state that for 2021 through 2025 the amount is 40 percent and paragraph (b)(2)(i)(B) to state that for 2026 and later, the amount is 50 percent.
- Paragraph (b)(3)(i)(A) to state that for 2021 through 2025 the amount is 35 percent, and paragraph (b)(3)(i)(B) to state that for 2026 and later, the amount is 50 percent.
- Paragraph (b)(4)(i)(A) to state that for 2021 through 2025 the amount is 25 percent, and paragraph (b)(4)(i)(B) to state that for 2026 and later, the amount is 35 percent.

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TABLE 53: QP Threshold Score Updates

Medicare Option - Payment Amount Method				
Performance year / Payment Year	2021/2023 (Percent)	2022/2024 (Percent)	2023/2025 (Percent)	2024/2026 and later (Percent)
QP Payment Amount Threshold	50	50	50	75
Partial QP Payment Amount Threshold	40	40	40	50

Medicare Option - Patient Count Method				
Performance year / Payment Year	2021/2023 (Percent)	2022/2024 (Percent)	2023/2025 (Percent)	2024/2026 and later (Percent)
QP Patient Count Threshold	35	35	35	50
Partial QP Patient Count Threshold	25	25	25	35

All-Payer Combination Option - Payment Amount Method								
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 and later (Percent)	
QP Patient Count Threshold	50	25	50	25	50	25	75	25
Partial QP Patient Count Threshold	40	20	40	20	40	20	50	20
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum

All-Payer Combination Option - Patient Count Method								
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 and later (Percent)	
QP Patient Count Threshold	35	20	35	20	35	20	50	20
Partial QP Patient Count Threshold	25	10	25	10	25	10	35	10
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum

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(5) APM Incentive Payment

Prior to amendments made by the CAA, 2023, section 1833(z)(1) of the Act provided for APM Incentive Payments for eligible clinicians who are QPs with respect to a year in each payment year from 2019 through 2024. Specifically, for each of the specified payment years, in addition to the amount of payment that would otherwise be made for covered professional services furnished by an eligible clinician who is a QP for such year, there is an additional lump sum APM Incentive Payment equal to 5 percent of the eligible clinician's estimated aggregate payment amounts for such covered professional services for the preceding year (which we defined as the ''base year''). Covered professional services is defined at § 414.1305, with reference to the statutory definition at section 1848(k)(3) of the Act, as services for which payment is made under, or based on, the PFS and which are furnished by an eligible clinician (physician; practitioner as defined in section 1842(b)(18)(C) of the Act; PT, OT, or speech-language pathologist; or qualified audiologist as defined under section 1861(ll)(4)(B) of the Act).

In the CY 2017 Quality Payment Program final rule (81 FR 77445), we established a policy that, beginning with the 2017 QP Performance Period, the QP Performance Period would be the calendar year that is 2 calendar years before the payment year for the APM Incentive Payment. Thus, we established that the first QP Performance Period would begin on January 1, 2017, the first ''base year'' (established at 81 FR 77481 and 77482) for which we would use claims for professional services to calculate the 5 percent APM Incentive Payment amount would be in 2018, and the first payment year for the APM Incentive Payment would be in 2019 as required by the statute. Under our previously finalized policies, the QP Performance Period, base year, and payment year continue in this fashion on a rolling basis through payment year 2024, which was the final year for which the statute authorized an APM Incentive Payment. In the CY 2023 PFS final rule (87 FR 70114 through 70116), we explained that, beginning in payment year 2025, which correlates with performance year 2023, the statute did not provide for any type of payment incentive for eligible clinicians who become QPs.

Section 4111(a) of the CAA, 2023 amended section 1833(z)(1) of the Act to provide that eligible clinicians who are QPs with respect to payment year 2025 (performance year 2023) will receive an APM Incentive Payment equal to 3.5 percent of their estimated aggregate payment amounts for Medicare Part B covered professional services in the preceding year. In effect, this statutory change extends the APM Incentive Payment for one additional year, at a new percentage of 3.5 percent rather than 5 percent.

Accordingly, we propose to incorporate the change made by the CAA, 2023, by amending the regulation text at § 414.1450 to add the payment year 2025 APM Incentive Payment amount of 3.5 percent of covered professional services payments. We propose to amend paragraph (b)(1) to state that the amount of the APM Incentive Payment for payment years 2019 through 2024 is equal to 5 percent and, for payment year 2025, 3.5 percent, of the estimated aggregate payments for covered professional services furnished during the calendar year immediately preceding the payment year.

We also note that the CAA, 2023, did not extend the APM Incentive Payment beyond payment year 2025. Beginning for the 2026 payment year, which relates to the 2024 QP Performance Period, section 1848(d)(1)(A) of the Act specifies that there shall be two separate PFS conversion factors, one for items and services furnished by a QP, and the other for other items and services (the nonqualifying APM conversion factor). Each conversion factor will be equal to the conversion factor for the previous year multiplied by the applicable update specified in section 1848(d)(20) of the Act. The update specified for the conversion factor for QPs will be 0.75 percent, while the update for all others will be 0.25 percent.

(6) Targeted Review of QP Determinations

In the CY 2021 PFS final rule (85 FR 84952), we finalized a policy to provide an opportunity for eligible clinicians to bring to our attention potential clerical errors we have may made that could have resulted in the omission of an eligible clinician from a Participation List used for purposes of QP determinations, and for us to review and make corrections if warranted. We also finalized 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 as provided under § 414.1455(a) of our regulations, there is no right to 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, or of the determination of the amount of the APM Incentive Payment under § 414.1450.

In the CY 2021 PFS final rule (85 FR 84953), we finalized our proposal to align the timing and procedures for 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.

In light of the transition in incentives for eligible clinicians who are QPs for a year, as provided in statute, from an APM Incentive Payment to the differentially higher PFS conversion factor beginning with the 2024 QP performance period and 2026 payment year, we are proposing at section IV.A.4.j. of this proposed rule to adjust the Targeted Review period in order to meet operational timelines to ensure that we can meet statutory requirements for the application of the differential conversion factors, and the resulting differential PFS payment rates, to eligible clinicians who are, and are not, QPs for the year. As discussed in section IV.A.4.j. of this proposed rule, we believe that adjusting the Targeted Review period will enable us to meet our statutory obligation to apply the differentially higher QP conversion factor beginning on January 1 of each payment year beginning with CY 2026. We encourage readers to review section IV.A.4.j. of this proposed rule.

n. Advanced APMs

(1) General Overview

In this section, we address policies regarding several aspects of the Advanced APM criterion for CEHRT use at § 414.1415(a). We are proposing to amend the definition of CEHRT at § 414.1305 that would apply to Advanced APM participants, and modify the Advanced APM CEHRT use criterion at § 414.1415(a) to recognize the CEHRT that is relevant to the clinical practice of participants in the Advanced APM.

We believe the Quality Payment Program must be responsive to, and supportive of, innovation in technology and in provider organization. It is our goal to encourage not only provider ownership of this technology, but full adoption and integration of the most advanced health information technology (health IT) into clinical practice. We developed these proposals to modify the CEHRT that is required for Advanced APMs with this goal in mind, and we will continue to monitor advancements

and opportunities in the health IT space to better prepare and align our program and APMs with the most cutting-edge technologies and innovative provider arrangements, for the benefit of eligible clinicians participating in APMs, and the Medicare beneficiaries we serve.

(2) Background

(a) Advanced APM CEHRT Use Criterion

Under section 1833(z)(3)(D)(i)(I) of the Act, Advanced APMs are those APMs that require participants to use CEHRT. We codified this CEHRT use criterion for Advanced APMs at § 414.1415(a)(1). As such, the CEHRT use criterion under § 414.1415(a)(1) states that, to be an Advanced APM, the APM must require at least a certain percentage of eligible clinicians in each APM Entity participating in the APM, or, for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or health care providers. In the CY 2017 Quality Payment Program final rule, we specified at § 414.1415(a)(1)(i) that an Advanced APM is one that requires at least 50 percent of eligible clinicians in each APM Entity to use CEHRT to document and communicate clinical care to their patients or health providers (81 FR 77410). In the CY 2019 PFS final rule (83 FR 59918), we amended § 414.1415(a)(1) to increase the required percentage from 50 percent to 75 percent.

(b) Definition of CEHRT

Section 1848(o)(4) of the Act defines CEHRT as a qualified electronic health record (as defined in section 3000(13) of the Public Health Service Act, or PHSA) that is certified by the Office of the National Coordinator for Health Information Technology (ONC) pursuant to section 3001(c)(5) of the PHSA in accordance with the certification standards that ONC adopted under section 3004 of the PHSA.

In implementing the definition of CEHRT at § 414.1305 for the MIPS track of the Quality Payment Program, we adopted the definition of CEHRT used for the Medicare EHR Incentive Program (also known as ''Meaningful Use'') at § 495.4 (81 FR 77211 through 77213). In the CY 2017 Quality Payment Program final rule, we explained that we intended ''to maintain continuity for MIPS eligible clinicians and health IT vendors who may already have CEHRT or who have begun planning for a transition to technology certified to the 2015 Edition based on the definition of CEHRT finalized for the EHR Incentive Programs in the 2015 EHR Incentive Programs final rule'' and ''to maintain consistency with the EHR Incentive Programs CEHRT definition at 42 CFR 495.4'' (81 FR 77212).

For the Advanced APM track of the Quality Payment Program, we in turn adopted the definition of CEHRT for MIPS under § 414.1305 (81 FR 77409 through 77410). We explained that applying the same definition of CEHRT for purposes of both the MIPS and Advanced APM tracks of the Quality Payment Program would reduce administrative costs and confusion among clinicians and maintain consistency across programs, permitting clinicians to use shared CEHRT systems to participate in either MIPS or Advanced APMs (81 FR 77409 through 77410).

Consequently, the MIPS and Advanced APM tracks of the Quality Payment Program share the same definition of CEHRT at § 414.1305. Since the CY 2019 performance period, this has generally meant 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 that has been certified to certain other 2015 Edition health IT certification criteria as specified in the definition of CEHRT at § 414.1305. The currently applicable definition of CEHRT at § 414.1305 specifically requires that the EHR technology has been certified to the following 2015 Edition health IT certification criteria: (1) family health history at 45 CFR 170.315(a)(12); (2) patient health information capture at 45 CFR 170.315(e)(3); and (3) as necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category, including applicable measure calculation certification criteria at 45 CFR 170.315(g)(1) or (2) and clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3)(i) and (ii) (and optionally (c)(4)) and can be electronically accepted by CMS.

Because our definition of CEHRT at § 414.1305 ultimately derives from the definition of CEHRT used for the Meaningful Use Program, our Advanced APMs have required their participants to use CEHRT that is capable of meeting all requirements of a qualified EHR. As such, Advanced APMs generally require participants to use CEHRT that meets requirements for 2015 Edition Base EHR (as defined at 45 CFR 170.102); all requirements of Meaningful Use set forth in section 1848(o)(2) of the Act; and all requirements for reporting on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category. When we adopted the same definition of CEHRT at § 414.1305 for purposes of MIPS and Advanced APMs in the CY 2017 Quality Payment Program final rule, we acknowledged that such a policy may include some requirements not directly applicable to the APM Entities' practice. Specifically, we stated at that time that ''we understand this proposed CEHRT definition may include some EHR functionality used by MIPS eligible clinicians which may be less relevant for an APM participant and likewise APM participants may use additional functions that are not required for MIPS participation'' (81 FR 77409). At the time, we reasoned that ''using the same CEHRT definition for both MIPS and Advanced APMs would allow eligible clinicians to continue to use shared EHR systems and give eligible clinicians flexibility of participation as a MIPS eligible clinician or an eligible clinician in an Advanced APM without needing to change or upgrade EHR systems'' (81 FR 77409).

Although we acknowledged that this CEHRT definition may impose more rigorous requirements on APM participants than necessary, we nonetheless maintained that ''we generally want APMs to retain the flexibility to require activities performed using CEHRT that may vary from those prescribed under the advancing care information performance category in MIPS'' (81 FR 77412).[327] We also recognized that aligning the CEHRT definition for Advanced APMs with MIPS ''would go beyond what the statute requires'' (81 FR 77412). When we adopted the CEHRT definition for MIPS and Advanced APMs, one commenter suggested that our proposed CEHRT criterion for Advanced APMs was narrow, and that ''a strong, broad health IT infrastructure should be a key element used to identify Advanced APMs rather than the narrow proposed CEHRT criteria'' (81 FR 77410). We

[327] Section 1848(q)(2)(A)(iv) and (B)(iv) of the Act requires that the Secretary assess MIPS eligible clinicians' performance with respect to the ''meaningful use of certified EHR technology'' in accordance with the requirements set forth at section 1848(o)(2) of the Act as one of the four performance categories for MIPS. In the CY 2017 Quality Payment Program final rule, we named this required MIPS performance category the ''advancing care information performance category.'' (81 FR 77010). We have since renamed this MIPS performance category, requiring the meaningful use of CEHRT, as the ''Promoting Interoperability performance category.'' (85 FR 84820 through 84821).

agreed that ''Advanced APMs need a strong health IT infrastructure as a foundation for communicating and delivering comprehensive and coordinated care to their patients,'' but at that time we wanted to prioritize continuity between the two tracks of the Quality Payment Program to maximize flexibility for eligible clinicians. However, we indicated that we would be prepared to update this definition as needed in the future.

(3) Proposal To Update CEHRT Definition and CEHRT Use Criterion for Advanced APMs

After several years of experience with the uniform definition of CEHRT for purposes of MIPS and Advanced APMs, and based on input we have received from interested parties, we now believe that the standard for CEHRT use for Advanced APMs may have been unnecessarily burdensome, imposing unwarranted barriers to organization of and participation in Advanced APMs, and not clinically relevant for many prospective and current participants in Advanced APMs. As previously discussed, our policy at § 414.1415(a)(1)(i) currently requires that at least 75 percent of eligible clinicians in each participating APM entity group, and each hospital that are APM Entities, to use CEHRT, as defined in § 414.1305, to document and communicate clinical care to their patients or health care providers. By referring in the Advanced APM CEHRT use criterion to CEHRT, as defined in § 414.1305, Advanced APMs required participants to adopt and implement health IT that is capable of meeting all requirements of a qualified EHR, which means CEHRT that meets all requirements for 2015 Edition Base EHR (as defined at 45 CFR 170.102); all requirements of Meaningful Use set forth in section 1848(o)(2) of the Act; and all requirements for reporting on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category. We have heard from many interested parties that our requirements for use of CEHRT are falling short of some of our intended goals. Specifically, we have heard from many interested parties that our current requirements for use of CEHRT have led Advanced APMs to apply an inflexible standard that does not allow them to take into account whether certain CEHRT modules are relevant for, and applicable to, the specific clinical practice areas of their intended or actual participants. By placing a broad set of requirements for use of CEHRT, particularly regarding the criteria the health IT must be certified as meeting to satisfy our definition of CEHRT at § 414.1305, interested parties report that we are needlessly burdening some potential and actual APM participants because they must adopt health IT modules that are not always clinically relevant across provider types that would participate in an Advanced APM. Specifically, interested parties noted that our requirement that Advanced APMs must require participants to use health IT certified as meeting criteria necessary to report on objectives and measures of the MIPS Promoting Interoperability performance category, even when such health IT is not clinically relevant for or applicable to APM participants' practice, is needlessly burdensome and a barrier to innovation and participation in APMs. To support their position, interested parties noted as an example, that application of our current Advanced APM CHERT use criterion and associated CEHRT definition has required specialists in the Kidney Care Choices (KCC) Model or providers in the ACO Realizing Equity, Access, and Community Health (REACH) Model to purchase certified Health IT Modules beyond those required as part of the 2015 Edition Base EHR definition at 45 CFR 170.102 that are not immediately necessary or applicable to their clinical practice.

We have learned that Advanced APMs have not had the flexibility to require certified health IT that is tailored to their specific participants' practice areas. Likewise, we could envision a scenario where, to achieve Advanced APM status under our current policy, an APM or APM Entity would exclude from participation specialists or other eligible clinician types, such as pathologists, for whom compliance with our current CEHRT requirements beyond the Base EHR definition would be burdensome and beyond the scope of their typical practice, even though participation of such eligible clinicians would be relevant and beneficial to the goals of the APM.

For Advanced APMs, we believe that it is important both to apply a rigorous standard for use of CEHRT and to allow sufficient flexibility to Advanced APMs to specify CEHRT modules that are clinically relevant for their participants. We believe that our current CEHRT use requirements meet the former goal (application of a rigorous standard), but not the latter (allowing sufficient flexibility).

Further, our current CEHRT use criterion specifies that 75 percent of participants in the APM must use CEHRT as defined in § 414.1305, and allows for 25 percent of participants to not have or use CEHRT. This policy establishes a minimum percentage of Advanced APM participants must use CEHRT, but without consideration of which eligible clinicians in each participating APM Entity (or hospital) must use CEHRT, or whether it is clinically appropriate for any of those eligible clinicians to not use CEHRT. As such, this policy could allow eligible clinicians who could and should be using CEHRT to forego CEHRT use solely because enough of their colleagues are using CEHRT to meet the requirement of the Advanced APM. Additionally, we have heard from interested parties that, for most Advanced APM participants, CEHRT use among eligible clinicians is close to 100 percent. Given this information and the fact that the 70 percent CEHRT use standard has been in effect for almost five years, we believe it would be appropriate to re-evaluate our approach to the application of the CEHRT use requirement to Advanced APMs and their participants. We want to maintain the rigor of our CEHRT use criterion for Advanced APMs while providing Advanced APMs flexibility to require CEHRT use that is applicable for the practice areas of their participants and their eligible clinicians. Further, we believe any exceptions to CEHRT use that are permitted under the Advanced APM should be based on clinical appropriateness, rather than on generalized application of percentages.

First, we are proposing to amend the definition of CEHRT at § 414.1305 by adding a new paragraph (3) to specify that, for purposes of the Advanced APM criterion under § 414.1415(a)(1), beginning with CY 2024, CEHRT means EHR technology certified under the ONC Health IT Certification Program that meets: (1) the 2015 Edition Base EHR definition, or any subsequent Base EHR definition (as defined in at 45 CFR 170.102); and (2) any such ONC health IT certification criteria adopted or updated in 45 CFR 170.315 that are determined applicable for the APM, for the year, considering factors such as clinical practice areas involved, promotion of interoperability, relevance to reporting on applicable quality measures, clinical care delivery objectives of the APM, or any other factor relevant to documenting and communicating clinical care to patients or their health care providers in the APM.

We believe our proposal to update the definition of CEHRT for Advanced APMs at § 414.1305 would provide flexibility to each APM to determine what CEHRT functionalities are relevant to the model and its participant APM

Entities and eligible clinicians. We believe that providing Advanced APMs with the greater flexibility permitted by the statute with respect to requiring CEHRT use will foster innovation in model design and diversity in APM participation. Specifically, we believe our proposed amendment to the CEHRT definition at § 414.1305 will facilitate innovation in APM design, and enable a broad range of participants and their eligible clinicians to meet Advanced APM CEHRT use requirements by adopting health IT that satisfies the 2015 Edition Base EHR definition at 45 CFR 170.102 and is certified as meeting other ONC health IT certification criteria adopted, or updated in 45 CFR 170.315, as is clinically relevant to their practice, without unnecessarily obtaining other health IT, such as the health IT necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category.

We note that participation in an Advanced APM does not automatically exclude eligible clinicians from MIPS. Eligible clinicians in an Advanced APM who do not achieve Qualifying APM Participant (QP) status or Partial QP status, or who are not otherwise exempt from MIPS, are subject to MIPS reporting requirements and the MIPS payment adjustment. Our proposed amendment to the CEHRT definition under paragraph (3) at § 414.1305 for Advanced APMs has limited effect upon the requirement to participate in MIPS if QP or Partial QP status is not achieved. Accordingly, under our proposal, eligible clinicians in Advanced APMs would still need to be prepared to report to MIPS, including using CEHRT as necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category, in the event that they do not achieve QP or Partial QP status.

In section IV.A.4.f.(4) of this proposed rule, we are also proposing other modifications to the CEHRT definition at § 414.1305 to be more flexible in reflecting any changes ONC may make to its Base EHR definition, certification criteria, and other standards for health IT at 45 CFR part 170. Our proposed amendment to the CEHRT definition under paragraph (3) at § 414.1305 for Advanced APMs is consistent with our other proposed amendments as set forth in section IV.A.4.f.(4) of this proposed rule.

Second, we are proposing to amend our current Advanced APM CEHRT use criterion at § 414.1415(a)(1). Specifically, we propose to amend the regulation to end the current 75 percent CEHRT use requirement at § 414.1415(a)(1)(i) with the CY 2023 QP performance period. Then we propose to add a new paragraph at § 414.1415(a)(1)(iii) to specify that, to be an Advanced APM, the APM must require all eligible clinicians in each participating APM Entity, or for APMs in which hospitals are the participants, each hospital, to use CEHRT that meets our proposed new paragraph (3) of the CEHRT definition at § 414.1305. In essence, we are proposing to no longer specify a minimum number of eligible clinicians that an Advanced APM must require to use CEHRT, and instead, simply specify that the Advanced APM must require all participating eligible clinicians to use CEHRT that meets our proposed modified, and more flexible, definition. We are also proposing to revise § 414.1415 by making non-substantive technical edits to paragraphs (a)(1)(i) and (a)(1)(ii) to improve clarity.

This proposal is consistent with section 1833(z)(3)(D)(i)(I) of the Act, which generally requires that Advanced APMs require their participants to use CEHRT as defined in section 1848(o)(4) of the Act. We believe this proposed amendment to the Advanced APM CEHRT use criterion will further enhance innovation in Advanced APM development and diversity in participation, allowing for novel APM Entity compositions, because Advanced APM participants will no longer have to concern themselves with what percentage of eligible clinicians meet our current CEHRT requirements. We further believe that, under our more flexible proposed CEHRT definition and Advanced APM CEHRT use criterion, Advanced APMs could create their own CEHRT use requirements, potentially beyond what we currently require, tailored to the various types of clinicians and practice areas the Advanced APM intends to include in its model. We believe our proposal would permit Advanced APMs to recruit and retain participants that represent a variety of practice types, and to require different types of EHR technologies certified under the ONC Health IT Certification Program as meeting the 2015 Edition Base EHR definition, or subsequent Base EHR definition, at 45 CFR 170.102 and additional ONC health IT certification criteria adopted and updated in 45 CFR 170.315 as specifically applicable to different types of clinical practice.

We seek comment on this proposal.

(4) All Payer Advanced APMs

In the CY 2017 Quality Payment Program final rule (81 FR 77459), we proposed policies, effective beginning for performance year 2021, that would allow eligible clinicians to earn QP status through participation in a combination of payment arrangements designed and implemented by Other Payers and Medicare Advanced APMs. The statute includes a CEHRT use criterion for Other Payer Advanced APMs as it does for Medicare Advanced APMs, and we finalized the same CEHRT use criterion for Other Payer Advanced APMs as for Medicare Advanced APMs (81 FR 77463). Likewise, in this rule, we are proposing to amend the Other Payer Advanced APM criteria at § 414.1420(b) to conform to the changes we now propose for the Medicare Advanced APMs, and to be reflected in amendments to § 414.1415(a)(1)(i), to remove the 75 percent minimum CEHRT use requirement for Advanced APMs and replace it with a more flexible CEHRT use requirement based on our proposed revised definition of CEHRT for purposes of Advanced APM determinations. We are also proposing to revise § 414.1420(b) by making additional non-substantive technical edits to improve clarity.

The changes we are proposing for Medicare Advanced APMs are designed to require use of technologically sufficient EHRs, while affording Advanced APMs the ability to tailor additional CEHRT use requirements to those features or capabilities that are clinically relevant to the APM and its participants. We believe that this same flexibility should be afforded in the context of Other Payer Advanced APMs. The All Payer Combination Option through which we consider the participation of eligible clinicians in Other Payer Advanced APMs offers an additional pathway to achieve QP status for eligible clinicians participating in both Medicare Advanced APMs and Other Payer Advanced APMs. Under the All Payer Combination Option, we consider the combined participation of eligible clinicians in Medicare and Other Payer Advanced APMs. Similar to the statutory CEHRT use requirement for Advanced APMs under section 1833(z)(3)(D)(i)(I) of the Act, section 1833(z)(2)(iii)(II)(bb) of the Act specifies that Other Payer Advanced APMs are those under which CEHRT is used. Since the All Payer Combination Option for QP determinations involves the same eligible clinician participants as the Medicare Option, and considers participation in both Medicare Advanced APMs and Other Payer Advanced APMs, we believe we should continue to apply the same CEHRT use

standard for both Medicare and Other Payer Advanced APMs. Further, we believe the same need exists for flexibility in the CEHRT that is required to be used in Other Payer Advanced APMs. This would allow Other Payer Advanced APMs to structure their CEHRT use requirements to be clinically relevant to the APM and participating eligible clinicians, and avoid the need to obtain clinically unnecessary technology simply for purposes of meeting what we now believe to be an overly restrictive CEHRT use criterion.

We seek comment on this proposal.

V. 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 the PRA'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 are soliciting public comment (see section VI. of this proposed rule) on each of these issues for the following sections of this document that contain information collection requirements. Comments, if received, will be responded to within the subsequent final rule.

A. Wage Estimates

Private Sector: To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2022 National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/2022/oes_nat.htm*). In this regard, Table 54 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage. There are many sources of variance in the average cost estimates, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Therefore, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 54: National Occupational Employment and Wage Estimates (Excluding Physicians)

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and other indirect costs ($/hr	Adjusted hourly wage ($/hr)
Billing and Posting Clerks	43-3021	21.54	21.54	43.08
Business Operations Specialists	13-1000	40.04	40.04	80.08
Computer System Analysts	15-1211	51.70	51.70	103.40
Financial Specialists	13-2000	44.37	44.37	88.74
General and Operations Manager	11-1021	59.07	59.07	118.14
Licensed Practical and Licensed Vocational Nurses	29-2061	26.86	26.86	53.72
Medical and Health Services Managers	11-9111	61.53	61.53	123.06
Secretaries and Administrative Assistants	43-6014	20.87	20.87	41.74

For our purposes, BLS' May 2022 National Occupational Employment and Wage Estimates does not provide an occupation that we could use for ''Physician'' wage data. To estimate a Physician's costs, we are using an average conglomerate wage of $274.44/hr as demonstrated below in Table 55.

TABLE 55: National Occupational Employment and Wage Estimates (Physicians)

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Anesthesiologists	29-1211	145.66	145.66	291.32
Family Medicine Physicians	29-1215	107.91	107.91	215.82
General Internal Medicine Physicians	29-1216	108.30	108.30	216.60
Obstetricians and Gynecologists	29-1218	133.33	133.33	266.66
Orthopedic Surgeons, Except Pediatric	29-1242	178.56	178.56	357.12
Pediatric Surgeons	29-1243	174.51	174.51	349.02
Pediatricians, General	29-1221	97.71	97.71	195.42
Physicians, All Other	29-1229	114.76	114.76	229.52
Psychiatrists	29-1223	118.92	118.92	237.84
Surgeons	29-1240	162.49	162.49	324.98
Surgeons, All Other	29-1249	167.25	167.25	344.50
Total				3,018.80
Average Physician Wage (3,018.80/11)				274.44

Beneficiaries: We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $21.98/hr.

The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices [328] identifies the approach for valuing time when individuals undertake activities on their own time. To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of $1,059 [329] for 2022, divided by 40 hours to calculate an hourly pre-tax wage rate of $26.48/hr. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent or $4.50/hr ($26.48/hr x 0.17), resulting in the post-tax hourly wage rate of $21.98/hr ($26.48/hr—$4.50/hr). Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

[328] *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//176806/VOT.pdf.*

[329] *https://fred.stlouisfed.org/series/LEU0252881500A.*

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts (§ 414.940)

The following proposed changes will be submitted to OMB for review under control number 0938–1435 (CMS–10835).

As discussed in section III.A. of this proposed rule, as a part of implementing section 1847A(h) of the Act, as added by section 90004 of the Infrastructure Act, the Secretary is authorized to recognize, through notice and comment rulemaking, drugs with unique circumstances that justify an increase of the applicable percentage greater than 10 percent. In section III.A.3.d of this proposed rule, we are proposing modifications to § 414.940 to establish an application process for drug manufacturers to request an increased applicable percentage for an individual drug product based on its unique circumstances.

We are proposing that, to request we consider increasing the applicable percentage for a particular refundable drug, a manufacturer must submit the following: (1) a written request that a drug be considered for an increased applicable percentage based on its unique circumstances; (2) FDA-approved labeling; (3) justification for the consideration of an increased applicable percentage based on such unique circumstances; and (4) justification for the requested increase in the applicable percentage. Such justification could include documents, such as (but not limited to) a minimum vial fill volume study or a dose preparation study.

As discussed in section VII.E.4. of this proposed rule, our estimates show a projected 28 billing and payment codes meeting the definition of refundable single-dose container or single-use package drug with 10 percent or more discarded units, which is the applicable percentage specified in section 1847A(h)(3) of the Act. Therefore, we anticipate a similar number of drugs could owe a refund under section 90004 of the Infrastructure Act. Since 25 of those billing codes have an estimated annual refund obligation of over $50,000, we expect that, initially (that is, the first year the proposed application process is available), the manufacturers of those 25 drugs to submit an application for consideration of an increased applicable percentage based on unique circumstances.

Once a manufacturer has applied for a drug and a decision has been made regarding whether an increased applicable percentage is appropriate, the manufacturer would not need to apply again. Therefore, subsequent years we would expect a smaller number of applications. When evaluating the

approval dates of these 25 drugs, we find that there is a range of 0 to 4 drugs per year approved that would be expected to owe a refund of more than $50,000 per year. From 2010 through 2020, the mean number of such approvals is 1.45 per year. If rounded up, we estimate that we would typically receive 2 applications per subsequent to the initial application year.

We estimate that the burden per respondent/applicant of drafting and submitting the unique circumstance application to be 5 hours. As we anticipate 25 applications in the initial year that applications are available, we estimate a total burden of 125 hours (25 applications × 5 hr) per at a cost of $5,218 ($41.74/hr × 125 hr). For subsequent years, we estimate a total annual burden related to drafting and submission of 10 hours (2 applications × 5 hr per respondent/applicant) at an annual cost of $418 (41.74/hr × 10 hr).

2. ICRs Regarding the Clinical Laboratory Fee Schedule: Data Reporting by Laboratories

As described in section III.D of this proposed rule, under the Clinical Laboratory Fee Schedule, ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' collected during a ''data collection period'' for their component ''applicable laboratories,'' and we proposed to revise the regulations at § 414.504(a)(1) to account for a delay in reporting until January 1, 2024 through March 31, 2024. As stated in section 1834A(h)(2) of the Act, chapter 35 of title 44 U.S.C., which includes such provisions as the PRA does not apply to information collected under section 1834A of the Act. Consequently, we are not setting out any proposed burden estimates under this section of the proposed rule. Please refer to section VII.E.7. of this proposed rule for a discussion of the impacts associated with the changes described in section III.D. of this proposed rule.

3. ICRs Regarding the Medicare Shared Savings Program

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 proposed Shared Savings Program burden estimates under this section of the preamble. Please refer to section VII.E.10. of this proposed rule for a discussion of the impacts associated with the changes to the Shared Savings Program as described in section III.G. of this proposed rule.

4. ICRs Regarding the Updates to the Medicare Diabetes Prevention Program

In section III.L. of this proposed rule, we propose to extend specific Medicare Diabetes Prevention Program (MDPP) flexibilities allowed during the PHE for COVID–19 1135 waiver event by 4 years. In addition, we are proposing to update the MDPP payment structure to pay for beneficiary attendance on a fee-for-service basis while retaining the diabetes risk reduction performance payments. Finally, we are proposing to remove the requirement for MDPP interim preliminary recognition and replace it with CDC preliminary recognition as well as remove most references to, and requirements of, the Ongoing Maintenance Sessions given that eligibility for these services will end on December 31, 2023. We expect the proposed policies will increase the number of eligible organizations willing to enroll as MDPP suppliers. We also anticipate that the extended PHE flexibilities will make MDPP more marketable to both suppliers and beneficiaries due to the continued flexibility in how the MDPP set of services are delivered live, either in-person or virtually (or a combination of the two). We anticipate the proposed payment structure changes will motivate suppliers to retain participants due to more frequent payments. 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. Accordingly, this collection of information section does not set out any burden for the provisions.

5. Appropriate Use Criteria for Advanced Diagnostic Imaging

As discussed in section III.J. of this proposed rule, we are proposing to pause efforts to implement the Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services program for reevaluation and to rescind the current AUC program regulations at § 414.94. The program was established in the Protecting Access to Medicare Act of 2014 (PAMA) and we have used rulemaking over the ensuing years to stand up the program in phases while aiming for a clinically useful and least provider-burdensome approach. At this time, we have exhausted all reasonable options for fully operationalizing the AUC program consistent with the statutory provisions as prescribed in section 1834(q)(B) of the Act directing CMS to require real-time claims-based reporting to collect information on AUC consultation and imaging patterns for advanced diagnostic imaging services to ultimately inform outlier identification and prior authorization. As a result, we propose in section III.J. of this proposed rule to pause implementation of the AUC program for reevaluation, and rescind the current AUC program regulations from § 414.94.

The following collection of information requests would be affected by this rule's proposal to rescind the AUC program regulations from § 414.94: CMS–10570 (OMB 0938–1288), CMS–10624 (OMB 0938–1315), and CMS–10654 (OMB 0938–1345). Given that the AUC program regulations, which include these information collection requirements, would be rescinded, all three collections would no longer be needed.

CMS–10570 (OMB 0938–1288) relates to the application and qualification process for provider-led entities (PLEs). If we finalize the proposal and rescind the current regulations at § 414.94, then we will discontinue this collection of information. The following table scores the impact of discontinuing the requirements and burden that are currently active and approved by OMB under the aforementioned control number, showing an expected 10 re-applications per year. We note however, that because we received less than 10 applicants in each year 2017–2022, there have been and will continue to be fewer than 10 re-applicants each year. In fact, the number of PLEs has overall decreased as qualified PLEs exit the program, choosing not to re-apply. In 2022 we expected all seven PLEs approved in 2017 to reapply; however, only two submitted re-applications and were re-qualified. For 2023, we froze the re-application process, continuing the approval of the three PLEs that had initially qualified in 2018. If we were not proposing to pause the AUC program and rescind the current regulations at § 414.94, then we would expect one re-application in 2024 and no re-applications in 2025.

At the time of the last approval in 2021, we expected the burden for PLEs re-applying for qualification to be half the burden of the initial application process. In the explanation below, we continue to use the previously approved number of responses, respondents and time, while updating the labor cost to reflect May 2022 BLS wages. As previously estimated, the PLEs would be able to make modifications to their original application which should result in a burden of 10 hours at $80.08/hr for a business operations specialist (occupation code 13–100) to compile, prepare and submit the required information, 2.5 hours at $123.06/hr for a medical and health services manager

(occupation code 11–911) to review and approve the submission, and 2.5 hours at $242.3/hr for a physician (occupation code 29–1210) to review and approve the submission materials. Annually, we estimate 15 hours per submission at a cost of $1,714.2 per organization. In aggregate, we estimate 150 hours (15 hr × 10 submissions) at $17,142 ($1,714 × 10 submissions).

TABLE 56: Burden of Pausing AUC Program Implementation Efforts for Reevaluation and Rescinding § 414.94

Regulation Section(s)	Respondents	Total Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)
§ 414.94(c)(2) (reapplication)	(10)	(10)	(15)	(150)	(1,714.2)	(17,142)

CMS–10624 (OMB 0938–1315) relates to the application and qualification process for Clinical Decision Support Mechanisms (CDSMs). This collection of information is no longer active. CMS–10624 was first approved on March 6, 2017, and was associated with the CY 2017 Physician Fee Schedule final rule (November 15, 2016; 81 FR 80170). CMS–10624 last expired on March 31, 2020. In June 2020, CMS filed a request to discontinue CMS–10624 (OMB 0938–1315).

CMS–10654 (OMB 0938–1345) relates to the consultation of AUC through a qualified CDSM by an ordering professional or clinical staff acting under the direction of the ordering professional. While this collection of information is no longer active, the impact of discontinuing the requirements and burden is addressed in this proposed rule RIA (*see* section VII. Regulatory Impact Analysis of this proposed rule).

6. ICRs for Medicare Provider and Supplier Enrollment

None of this rule's Medicare and Medicaid provider enrollment provisions propose any new, revised, or removed information collection requirements or burden. Regarding the proposal to reduce the timeframe for reporting practice location changes from 90 days to 30 days, this change would not alter the requirement for disclosing the change via the applicable Form CMS–855 or Form CMS–20134. It would only revise the timeframe in which the change must be reported. Hence, there would be no change in the ICR burden.

7. ICRs Regarding the Medicare Ground Ambulance Data Collection System (GADCS) (§ 414.626)

Section 1834(l)(17) of the Act requires that the Secretary develop a ground ambulance data collection system that collects cost, revenue, utilization, and other information determined appropriate by the Secretary with respect to providers of services and suppliers of ground ambulance services (ground ambulance organizations). Section 1834(l)(17)(I) of the Act states that the PRA does not apply to the collection of information required under section 1834(l)(17) of the Act. Accordingly, we are not setting out any proposed burden estimates under this section of the rule.

8. ICRs Related to the Changes in the RHC/FQHC CfCs and Hospice CoPs

a. Permitting MFT and MHCs To Furnish Services in RHC/FQHCs

The following proposed changes will be submitted to OMB for review under control number 0938–0344 (CMS–R–38).

In section III.C. of this proposed rule, we implement section 4121 of the CAA by proposing conforming changes at § 491.8(a)(3) and (a)(6) that would add MFT and MHCs to the list of staff who may be the owner or an employee of the clinic or center or may furnish services under contract to the clinic or center as well as included as staff available to furnish patient care services at all times the clinic or center operates. If an RHC or FQHC provides services furnished by an MFT or MHC they would be required to update their patient care policy, as set out in section § 491.9(b)(2) of the CfCs.

The existing requirement at § 491.9(b)(2), *Patient care policies,* requires that policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioners, with at least one member who is not a member of the clinic or center staff. The patient care policies must describe the services the clinic or center furnishes directly, through agreement or arrangement, guidelines for medical management of health problems, and rules for the storage, handling, and administration of drugs and biologicals.

As we are proposing to include MFTs and MHCs as professionals who can provide services in an RHC and FQHC, there will be a burden associated with the existing requirement at § 491.9(b)(3)(i). This requirement states that policies include ''A description of the services they provide directly or through agreement or arrangement.'' Therefore, if an RHC or FQHC provides services furnished by an MFT or MHC they must update their policies to include a description of the services provided.

We note that the time and effort required to conduct this activity will vary depending on if a clinic or center chooses to provide services furnished by an MFT or MHC. We also believe that some RHCs and FQHCs may already provide services furnished by an MFT or MHC. State Medicaid programs can cover ambulatory care services (including mental health and substance use disorder services) under a number of different mandatory Medicaid benefits such as outpatient hospital services, physician services, RHC and FQHC services, as well as optional benefits such as rehabilitative services, and services of other licensed practitioners.

The National Association of Community Health Center's 2017 policy assessment suggests that 21 State Medicaid programs cover services provided by MFTs, and 25 State Medicaid programs cover services provided by licensed professional counselors.[330] Due to approximately half of the State's Medicaid programs already covering services furnished by an MFT or MHC and the assumption that some centers and clinics will not

[330] *https://www.nachc.org/wp-content/uploads/2019/03/BH-Fact-Sheet-3.20.19.pdf.*

provide these services, we believe only 50 percent of RHCs and 50 percent of FQHCs will incur this burden. The total RHCs and FQHCs who will have to meet this 1-time burden is 2,643 clinics and 5,643 centers, or 8,286 combined.[331] [332]

Each clinic or center is required by the existing requirement at 491.9(b)(2) to have at least two clinical professionals (one physician/administrator at $229.52/hr and one advanced practice provider at $119.88/hr) reviewing and updating the policies. We estimate that it takes existing RHCs and FQHCs 4 hours every 2 years for clinical staff to review and make changes to all patient care policies. Based on this, we estimate that adding MFT and MHC services (as necessary) to the patient care policies would take approximately 15 minutes (.25 hr) for each clinical professional. In aggregate, we estimate an annual burden of 2,071.50 hours (0.25 hr × 8,268 RHC and FQHCs) at a cost of $361,891.05 [(1,035.75 hr × $229.52/hr) + (1,035.75 hr × $119.88/hr)].

TABLE 57: One-time Burden for Time Spent on Clinics or Centers Updating Patient Care Policies to Include a Description of MFT and MHC Services

Occupation	Hourly wage (a)	One-time hourly burden (b)	Number of clinics and centers (c)	Total time (d)=(b) x (c)	One-time cost estimate (a) x (d)	
Physician	$229.52	.25 hr	8,286		1035.75	$237,725.34
Advanced Practice Provider	$119.88	.25 hr	8,286		1035.75	$124,165.71
Total:	Varies				2071.50	$361,891.05

b. ICRs Related to Permitting MFTs and MHCs To Serve as Members of the Interdisciplinary Group (IDG) in Hospices (§ 418.56 and § 418.114)

In section III.O. of this proposed rule, we would implement subtitle C, section 4121 of the CAA 2023 by proposing conforming changes at § 418.56(a)(1)(iii) that would permit MFTs or MHCs, in addition to social workers, to serve as members of the IDG. The conforming change would require hospices to include at least one SW, MFT or MHC to serve as a member of the IDG. Hospices would have the flexibility to determine which discipline(s) are appropriate to serve on the IDG based on the needs of the patients. We believe that with the introduction of MHC and MFT into the hospice CoPs, it is important to include these new disciplines into the personnel qualifications at § 418.114.

In this rule we are also proposing to add both MFT and MHC to the provider requirements under 42 CFR subpart B (Medical and Other Health Services) at §§ 410.53 and 410.54. Therefore, to avoid duplication and confusion between the CoP and the provider requirements under the Medical and Other Health Services provision, we are proposing to add both MFT and MHC to the requirements at § 418.114(c)(3) and (4) and referencing the new requirement at §§ 410.53 and 410.54, respectively.

In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe that both the existing requirements and the proposed revisions to the requirements at §§ 418.56(a)(iii) and 418.114(c)(3) and (4) are exempt from the PRA. We believe permitting hospices the ability to select one of these disciplines (SW, MFT or MHC) to serve as a member of the IDG and the addition of both MFT and MHC to the personnel requirements with reference to the new requirement at §§ 410.53 and 410.54 respectively, is reasonable and customary business practice. We state such in the information collection request that is currently approved under OMB control number: 0938–1067 ((CMS–10277). Therefore, we are not proposing to seek OMB's approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to §§ 418.56(a)(1)(iii) and 418.114(c)(3) and (4), but we request public comment on our determination that the time and effort necessary to comply with these evaluation requirements is usual and customary and this time and effort would be incurred by hospice staff even absent this regulatory requirement.

9. RFI: Histopathology, Cytology, and Clinical Cytogenetics Regulations Under the Clinical Laboratory Improvement Amendments (CLIA) of 1988

Please note that this is an RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal, applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all

[331] *https://qcor.cms.gov/active_nh.jsp?which=12&report=active_nh.jsp&jumpfrom=#pagetop.*

[332] *https://qcor.cms.gov/active_nh.jsp?which=11&report=active_nh.jsp&jumpfrom=#pagetop*

costs associated with responding to this RFI will be solely at the interested party's expense. We note that not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. In addition, we note that we will not respond to questions about the policy issues raised in this RFI.

We will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. We may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this RFI. Responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned.

10. Basic Health Program (BHP) Provisions

a. Proposed Information Collection Requirements (ICRs)

The following proposed changes will be submitted to OMB for review under OMB control number 0938–1218 (CMS–10510).

(1) ICRs Regarding the BHP Blueprint (§ 600.125)

We propose at § 600.125(a)(1)–(3) that Blueprint revisions must be submitted to reflect: (1) changes in Federal laws, regulations, policy interpretations or court decisions that affect provisions in the certified Blueprint; (2) significant changes that alter core program operations or the BHP benefit package; or (3) changes to enrollment, disenrollment, and verification policies described in the certified Blueprint. We note that only § 600.125(a)(1) is a new requirement. The requirements under § 600.125(a)(2) and (3) are existing. We propose at § 600.125(b) that a State may submit revisions to its certified Blueprint at any time within the same quarter of the proposed effective date of revised Blueprint. We propose at § 600.125(c) that HHS must review the revised Blueprint within 90 calendar days or provide the State written notice of disapproval or additional information it needs to make a final determination.

We estimate that, on average, a State operating a BHP will submit one revised Blueprint in response to § 600.125(a)(1) annually. Because only two States are currently certified to operate a BHP, we are providing the burden estimate for two States. We estimate that the proposal under § 600.125(a)(1) will increase State burden. We estimate that the proposals under § 600.125(b) and (c) will have no impact on State burden. We estimate that, on average, it will take a State 4 additional hours at $80.08/hr for a Business Operations Specialist and 2 additional hours at $118.14/hr for a General Manager to meet the new Blueprint requirements under § 600.125(a)(1). In aggregate, we estimate an increased burden of 12 hours (2 States × 6 hr/State) at a cost of $1,113 [2 States × ((4 hr × $80.08/hr) + (2 hr × $118.14/hr))]. We note that this cost will be incurred 100 percent by the State, as Federal BHP funds cannot be used for program administration.

(2) ICRs Regarding the Operation of a BHP (§§ 600.145(a), 600.145(f)(2), and 600.330(f))

We propose at § 600.145(a) that a State must implement its BHP in accordance with: (1) the approved and full certified State BHP Blueprint; or (2) the approved suspension application (see ICR section 3 below).

We propose at § 600.145(f)(2) that the State operating a BHP must perform eligibility and health services appeals as specified in § 600.335.

The ongoing burden associated with the requirements under § 600.145 is the time and effort it would take each participating State to perform the recordkeeping and reporting portions of the core operating functions of a BHP including eligibility determinations and appeals as well as enrollment and disenrollment, health plan contracting, oversight and financial integrity, consumer assistance, and if necessary program termination or suspension.

Because only two States are currently certified to operate a BHP, we are providing the burden estimate for two States. We estimate that it would take a business operations specialist 4 additional hours at $80.08/hr to meet these new recordkeeping and reporting requirements for health services appeals. In aggregate, we estimate an increased burden of 8 hours (2 States × 4 hr/response) at a cost of $641 (2 States × 4 hr × $80.08/hr). We note that this cost will be incurred 100 percent by the State, as Federal BHP funds cannot be used for program administration.

We propose at § 600.330(f), BHP eligibility notices must be written in plain language and be provided in a manner which ensures individuals with disabilities are provided with effective communication and takes steps to provide meaningful access to eligible individuals with limited English proficiency. These notices must be developed and processed in a coordinated fashion with other insurance affordability programs which have the same accessibility standards at 45 CFR 155.230(b). As such, we propose no additional burden for the BHP for the noticing requirement.

(3) ICRs Regarding Suspension of a BHP (§§ 600.140(b) and 600.170(a)(2))

We propose at § 600.140(b)(1) if a State decides to suspend its BHP or requests a suspension extension, a State must submit to the Secretary a suspension application or suspension extension application. We propose at § 600.140(b)(3) that a State must submit written notices to all BHP enrollees and participating standard health plan offers at least 90 days prior to the effective date of the suspension. We propose at § 600.140(b)(4) that the State must submit to HHS within 12 months of the suspension effective date the data required by § 600.610 needed to complete the financial reconciliation process with HHS. We propose at § 600.140(b)(5) that the State must submit the annual report required by § 600.170(a)(2). We propose at § 600.140(b)(6) that the State must annually remit to HHS any interest that has accrued on the balance of the BHP trust fund during the suspension period. We propose at § 600.140(b)(7) that the State must submit a transition plan to HHS that describes how the State will reinstate its BHP or terminate the program.

Two States are currently certified to operate a BHP; therefore, we are providing the burden estimate for two States.

We estimate that, on average, it would take a Business Operations Specialist 30 hours at $80.08/hr and a General Manager 4 hours at $118.14/hr to submit a suspension application to the Secretary. In aggregate, we estimate a one-time burden of 68 hours (2 States × 34 hr/response) at a cost of $5,780 [2 States × ((30 hr × $80.08/hr) + (4 hr × $118.14/hr))]. We estimate that, on average, it would take a Business Operations Specialist 30 hours at $80.08/hr and a General Manager 4

hours at $118.14/hr to submit a suspension extension application to the Secretary. In aggregate, we estimate a one-time burden of 68 hours (2 States × 34 hr/response) at a cost of $5,780 [2 States × ((30 hr × $80.08/hr) + (4 hr × $118.14/hr))].

We estimate that, on average, it would take a Business Operations Specialist 32 hours at $80.08/hr to prepare and submit notification to all participating standard health plans and enrollees. In aggregate, we estimate a one-time burden of 64 hours (2 States × 32 hr/response) at a cost of $5,125 [2 States × (32 hr × $80.08/hr)].

We estimate that it would take a Business Operations Specialist 25 hours at $80.08/hr and a General Manager 4 hours at $118.14/hr to compile and submit data required for quarterly financial reconciliation. In aggregate, we estimate an annual burden of 232 hours (2 States × 29 hr/response × 4 responses/yr) at a cost of $19,796 [2 States × 4 responses/yr ((25 hr × $80.08/hr) + (4 hr × $118.14/hr)).

We estimate that, on average, it would take a Financial Specialist 8 hours at $88.74/hr to remit annually the interest accrued on the balance of the BHP trust fund while in suspension. In aggregate, we estimate an annual burden of 16 hours (2 States × 8 hr/response) at a cost of $1,420 [2 States × (8 hr × $88.74/hr)].

We estimate that it would take a Business Operations Specialist 20 hours at $80.08/hr and a General Manager 4 hours at $118.14/hr to submit a transition plan to reinstate its BHP or terminate the program. In aggregate, we estimate a one-time burden of 48 hours (2 States × 24 hr/response) at a cost of $4,148 [2 States × ((20 hr × $80.08/hr) + (4 hr × $118.14/hr))].

We estimate that, on average, it will take a Business Operations Specialist 40 hours at $80.08/hr and 4 hours at $118.14/hr for a General Manager to complete and submit the State's annual report, for a total annual burden of 88 hours at a cost of $7,352 [2 States × ((40 hr × $80.08/hr) + (4 hr × $118.14/hr))]. We note that these costs will be incurred 100 percent by the State, as Federal BHP funds cannot be used for program administration.

b. Burden Summary

TABLE 58: Summary of Proposed Burden Estimates

Regulation Section(s)/ ICR Provision	OMB Control No./ CMS-ID	Year	Number of Respondents	Number of Responses	Time per Response (hrs)	Total Time (hr)	Hourly Labor Rate ($/hr)	Total Labor Cost ($)	State Share ($)	Total Beneficiary Cost ($)
600.125(a)(1)	0938–1218 (CMS-10510)	2024	2	2	6	12	Varies	1,113	1,113	N/A
600.145(a) and 600.145(f)(2)	0938–1218 (CMS-10510)	2024	2	2	4	8	80.08	641	641	N/A
600.140(b)(1) (suspension application)	0938–1218 (CMS-10510)	2024	2	2	34	68	Varies	5,780	5,780	N/A
600.140(b)(1) (extension application	0938–1218 (CMS-10510)	2024	2	2	34	68	Varies	5,780	5,780	N/A
600.140(b)(3)	0938–1218 (CMS-10510)	2024	2	2	32	64	80.08	5,125	5,125	N/A
600.140(b)(4)	0938–1218 (CMS-10510)	2024	2	4	29	232	Varies	19,796	19,796	N/A
600.140(b)(5) and 600.170(a)(2)	0938–1218 (CMS-10510)	2024	2	2	44	88	Varies	7,352	7,352	N/A
600.140(b)(6)	0938–1218 (CMS-10510)	2024	2	2	8	16	88.74	1,420	1,420	N/A
600.140(b)(7)	0938–1218 (CMS-10510)	2024	2	2	24	48	Varies	4,148	4,148	N/A
Total					Varies		Varies	51,155	51,155	

11. The Quality Payment Program (QPP) (42 CFR Part 414 and Section IV. of This Proposed Rule)

The following QPP-specific ICRs reflect changes to our currently approved burden due to proposed policy changes in this CY 2024 proposed rule as well as adjustments to the policies that have been previously finalized in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568, respectively), CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 59452, 84 FR 62568, 85 FR 84472, 86 FR 64996, and 87 FR 70131, respectively) due to revised assumptions based on updated data available at the time of the publication of this proposed rule.

a. Background

(1) ICRs Associated With Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs)

In the following sections, we discuss a series of ICRs associated with the Quality Payment Program, including for MIPS and Advanced APMs. The following sections describe the changes in the estimated burden for the information collections relevant to the proposed revisions in the policies associated with the CY 2024 PFS proposed rule and the proposed revisions to our currently approved information requests for MIPS and Advanced APM ICRs. The proposed estimated burden will be submitted to OMB under control number 0938–1314 (CMS–10621). The proposed estimated burden for the CAHPS for MIPS Survey discussed in sections V.B.11.c.(5), V.B.11.e.(8), and V.B.11.e.(9) of this rule will be submitted under OMB control number 0938–1222 (CMS–10450). We note that we have received approvals for the collection of information associated the virtual group election process under OMB control number 0938–1343 (CMS–10652).

(2) Summary of Proposed Changes for the Quality Payment Program: MIPS

We have included the change in the estimated burden for the CY 2024 performance period/2026 MIPS payment year due to the proposed policies and information collections in this proposed rule. The proposed policies in this proposed rule impact the burden estimates for the CY 2024 performance period/2026 MIPS payment year.

The following five MIPS ICRs show changes in burden due to the proposed policies in this proposed rule: (1) Quality performance category data submission by Medicare Part B claims collection type; (2) Quality performance category data submission by qualified clinical data registry (QCDR) and MIPS CQM collection type; (3) Quality performance category data submission by eCQM collection type; (4) MIPS Value Pathways (MVP) quality performance category submission, and (5) MVP registration. In aggregate, we estimate the proposed policies will result in a net decrease in burden of 4,002 hours and $459,553 for the CY 2024 performance period/2026 MIPS payment year. The remaining changes to our currently approved burden estimates are proposed adjustments due to the revised burden assumptions based on the updated data available at the time of publication of this proposed rule. As discussed in section VII.E.23.a. of this proposed rule, we are basing our estimates on data from the CY 2021 performance period.

We are proposing to add two new ICRs, ''QCDR full self-nomination process'' and ''qualified registry full self-nomination process'' in sections V.B.11.c.(2) and V.B.11.c.(3) of this rule to distinctly capture the burden for the number of QCDRs and qualified registries submitting applications for the simplified and full self-nomination process. We note that the proposed addition of these ICRs is not due to the proposed policy changes in section IV.A.4.k. of this rule. It is a proposed change in our approach in representing the estimated burden for the third -party intermediary self-nomination process due to availability of updated data.

We are proposing to remove one ICR, ''nomination of Promoting Interoperability measures,'' in section V.B.11.h. of this rule. We note that the proposed removal of the ICR is not due to proposed policy changes in section IV.A.4.f.(4) of this rule. It is due to a consistent decline in the number of submissions received for the ICR.

We are not proposing any changes or adjustments to the following ICRs: Registration for virtual groups; OAuth credentialing and token request process; Quality Payment Program identity management application process; subgroups registration; submitting Promoting Interoperability data; improvement activities submission; nomination of MVPs; and opt-out of performance data display on Compare Tools for voluntary participants. See section V.B.11. of this proposed 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 by two primary factors. First, we are unable to predict with absolute certainty who will be a Qualifying APM Participant (QP) for the CY 2024 performance period/ 2026 MIPS payment year. New eligible clinician participants in Advanced APMs who become QPs will be excluded from MIPS reporting requirements and payment adjustments, and as such, are unlikely to report under MIPS; while some current Advanced APM participants may end participation such that the APM Entity's eligible clinicians may 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 whether Partial QPs, who can elect to report to MIPS, will choose to participate in the CY 2024 performance period/2026 MIPS payment year compared to the CY 2021 performance period/2023 MIPS payment year. 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. Additionally, we will continue to update our estimates annually as data becomes available.

(3) Summary of Quality Payment Program Changes: Advanced APMs

For these ICRs (identified above under, ''ICRs Associated with MIPS and Advanced APMs''), we did not implement any changes to currently approved burden estimates for the CY 2024 performance period/2026 MIPS payment year. Therefore, we did not propose any changes to the Partial QP elections; Other Payer Advanced APM identification: Payer Initiated and Eligible Clinician Initiated Processes; and submission of Data for QP determinations under the All-Payer Combination Option.

(4) Framework for Understanding the Burden of MIPS Data Submission

Because of the wide range of information collection requirements under MIPS, Table 59 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. In Table 59, MIPS eligible clinicians and other clinicians voluntarily submitting

data to MIPS may submit data 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. Beginning with the CY 2023 performance period/2025 MIPS payment year, clinicians could also participate as subgroups for reporting measures and activities in an MVP. We note that the subgroup reporting option is not available for clinicians participating in traditional MIPS. We finalized in the CY 2022 PFS final rule that a subgroup reporting measures and activities in an MVP will submit its affiliated group's data for the Promoting Interoperability performance category and in the scenario that a subgroup does not submit its affiliated group's data, the subgroup will receive a zero score for the Promoting Interoperability performance category (86 FR 65413 through 65414).

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 59.

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. We previously finalized in the CY 2021 PFS final rule that the APM Performance Pathway is available for both Accountable Care Organization (ACO) participants and non-ACO participants to submit quality data (85 FR 84859 through 84866). Due to data limitations and our inability to determine who will use the APM Performance Pathway versus the traditional MIPS submission mechanism for the CY 2024 performance period/2026 MIPS payment year, we assume ACO APM Entities will submit data through the APM Performance Pathway, using the CMS Web Interface option, and non-ACO APM Entities will participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity. We also want to note that as finalized in the CY 2022 PFS final rule (86 FR 65259 through 65263), the CMS Web Interface collection type is available through the CY 2024 performance period/2026 MIPS payment year only for clinicians participating in the Shared Savings Program. Per section 1899(c) of the Act, submissions received from eligible clinicians in ACOs are not included in burden estimates for this proposed rule because quality data submissions to fulfill requirements of the Shared Savings Program are not subject to the PRA.

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. Additionally, we finalized the introduction of a voluntary reporting option for APM Entities to report the Promoting Interoperability performance category at the APM Entity level beginning with the CY 2023 performance period/2025 MIPS payment year (87 FR 70087 and 70088). 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 established 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 Entity receives less than the maximum improvement activities performance category score, to date all MIPS APM Entities 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).

TABLE 59: Clinicians or Organizations Submitting MIPS Data on Behalf of Clinicians, by Type of Data and Category of Clinician

Type of Data Submitted	Category of Clinician
Quality Performance Category	Individual clinician (MIPS eligible, voluntary, opt-in), group, virtual group, subgroup, or APM Entity. Subgroup reporting is only available for clinicians participating in MVP reporting.
Promoting Interoperability Performance Category	Individual clinician (MIPS eligible, voluntary, opt-in), group, virtual group, subgroup, or APM Entity. Each eligible clinician in an APM Entity could report data for the Promoting Interoperability performance category at the individual level, or as part of their group TIN, or under their APM Entity TIN. The burden estimates for this proposed rule assume group TIN-level reporting.
Improvement Activities Performance Category	Individual clinician (MIPS eligible, voluntary, opt-in), group, virtual group, subgroup, or APM Entity. The burden estimates for this proposed rule assume no improvement activities performance category reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity score. 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.
Reweighting Applications for extreme and uncontrollable circumstances and significant hardship or other exceptions	Clinicians who submit an application may be eligible for a reweighting of the approved performance category to zero percent under specific circumstances as set forth in § 414.1380(c)(2), including, but not limited to, extreme and uncontrollable circumstances and significant hardship or another type of exception. Certain types of MIPS eligible clinicians are automatically eligible for a zero percent weighting for the Promoting Interoperability performance category as described in § 414.1380(c)(2)(i)(A)(4).
MVP and Subgroup Registration	An MVP participant, as described at § 414.1305, electing to submit data for the measures and activities in an MVP must register. Clinicians who choose to participate as a subgroup for reporting an MVP must also register.
Partial QP Election	Eligible clinicians who attain Partial QP status and choose to participate in MIPS would need to submit a partial QP election form.
Registration for the CAHPS for MIPS Survey	Groups electing to use a CMS-approved survey vendor to administer the CAHPS for MIPS survey must register.
Virtual Group Registration	Virtual groups must register via email. Virtual group participation is limited to MIPS eligible clinicians, specifically, solo practitioners and groups consisting of 10 eligible clinicians or fewer.
APM Performance Pathway	Clinicians in MIPS APMs electing the APM Performance Pathway. The burden estimates for this proposed rule assume that ACO APM Entities will submit data through the APM Performance Pathway, using the CMS Web Interface option (available through the CY 2024 performance period/2026 MIPS payment year), and non-ACO APM Entities will participate through traditional MIPS, thereby submitting as an individual or group rather than as an APM Entity.

The policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568), the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 59452, 84 FR 62568, 85 FR 84472, 86 FR 64996, and 87 FR 70131), and continued in this proposed rule create some additional data collection requirements not listed in Table 59. 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 V.B.11.c. of this proposed rule):

- 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)
- Third party intermediary plan audits
- Approval process for new and returning CAHPS for MIPS survey vendors (82 FR 53908) (OMB 0938–1222).
- Open Authorization Credentialing and Token Request Process (OMB 0938–1314) (85 FR 84969 through 84970).

Additional ICRs related to the data submission and the quality performance category (see section V.B.11.e. of this proposed rule):

- 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 V.B.11.g. of this proposed rule):

- 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 V.B.11.j, V.B.11.f, V.B.11.k., and V.B.11.h. of this proposed rule):

- Nomination of improvement activities (82 FR 53922 and 83 FR 60017 through 60018) (OMB 0938–1314).
- Call for MIPS quality measures (83 FR 60010 through 60011) (OMB 0938–1314).
- Nomination of MVPs (85 FR 84990 through 84991) (OMB 0938–1314)

Additional ICRs related to MIPS (see section V.B.11.o. of this proposed rule):

- Opt out of performance data display on Compare Tools for voluntary reporters under MIPS (82 FR 53924 through 53925 and 83 FR 60022) (OMB 0938–1314).

Additional ICRs related to APMs (see sections V.B.11.m. and V.B.11.n. of this proposed rule):

- 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 does not propose 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 proposing any changes under that control number.

c. ICRs Regarding Third Party Intermediaries (§ 414.1400)

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621). As discussed above in section V.B.11.a.(2) of this rule, we are proposing to add two new ICRs, ''QCDR simplified self-nomination process'' and ''qualified registry self-nomination process'', to represent the estimated burden for the third-party intermediaries submitting applications for the simplified self-nomination process. We discuss the details of these proposed changes in the below sections.

In section IV.A.4.k. of this rule, we are proposing to: (1) add requirements for third party intermediaries to obtain documentation; (2) add requirements for third party intermediaries to submit data in the form and manner specified by CMS; (3) specify the use of a simplified self-nomination process for existing QCDRs and qualified registries; (4) add requirements for QCDRs and qualified registries to provide measure numbers and identifiers for performance categories; (5) add a requirement for QCDRs and qualified registries to attest that information on the qualified posting is correct; (6) modify requirements for QCDRs and qualified registries to support MVP reporting; (7) specify requirements for a transition plan for QCDRs and qualified registries; (8) specify requirements for data validation execution reports; (9) eliminate the Health IT vendor category; (10) add failure to maintain updated contact information as criteria for remedial action; (11) revise corrective action plan requirements; (12) specify the process for publicly posting remedial action; and (13) specify the criteria for audits. Specifically, we note that the proposed policy to eliminate the health IT vendor category beginning with the CY 2025 performance period/2027 MIPS payment year, if finalized, would not have any impact on the estimated burden for third party self-nomination process in the CY 2024 performance period/2026 MIPS payment year. If the proposed removal of health IT vendor category is finalized for the CY 2025 performance period/2027 MIPS payment year, we recognize that it could encourage some existing health IT vendors to complete the requirements under the qualified registry self-nomination process. However, we believe that many third-party intermediaries serve as both health IT vendors and qualified registries for the purposes of submitting data for MIPS eligible clinicians. Therefore, we assume that there would not be an increase in the number of qualified registries that would submit applications for the qualified registry self-nomination process during the CY 2024 performance period/2026 MIPS payment year.

We assume that the proposed changes to codify previously finalized preamble language related to third party intermediaries in the regulatory text would result in modifying the regulatory text to reflect previously finalized policies for third party intermediaries or provide additional clarification of the previously finalized policies. We do not expect to receive additional information from QCDRs and qualified registries during the self-nomination process due to the above proposed policies and therefore, we are not proposing any adjustments to the currently approved burden estimates for third party intermediaries. We refer readers to section IV.A.4.k. of this rule for details on proposed policies for third party intermediaries. Additionally, we refer readers to section VII.E.23.e.(2)(a) of this proposed rule where we discuss the details in our impact analysis for these policies.

(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-nomination process annually.[333] The processes for self-nomination of 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

As described below in section V.B.11.c.(2)(a) of this rule, we are proposing to separate the burden for the number of QCDR self-nomination applications submitted for the simplified and full self-nomination process for the CY 2024 performance period/2026 MIPS payment year. In the CY 2023 PFS final rule (87 FR 70137 through 70139), we used the same estimate for the number of respondents that submitted applications for the simplified and full self-nomination process because we did not have separate estimates at the time. Additionally, we only used the burden for the full QCDR self-nomination process in our final burden summary estimates. Due to the availability of updated data and the distinct number of estimated respondents for the simplified and full self-nomination process, we are proposing to add a new ICR to capture the burden for the simplified QCDR self-nomination process. We note that the proposed change in estimated burden is not due to policy proposals in section IV.A.4.k. of this rule. In order to accurately represent the estimated burden incurred by the QCDRs for the simplified and full self-nomination process, we discuss the burden under separate ICRs. We are not proposing any changes to our estimates for the number of existing or borrowed QCDR measures submitted for consideration by each QCDR at the time of self-nomination and the average time required to submit information for each QCDR measure.

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77507 through 77508, and 82 FR 53906 through 53908, respectively), and the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 59998 through 60000, 84 FR 63116 through 63121, 85 FR 84964 through 84969, 86 FR 65569 through 65573, and 87 FR 70138 through 70139, respectively) for our previously finalized requirements and estimated burden for self-nomination of QCDRs and nomination of QCDR measures.

(a) Self-Nomination Process and Other Requirements

Based on the number of applications that we expect to receive during the CY 2023 self-nomination period for the CY 2024 performance period/2026 MIPS payment year, we estimate that 45 QCDRs would submit applications using the simplified self-nomination process. We note that we are not making any changes to the currently approved time of 8.1 hours required for the simplified QCDR self-nomination process (87 FR 70139).

Based on the above assumptions, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered ''qualified'' to submit data on behalf of MIPS eligible clinicians.

As shown in Table 60, we assume that the staff involved in the simplified QCDR self-nomination process will continue to be computer systems analysts or their equivalent who have an average adjusted labor rate of $103.40/hr. We estimate the burden per response would be $837.54 (8.1hr × $103.40/hr). In aggregate, for the CY 2024 performance period/2026 MIPS payment year, we estimate that the annual burden for the simplified QCDR self-nomination process would be 365 hours (45 responses × 8.1 hr) at a cost of $37,689 (45 applications × $837.54/application).

TABLE 60: Estimated Burden for Simplified QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Burden Estimate
# of Simplified QCDR Self-Nomination Applications submitted (a)	45
Annual Hours Per QCDR for Simplified Process (b)	8.1
Total Annual Hours for Self-nomination (c) = (a) * (b)	**365**
Cost per Application at Labor Cost for computer systems analysts at $103.40/hr (d)	$837.54
Total Annual Cost (**e**) = (a) * (d)	**$37,689**

In Table 61, the addition of this new ICR for the CY 2024 performance period/2026 MIPS payment year would result in an increase of 365 hours at a cost of $37,689 for the simplified QCDR self-nomination process. We note that the proposed increase in burden is due to separating the estimated burden for the simplified QCDR self-nomination process.

[333] As stated in the CY 2019 PFS final rule (83 FR 59998), health IT vendors are not included in the burden estimates for MIPS.

TABLE 61: Change in Estimated Burden for Simplified QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Time (hr) (a)	0
Total Annual Time (hr) for Respondents in CY 2024 PFS proposed rule (b) (See Table 60, row (c))	365
Difference (c) = (b) - (a)	**+365**
Total Currently Approved Annual Cost (d)	0
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 60, row (e))	$37,689
Difference (f) = (e) - (d)	**+$37,689**

(b) Full QCDR Self-Nomination Process and Other Requirements

Based on the number of applications that we expect to receive during the CY 2023 self-nomination period for the CY 2024 performance period/2026 MIPS payment year, we estimate that 10 QCDRs would submit applications using the full self-nomination process. This is a decrease of 53 respondents from the currently approved estimate of 63 for the QCDR self-nomination process (87 FR 70139). We note that we are not making any changes to the currently approved time of 10.1 hours required for the full QCDR self-nomination process (87 FR 70139).

Based on the above assumptions, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered ''qualified'' to submit data on behalf of MIPS eligible clinicians.

In Table 62, we assume that the staff involved in the full QCDR self-nomination process will continue to be computer systems analysts or their equivalent who have an average adjusted labor rate of $103.40/hr. We estimate the burden per response would be $1,044.34 (10.1hr × $103.40/hr). In aggregate, for the CY 2024 performance period/2026 MIPS payment year, we estimate that the annual burden for the full QCDR self-nomination process would be 101 hours (10 responses × 10.1 hr) at a cost of $10,443 (10 applications × $1,044.34/application).

TABLE 62: Estimated Burden for Full QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Burden Estimate
# of Full QCDR Self-Nomination Applications submitted (a)	10
Annual Hours Per QCDR for Full Process (b)	10.1
Total Annual Hours for Full Self-nomination (c) = (a) * (b)	**101**
Cost per Application at Labor Cost computer systems analyst at $103.40/hr (d)	$1,044.34
Total Annual Cost (**e**) = (a) * (d)	**$10,443**

In Table 63, we use the currently approved burden as the baseline for calculating the net change in burden for the full QCDR self-nomination process. We note that we discussed the estimated burden for the full QCDR self-nomination process under ''maximum burden'' in Table 105 in the CY 2023 PFS final rule (87 FR 70139). For the CY 2024 performance period/2026 MIPS payment year, the change in the representation of burden for this ICR described above results in a decrease of 535 hours and $55,350 for the full self-nomination process. We also note that the decrease in burden accounts for the change due to separating the estimated burden based on the simplified and full self-nomination process.

TABLE 63: Change in Estimated Burden for Full QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Time (hr) (a)	636
Total Annual Time (hr) for Respondents in CY 2024 PFS proposed rule (b) (See Table 62, row (c))	101
Difference (c) = (b) - (a)	**-535**
Total Currently Approved Annual Cost (d)	$65,793
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 62, row (e))	$10,443
Difference (f) = (e) - (d)	**-$55,350**

(c) QCDR Measure Requirements

In the CY 2017 Quality Payment Program final rule (81 FR 77375 through 77377), we established that QCDRs could submit measures that are not on the annual list of MIPS quality measures as part of the self-nomination process for an entity to become a QCDR.

In section IV. of this rule, we are proposing to add that if the measure was submitted for consideration after self-nomination to our list of reasons for rejecting a QCDR measure at § 414.1400(b)(4)(iv)(O). We will not revise or adjust our active requirements or burden estimates because the proposed policy only clarifies requirements for rejecting a QCDR measure and will not substantively change the currently approved estimated average weighted time required for a QCDR to submit information for a QCDR measure at the time of self-nomination.

In section IV. of this rule, we are proposing at § 414.1400(b)(4)(iv)(P) that a QCDR measure may be rejected if the QCDR submits more than 30 quality measures not in the annual list of MIPS quality measures for CMS consideration. We will not revise or adjust our currently approved burden estimates as result of this change because limiting the number of measures submitted during the QCDR self-nomination process would not substantively change the currently approved estimated average weighted time required for a QCDR to submit information for a QCDR measure at the time of self-nomination.

In section IV.A.4.k.(4)(b)(i) of this rule, we are proposing to revise § 414.1400(b)(4)(i)(B) to add a provision that the approved QCDR measure specifications must remain published through the performance period and data submission period. We will not revise or adjust our currently approved burden estimates as result of this change because establishing a standard for the duration of posting the approved QCDR measure specifications would not substantively change the currently approved estimated average weighted time required for a QCDR to submit information for a QCDR measure at the time of self-nomination.

(3) Qualified Registry Self-Nomination Process and Other Requirements

We refer readers to § 414.1400(b)(2) 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.

As described below, in this rule we are proposing to separate the burden for the number of qualified registry self-nomination applications submitted for the simplified and full self-nomination process for the CY 2024 performance period/2026 MIPS payment year. In the CY 2023 PFS final rule (87 FR 70139 through 70140), we used the same estimate for the number of respondents that submitted applications for the simplified and full self-nomination process because we did not have separate estimates at the time. Additionally, we only used the burden for the full qualified registry self-nomination process in our final burden summary estimates. Due to the availability of updated data and the distinct number of estimated respondents for the simplified and full self-nomination process, we are proposing to add a new ICR to capture the burden for the qualified registry self-nomination process. We note that the proposed change is not due to policy proposals in section IV.A.4.k. of this rule. With the addition of a new ICR, we believe that we would be able to accurately represent the estimated burden incurred by the qualified registries for both the simplified and full self-nomination process.

(a) Simplified Qualified Registry Self-Nomination Process

Based on the number of applications that we expect to receive during the CY 2023 self-nomination period for the CY 2024 performance period/2026 MIPS payment year, we estimate that 89 qualified registries would submit applications using the simplified self-nomination process. We note that we are not making any changes to the currently approved time of 0.5 hours required for the simplified qualified registry self-nomination process (87 FR 70140).

Based on the above assumptions, we provide an estimate of the total annual burden associated with a qualified registry self-nominating to be considered ''qualified'' to submit data on behalf of MIPS eligible clinicians.

In Table 64, we assume that the staff involved in the simplified qualified registry self-nomination process will continue to be computer systems analysts or their equivalent, who have an average adjusted labor rate of $103.40/hr. We estimate the burden per response would be $51.70 (0.5hr × $103.40/hr) for the simplified self-nomination process. In aggregate, for the CY 2024 performance period/2026 MIPS payment year, we estimate that the annual burden for the simplified qualified registry self-nomination process would be 45 hours (89 responses × 0.5 hr) at a cost of $4,601 (89 applications × $51.70//application).

TABLE 64: Estimated Burden for Simplified Qualified Registry Self-Nomination

Burden and Respondent Descriptions	Burden Estimate
# of Simplified Self-Nomination Applications submitted (a)	89
Annual Hours Per Qualified Registry for Simplified Process (b)	0.5
Total Annual Hours for Simplified Self-nomination (c) = (a) * (b)	**45**
Cost per Application at Labor Cost computer systems analyst at $103.40/hr (d)	$51.70
Total Annual Cost (**e**) = (a) * (d)	**$4,601**

In Table 65, the addition of this ICR for the CY 2024 performance period/2026 MIPS payment year would result in a change of +45 hours at a cost of $4,601 for the simplified qualified registry self-nomination process. We note the increase in burden is due to separating the estimated burden for the simplified and full qualified registry self-nomination process.

TABLE 65: Change in Estimated Burden for Simplified Qualified Registry Self-Nomination

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Time (hr) (a)	0
Total Annual Time (hr) for Respondents in CY 2024 PFS proposed rule (b) (See Table 64, row (c))	45
Difference (c) = (b) - (a)	**+45**
Total Currently Approved Annual Cost (d)	$0
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 64, row (e))	$4,653
Difference (f) = (e) - (d)	**+$4,653**

(b) Full Qualified Registry Self-Nomination Process

Based on the number of applications we expect to receive during the CY 2023 self-nomination period for the CY 2024 performance period/2026 MIPS payment year, we estimate 36 qualified registries would submit applications using the full self-nomination process. This is a decrease of 96 from the currently approved estimate of 132 for the qualified registry self-nomination process (87 FR 70140). We note we are not making any changes to our currently approved per response time estimate of 0.5 hours for the simplified qualified registry self-nomination process and 2 hours for the full qualified registry self-nomination process (87 FR 70139 through 70140).

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 data on MIPS eligible clinicians.

In Table 66, we assume 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 $103.40/hr. We estimate the burden per response would be $206.80 (2 × 103.40/hr) for the full self-nomination process. In aggregate, for the CY 2024 performance period/2026 MIPS payment year, we estimate that the annual burden for the full qualified registry self-nomination process would be 72 hours (36 responses × 2 hr) at a cost of $7,445 (36 applications × $206.80/application).

TABLE 66: Estimated Burden for Qualified Registry Full Self-Nomination

Burden and Respondent Descriptions	Burden Estimate
# of Qualified Registry Full Self-Nomination Applications submitted (a)	36
Annual Hours Per Qualified Registry for Full Process (b)	2
Total Annual Hours for Full Self-Nomination (c) = (a) * (b)	**72**
Cost per Application at Labor Cost (computer systems analyst's labor rate of $103.40/hr) (d)	$206.80
Total Annual Cost (e) = (a) * (d)	**$7,445**

In Table 67, we use the currently approved burden as the baseline for calculating the net change in burden for the simplified qualified registry self-nomination process. We note that we discussed the estimated burden for the

full qualified registry self-nomination process under ''maximum burden'' in Table 107 in the CY 2023 PFS final rule (87 FR 70140). For the CY 2024 performance period/2026 MIPS payment year, the change in the representation of burden for this ICR described above results in a decrease of 192 hours and a decrease of $19,853 for the full qualified registry self-nomination process. We note the decrease in burden accounts for the changes due to separating the estimated burden based on the simplified and full qualified registry self-nomination process.

TABLE 67: Change in Estimated Burden for Full Qualified Registry Self-Nomination

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Time (hr) (a)	264
Total Annual Time (hr) for Respondents in CY 2024 PFS proposed rule (b) (See Table 66, row (c))	72
Difference (c) = (b) - (a)	**-192**
Total Currently Approved Annual Cost (d)	$27,298
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 66, row (e))	$7,445
Difference (f) = (e) - (d)	**-$19,853**

(4) Third Party Intermediary Plan Audits

The following proposed changes associated with developing the plans and audits by QCDRs and qualified registries will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

(a) Targeted Audits

In the CY 2022 PFS final rule (86 FR 65547 through 65548), we finalized that beginning with the CY 2021 performance period/CY 2023 MIPS payment year, the QCDR or qualified registry must conduct targeted audits in accordance with requirements at § 414.1400(b)(3)(vi). Consistent with our assumptions in the CY 2022 PFS and CY 2023 PFS final rules for the QCDRs (86 FR 65574 and 87 FR 70141 respectively) and qualified registries (86 FR 65571 and 87 FR 70141 respectively) that would submit the results of targeted audits, we estimate the time required for a QCDR or qualified registry to submit a targeted audit ranges between 5 and 10 hours for the simplified and full self-nomination process, respectively. We assume the staff involved in submitting the targeted audits will continue to be computer systems analysts or their equivalent, who have an average labor rate of $103.40/hr.

Based on the number of data validation execution reports submitted for the CY 2021 performance period/2023 MIPS payment year, we estimate that 33 third party intermediaries (13 QCDRs and 20 qualified registries) will submit targeted audits for the CY 2024 performance period/2026 MIPS payment year (See Table 68). We estimate that the cost for a QCDR or a qualified registry to submit a targeted audit will range from $517 (5 hr × $103.40/hr) to $1,034 (10 hr × $103.40/hr). In aggregate, we estimate an annual burden ranging from 165 hours (33 responses × 5 hr/audit) and $17,061 (33 targeted audits × $517/audit) to 330 hours (33 responses × 10 hr/audit) and $34,122 (33 targeted audits × $1,034/audit) (see Table 69 for the cost per audit).

(b) Participation Plans

In the CY 2022 PFS final rule (86 FR 65546), we finalized requirements for approved QCDRs and qualified registries that did not submit performance data and therefore will need to submit a participation plan as part of their self-nomination process. We refer readers to § 414.1400(e) for additional details on policies for remedial action and termination of third-party intermediaries.

Consistent with our assumptions in the CY 2023 PFS final rule for the QCDRs and qualified registries (87 FR 70141) that will submit participation plans, we estimate that it will take 3 hours for a QCDR or qualified registry to submit a participation plan during the self-nomination process. We assume the staff involved in submitting a participation plan will continue to be computer systems analysts or their equivalent, who have an average labor rate of $103.40/hr.

As shown in Table 68, we are not changing our currently approved estimate that 75 third party intermediaries [five self-nomination participation plans (two QCDRs and three qualified registries) and 70 QCDR measure participation plans] will submit participation plans for the CY 2024 performance period/2026 MIPS payment year.

In Table 69, we estimate that the cost for a QCDR or a qualified registry to submit a participation plan is $310.20 (3 hours × $103.40/hr). In aggregate, we estimate the total impact associated with QCDRs and qualified registries to submit participation plans would be 225 hours (75 participation plans × 3 hr/plan) at a cost of $23,265 (75 participation plans × $310.20/plan) (see Table 69 for the cost per audit).

(c) Corrective Action Plans (CAPs)

In the CY 2017 Quality Payment Program final rule, we established the process for corrective action plans (CAPs) (81 FR 77386 through 77389). In section IV.A.4.k.(6)(b), we are proposing an additional provision at § 414.1400(e)(2)(iv) to allow us to immediately or with advance notice terminate a third party intermediary that has not maintained current contact information for correspondence. Additionally, we propose to add at § 414.1400(e)(2)(v) that we may terminate third party intermediaries that are on remedial action for two consecutive years. We are not proposing any changes to our currently approved estimated burden due to these proposals because these changes provide additional rationale for remedial action policies and do not add any additional requirements for third party intermediaries.

Based on the increased number of QCDR and qualified registries that required remedial actions for the CY 2022 performance period/2024 MIPS payment year, we anticipate the same

trend would continue for the CY 2024 performance period/2026 MIPS payment year. Therefore, we estimate 17 third party intermediaries will submit CAPs for the CY 2024 performance period/2026 MIPS payment year. This is an increase of seven respondents from the currently approved estimate of ten (87 FR 70142). We are not changing our currently approved estimate of 3 hours for a QCDR or qualified registry to submit a CAP. We also assume the staff involved in submitting the CAP will continue to be computer systems analysts or their equivalent, who have an average labor rate of $103.40/hr. As shown in Table 69, we estimate that the cost for a QCDR or a qualified registry to submit a CAP is $310.20 (3 hours × $103.40/hr). In aggregate, we estimate the total impact associated with QCDRs and qualified registries to CAPs will be 51 hours (17 CAPs × 3 hr/plan) at a cost of $5,273 (17 CAPs × $310.20/plan).

(d) Transition Plans

In the CY 2020 PFS final rule (84 FR 63052 through 63053), we established a policy at § 414.1400(a)(4)(vi) which states a condition of approval for the third party intermediary is to agree that 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 transition plan. In this rule, we estimate we will receive five transition plans for the CY 2024 performance period/2026 MIPS payment year. This adjustment would result in a decrease of five from the currently approved estimate of 10 (87 FR 70142). We continue to estimate it will take approximately 1 hour for a computer system analyst or their equivalent at a labor rate of $103.40/hr to develop a transition plan on behalf of each QCDR or qualified registry during the self-nomination period. However, we are unable to estimate the burden for implementing the actions in the transition plan because the level of effort may vary for each QCDR or qualified registry. In aggregate, we estimate the impact associated with qualified registries completing transition plans is 5 hours (5 transition plans × 1 hr/plan) at a cost of $517 (5 hr × $103.40/hr). We refer readers to section VII.E.23.e.(2)(a) of this proposed rule where we discuss our impact analysis for the transition plans submitted by QCDRs and qualified registries.

In section IV.A.4.k.(6)(c) of this rule, we are proposing at § 414.1400(e)(1)(i)(F) an additional requirement for the QCDR or qualified registry under a corrective action plan to communicate the final resolution to CMS once the resolution is complete and to provide an update, if any, to the monitoring plan provided under § 414.1400(e)(1)(i)(C). We believe the proposed revision would ensure third party intermediaries complete the requirements within the communication plan and would not add any additional requirements for a third-party intermediary to submit a CAP.

In section IV.A.4.k.(6)(d) of this rule, we are proposing to add a new provision at § 414.1400(e)(1)(ii)(B) that we may publicly disclose on the CMS website that CMS took remedial action on the third party intermediary or terminated it. We are also proposing to modify § 414.1400(e)(1)(ii) by redesignating it as § 414.1400(a)(2)(ii)(A) and ending the policy after the CY 2025 MIPS reporting period/CY 2027 MIPS payment year.

In section IV.A.4.k.(6)(e) of this rule, we are proposing to modify § 414.1400(a)(2)(ii)(A) to state that our consideration can include past compliance including remedial actions. We are proposing at § 414.1400(f) that third party intermediaries may be randomly selected for compliance evaluation or may be selected at the suggestion of CMS if there is an area of concern regarding the third party intermediary. We are also proposing to redesignate the existing section § 414.1400(f) (which includes paragraphs (f)(1), (2), and (3)) as paragraph (a)(3)(vii) with no changes in the text.

We do not expect to receive additional information from QCDRs and qualified registries during the self-nomination process due to the above proposed policies and therefore, are not proposing any adjustments to the currently approved burden estimates for third party intermediary plan audits. Additionally, we refer readers to section VII.E.23.e.(2)(a) of this proposed rule where we discuss the details in our impact analysis for these policies.

(e) Final Burden for Third Party Intermediary Plan Audits

In aggregate, as shown in Table 68, we assume that 130 third party intermediaries will submit plan audits (33 targeted audits, 75 participation plans, 17 CAPs, and 5 transition plans).

TABLE 68: Estimated Number of Respondents to Submit Plan Audits

Burden and Respondent Descriptions	# of Respondents
# of Targeted Audits (a)	33
# of Participation Plans (b)	75
# of Corrective Action Plans (CAPs) (c)	17
# of Transition Plans (d)	5
Total Respondents (e) = (a) + (b) + (c) + (d)	**130**

In Table 69, we assume that the staff involved in the submission of the plan audits during the third party intermediary self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $103.40/hr. For the CY 2024 performance period/2026 MIPS payment year, in aggregate, the proposed estimated annual burden for the submission of third party intermediary plan audits will range from 446 hours to 611 hours at a cost ranging from $46,116 (446 hr × $103.40/hr) and $63,177 (611 hr × $103.40/hr) (see Table 69).

TABLE 69: Estimated Burden for Third Party Intermediary Plan Audits

Burden and Respondent Descriptions	Simplified Process	Full Process
# of Hours per Completion of Targeted Audit (a)	5	10
Total Annual Hours for Completion of 33 Targeted Audits (b)	**165**	**330**
# of Hours per Submission of Participation Plan (c)	3	3
Total Annual Hours for Submission of 75 Participation Plans (d)	**225**	**225**
# of Hours per Submission of CAP (e)	3	3
Total Annual Hours for Submission of 17 CAPs (f)	**51**	**51**
# of Hours per Submission of Transition Plan (g)	1	1
Total Annual Hours for Submission of 5 Transition Plans (h)	**5**	**5**
Total Annual Hours for Submission of Plan Audits (i) = (b) + (d) + (f) + (h)	**446**	**611**
Cost Per Targeted Audit (@ computer systems analyst's labor rate of $103.40/hr) (j) = (a) * $103.40/hr	$517	$1,034
Cost Per Participation Plan (@ computer systems analyst's labor rate of $103.40/hr) (k) = (c) * $103.40/hr	$310.20	$310.20
Cost per CAP (@ computer systems analyst's labor rate of $103.40/hr) (l) = (e) * $103.40/hr	$310.20	$310.20
Cost per Transition Plan @computer systems analyst's labor rate of $103.40/hr (m) = (g) * $103.40/hr	$103.40	$103.40
Total Annual Cost (n) = 33 * (j) + 75 * (k) + 17 * (l) + 5 * (m) (simplified) and 33 * (j) + 75 * (k) + 17 * (l) + 5 * (m) (full)	**$46,116**	**$63,177**

In Table 70, for the CY 2024 performance period/2026 MIPS payment year, the change in the number of respondents for third party intermediary plan audits results in a change of +21 hours at a cost of +$2,171 for the simplified self-nomination process and +26 hours at a cost of +$2,688 for the full self-nomination process.

We note for the purposes of calculating proposed estimated change in burden in Tables 96 through 98 of this rule, we use only estimated burden for the plan audits submitted under the full self-nomination process.

TABLE 70: Change in Estimated Burden for Third Party Intermediary Plan Audits

Burden and Respondent Descriptions	Simplified Process	Full Process
Total Currently Approved Annual Hours (a)	425	585
Total Annual Hours for Respondents in CY 2023 PFS final rule (b) (See Table 69, row (i))	446	611
Difference (c) = (b) - (a)	**+21**	**+26**
Total Currently Approved Annual Cost (d)	$43,945	$60,489
Total Annual Cost for Respondents in CY 2023 PFS final rule (e) (See Table 69, row (n))	$46,116	$63,177
Difference (f) = (e) - (d)	**+$2,171**	**+$2,688**

(5) Survey Vendor Requirements

The following proposed changes associated with CAHPS survey vendors to submit data for eligible clinicians will be submitted to OMB for review under control number 0938–1222 (CMS–10450). We note that the associated burden will be made available for public review and comment under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices.

We refer readers to § 414.1400(d) for the requirements for CMS-approved survey vendors that may submit data on the CAHPS for MIPS Survey.

In this rule, we are adjusting the estimated number of vendors that will apply to participate as CAHPS for MIPS Survey vendors that were previously approved in the CY 2018 Quality Payment Program final rule (82 FR 53908). We estimate that we will receive approximately 10 survey vendor applications for the CY 2024 performance period/2026 MIPS payment year. This adjustment will result in a decrease of 5 survey vendor applications from our currently approved estimate of 15 vendors in the CY 2018 QPP final rule (82 FR 53908). As shown in Table 71, for the CY 2024 performance period/2026 MIPS payment year, we continue to estimate that the per response time is 10 hours. This will result in an estimated annual

burden of 100 hours (10 survey vendor applications × 10 hr/application) at a cost of $10,340 (10 applications × $1,034/application)).

TABLE 71: Estimated Burden for Survey Vendor Requirements

Burden and Respondent Descriptions	Burden Estimate
# of Survey Vendor Applications (a)	10
# of Hours Per Computer Systems Analyst (b)	10
Total Annual Hours (c) = (a) * (b)	**100**
Cost to Submit a Survey Vendor Application (computer systems analyst @ $103.40/hr) (d)	$1,034
Total Annual Cost (e) = (a) * (d)	**$10,340**

In Table 72, we illustrate the net change in estimated burden for survey vendor requirements using the currently approved burden in the CY 2018 QPP final rule (82 FR 53908). In aggregate, using our currently approved per response time estimate, the decrease in the number of respondents participating as CAHPS for MIPS Survey vendors would result in a total annual adjustment of -50 hours (-5 responses × 10 hr/application) at a cost of -$5,170 (-5 × (10 hr × $103.40/hr)) for the CY 2024 performance period/2026 MIPS payment year.

TABLE 72: Change in Estimated Burden for Survey Vendor Requirements

Burden and Respondent Descriptions	CY 2024 Performance Period
Total Currently Approved Annual Hours (a)	150
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (See Table 71, row (d))	100
Difference (c) = (b) - (a)	**-50**
Total Currently Approved Annual Cost (d)	$15,510
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 71, row (i))	$10,340
Difference (f) = (e) - (d)	**-$5,170**

d. ICRs Regarding Open Authorization (OAuth) Credentialing and Token Request Process

This rule is not proposing any new or revised collection of information requirements or burden related to the OAuth credentialing and token request process. The requirements and burden for the OAuth credentialing and token request process are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to the OAuth credentialing and token burden under that control number.

e. ICRs Regarding Quality Data Submission (§§ 414.1318, 414.1325, 414.1335, and 414.1365)

(1) Background

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77502 through 77503 and 82 FR 53908 through 53912, respectively), the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 60000 through 60003, 84 FR 63121 through 63124, 85 FR 84970 through 84974, 86 FR 65576 through 65588, and 87 FR 70145 through 70154, respectively) for our previously finalized estimated burden associated with data submission for the quality performance category.

Under our current policies, two groups of clinicians must submit quality data under MIPS: those who submit data as MIPS eligible clinicians, and those who 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 Advanced APM payment and patient percentages from the APM Participant List for the third snapshot date for the 2022 QP Performance period. From this data, we calculated the QP determinations as described in the Qualifying APM Participant (QP) definition at § 414.1305 for the CY 2024 performance period/2026 MIPS payment year. 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 for the CY 2024 performance period/2026 MIPS payment year (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 CY 2019 performance period/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). We note in this proposed rule, we are using the same CY 2021 performance period/2023 MIPS payment year submissions data used in the 2023 PFS Final Rule (87 FR 70145 through 70148).

We assume 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 2021, CY 2022 and CY 2023 PFS final rules (85 FR 84972, 86 FR 65567 and 87 FR 70145), we include all quality data voluntarily submitted by MIPS APM participants at the individual or TIN-level in our respondent estimates. As stated in section V.B.11.a.(4) of this proposed 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 CY 2024 performance period/2026 MIPS payment year, we used the Advanced APM payment and patient percentages from the APM Participant List for the final snapshot date for the 2021 QP performance period. We elected to use this data source because the overlap with the data submissions for the CY 2019 performance period/2021 MIPS payment year enabled the exclusion of Partial QPs that elected to not participate in MIPS and required fewer assumptions as to who is a QP or not. 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 2021 performance period/2023 MIPS payment year.

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 associated burden is excluded from this collection of information section but is discussed in the regulatory impact analysis section of this proposed rule because 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.[334]

For the CY 2024 performance period/2026 MIPS payment year, respondents will have the option to submit quality performance category data via Medicare Part B claims, direct, and log in and upload submission types. We estimate the burden for collecting data via collection type: Medicare Part B claims, QCDR and MIPS CQMs, and eCQMs. Additionally, we capture the burden for clinicians who choose to submit via these collection types for the quality performance category of MVPs. 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 maintaining consistency with previous rulemaking.

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 CY 2021 performance period/2023 MIPS payment year. 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 73 uses methods similar to those described above to estimate the number of MIPS eligible clinicians that will submit data as individual clinicians via each collection type in the CY 2024 performance period/2026 MIPS payment year. For the CY 2024 performance period/2026 MIPS payment year, we estimate approximately 14,402 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 11,197 clinicians will submit data as individuals using MIPS CQM and QCDR collection type; and approximately 17,944 clinicians will submit data as individuals using eCQMs collection type. Based on performance data from the CY 2021 performance period/2023 MIPS payment year, these are decreases of 334, 261, and 418 respondents from the currently approved estimates of 14,736, 11,458, and 18,362 for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, respectively.

[334] 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.

TABLE 73: Estimated Number of Clinicians Submitting Quality Performance Category Data as Individuals by Collection Type

Burden and Respondent Description	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	Total
2024 MIPS performance period (excludes QPs) (a)	16,746	13,020	20,865	50,632
MVP Adjustment @ 14% (b) = (a)* 0.14	-2,344	-1,823	-2,921	-7,091
2024 MIPS Performance Period (excludes QPs and Adjusted for MVP) (c)= (a) – (b)	**14,402**	**11,197**	**17,944**	**43,541**
**Currently approved 2023 MIPS Performance Period (excludes QPs) (d)	14,736	11,458	18,362	44,556
Difference (e) = (c) – (d)	**-334**	**-261**	**-418**	**-1,015**

* We estimate 14 percent of clinicians will participate in MVP reporting as discussed in section V.11.e.(7) of this rule.

**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 73 are not mutually exclusive.

Table 74 provides our estimated counts of groups or virtual groups that will submit quality data on behalf of clinicians for each collection type in the CY 2024 performance periods/2026 MIPS payment year. We assume clinicians who submitted quality data as groups in the CY 2021 performance period/2023 MIPS payment year will continue to submit quality data either as groups, or virtual groups for the same collection types for the 2024 performance period/2026 MIPS payment years. We used the same methodology described in the CY 2022 PFS final rule (86 FR 65577) on our assumptions related to the use of an alternate collection type for groups that submitted data via the CMS Web Interface collection type for the CY 2021 performance period/2023 MIPS payment year.

As shown in Table 74, for the CY 2024 performance period/2026 MIPS payment year we estimate 6,312 groups and virtual groups will submit data for the MIPS CQM and QCDR collection type and 5,402 groups and virtual groups will submit for eCQM collection types. These are decreases of 146 and 125 respondents from the currently approved estimates of 6,458, and 5,527 for the groups and virtual groups that will submit data using MIPS CQM and QCDR, and eCQM collection types, respectively.

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 will participate through traditional MIPS and base our estimates on submissions received in the CY 2021 performance period/2023 MIPS payment year.

TABLE 74: Estimated Number of Groups and Virtual Groups Submitting Quality Performance Category Data by Collection Type

Burden and Respondent Description	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	Total
2024 MIPS performance period (excludes QPs) (a) prior to adjustments	0	7,339	6,281	13,620
Adjustment for MVPs (14%) (b) = (a) * 0.14	0	-1,027	-879	-1,906
2024 MIPS performance period (excludes QPs and) Adjusted for MVP). (c) = (a) – (b)	0	**6,312**	**5,402**	**11,714**
**Currently approved 2023 MIPS performance period (excludes QPs) (d)	0	6,458	5,527	11,985
Difference (e) = (d) - (c) - (d)	0	**-146**	**-125**	**-271**

* We estimate 12 percent of clinicians will participate in MVP reporting as discussed in section V.B.11.e.7. of this rule.

**Currently approved by OMB under control number 0938-1314 (CMS-10621) from the CY 2021 PFS final rule.

The burden associated with the submission of quality performance category data has 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 Electronic Health Record (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. Additionally, as finalized in the CY 2022 PFS final rule (86 FR 65394 through 65397), group TINs could also choose to participate as subgroups for MVP reporting beginning with the CY 2023 performance period/2025 MIPS payment year. We refer readers to the CY 2022 PFS final rule for additional details on MVP quality reporting requirements (86 FR 65411 through 65412).

In terms of the quality measures available for clinicians and groups to report for the CY 2024 performance period/2026 MIPS payment year, we propose a measure set of 200 quality measures. The new MIPS quality measures proposed for inclusion in MIPS for the CY 2024 performance period/2026 MIPS payment year and future years are found in Table Group A of Appendix 1; MIPS quality measures with substantive changes can be found in Table Group D of Appendix 1; and MIPS quality measures proposed for removal can be found in Table Group C of Appendix 1. These measures are stratified by collection type in Table 75, as well as counts of new, removed, and substantively changed measures. There are no changes to the remaining measures not included in Appendix 1. We refer readers to Appendix 1: MIPS Quality Measures of this proposed rule for additional information.

TABLE 75: Summary of Quality Measures Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year

Collection Type	# Measures Proposed as New	# Measures Proposed for Removal*	# Measures Proposed with a Substantive Change*	# Measures Proposed for CY 2024*
Medicare Part B Claims	0	-4	10	26
MIPS CQMs Specifications	+13	-11	51	174
eCQM Specifications	+1	-3	26	45
Survey – CSV	0	0	0	1
Administrative Claims	0	0	0	4
Total*	+14	-12**	59	200

*A measure may be specified under multiple collection types but will only be counted once in the total.
**We are proposing to remove 12 MIPS quality measures and partially remove 3 MIPS quality measures that are proposed for removal from traditional MIPS and proposed for retention for use in MVPs. NOTE: The 3 MIPS quality measures that are proposed for partial removal from traditional MIPS are not included in the total number of measures proposed for removal from MIPS starting with the CY 2024 performance period.

For the CY 2024 performance period/2026 MIPS payment year, we are proposing 200 measures, a net increase of 2 quality measures across all collection types compared to the currently approved estimate of 198 measures. Specifically, as discussed in section IV.A.4.f.(1)(e) of this rule, we are proposing to add 14 new MIPS quality measures, remove 12 MIPS quality measures, partially remove 3 MIPS quality measures that are proposed for removal from traditional MIPS and proposed for retention for use in MVPs, and make substantive updates to 59 MIPS quality measures. We do not anticipate our provision to remove 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 does not propose any new or revised collection of information requirements or burden related to the identity management application process. The identity management application process requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes for the identity management application process under that control number.

(4) Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

This rule does not propose any new or revised collection of information requirements or burden related to the submission of Medicare Part B claims data for the quality performance category. Our updated estimate for MVP participation due to policy changes to the MVP inventory as discussed in section IV.A.4.a. of this rule, impacts the number of clinicians submitting quality data for MIPS using the Medicare Part B Claims-based collection type. We refer readers to Table 79 of this section for the change in associated burden related to the submission of Medicare Part B claims data for the MVP quality performance category in the CY 2024 performance period/2026 MIPS payment year.

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77501 through 77504 and 82 FR 53912, respectively), the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 60004 through 60005, 84 FR 63124 through 63126, 85 FR 84975 through 84976, 86 FR 65582 through 65584, and 87 FR 70149 through 70151 respectively) for our previously finalized requirements and burden for quality data submission via the Medicare Part B claims collection type.

As noted in Table 73, we estimate that 14,402 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type, a decrease of 334 from the currently approved estimate of 14,736 (87 FR 70150).

In Table 76, consistent with our currently approved per response time figures and using the updated wage rates in Table 54 of this proposed rule, we continue to estimate the burden of quality data submission using Medicare Part B claims will range from 0.15 hours (9 minutes) at a cost of $15.51 (0.15 hr × $103.40) for a computer systems analyst to 7.2 hours at a cost of $744.48 (7.2 hr × $103.40/hr). The burden also accounts for the effort needed to become familiar with MIPS quality measure specifications.

Consistent with our currently approved per response time estimates and using the updated wage rates in Table 54 of this proposed rule, we believe that the start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of 3 hours for a medical and health services manager at $123.06/hr, 1 hour for a physician at $274.44/hr, 1 hour for an LPN at $53.72/hr, 1 hour for a computer systems analyst at $103.40/hr, and 1 hour for a billing and posting clerk at $43.08/hr.

In Table 76, considering both data submission and start-up requirements for our adjusted number of clinicians, 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 aggregate, the total annual time for the CY 2024 performance period/2026 MIPS payment year ranges from 102,974 hours (7.15 hr × 14,402 clinicians) to 204,508 hours (14.2 hr × 14,402 clinicians). The total annual cost for the CY 2024 performance period/2026 MIPS payment year ranges from a

minimum of $12,376,071 to a maximum of $22,874,697.

TABLE 76: Estimated Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

Burden and Respondent Descriptions	Minimum Burden	Median Burden	Maximum Burden
# of Clinicians (a)	14,402	14,402	14,402
Hours Per Computer Systems Analyst 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)	**102,974**	**115,936**	**204,508**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $103.40/hr @ varying times) (j)	$15.51	$108.57	$744.48
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $123.06/hr @ 3 hr) (k)	$369.18	$369.18	$369.18
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $103.40/hr @ 1 hr) (l)	$103.40	$103.40	$103.40
Cost to Review Measure Specifications (@ LPN's labor rate of $53.72/hr @1 hr) (m)	$53.72	$53.72	$53.72
Cost to Review Measure Specifications (@ billing clerk's labor rate of $43.08/hr @ 1 hr) (n)	$43.08	$43.08	$43.08
Cost to Review Measure Specifications (@ physician's labor rate of $274.44/hr @ 1 hr) (o)	$274.44	$274.44	$274.44
*Total Annual Cost Per Clinician (p) = (j) + (k) + (l) + (m) + (n) + (o)	$859.33	$952.39	$1,588.30
*Total Annual Cost (q) = (a) * (p)	**$12,376,071**	**$13,716,321**	**$22,874,697**

In Table 77, we used the currently approved burden as the baseline to calculate the net burden for the quality data submissions from clinicians using the Medicare Part B Claims-based collection type. In aggregate, using our currently approved per response time estimates, the decrease in number of responses from 14,736 to 14,402 (−334) results in a total maximum adjustment of −4,743 hours (−334 responses × 14.2 hr/response) at a cost of −$530,492 (−334 response × $1,588.30/response). For purposes of calculating total burden associated with this proposed rule as shown in Tables 99 through 101, only the maximum burden is used.

TABLE 77: Burden Adjustments for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	209,251
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (see Table 76, row (i))	204,508
Difference (c) = (b) - (a)	**-4,743**
Total Currently Approved Annual Cost (d)	$23,405,189
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (see Table 76, row (q)	$22,874,697
Difference (f) = (d) - (e)	**-530,492**

(5) Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77504 through 77505 and 82 FR 53912 through 53914, respectively), the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 60005 through 60006, 84 FR 63127 through 63128, 85 FR 84977 through 84979, 86 FR 65584 through 65586, and 87 FR 70151 through 70153, respectively) for our previously finalized requirements and burden for quality data submission via the MIPS CQM and QCDR collection types. We refer readers to Table 74 for the estimated change in associated burden for quality data submission using MIPS CQM and QCDR collection types related to MVP and subgroup reporting in the CY 2024 performance period/2026 MIPS payment year.

As noted in Tables 73 and 74, based on data from the CY 2021 performance period/2023 MIPS payment year, for the CY 2024 performance period/2026 MIPS payment year, we assume that 17,509 clinicians (11,197 individuals and 6,312 groups and virtual groups) will submit quality data as individuals or groups using MIPS CQM or QCDR collection types. This is a decrease of 407 clinicians from the currently approved estimate of 17,916 clinicians provided in the CY 2023 PFS final rule (87 FR 70152). Given the number of measures required for clinicians and groups is the same, 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 the burden for an individual clinician or group to review measure specifications and submit quality data is a total of 9 hours at a cost of $1,039.54 per response. This consists of 3 hours at $103.40/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $123.06/hr for a medical and health services manager, 1 hour at $103.40/hr for a computer systems analyst, 1 hour at $53.72/hr for a LPN, 1 hour at $43.08/hr for a billing clerk, and 1 hour at $274.44/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 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 hr) at $103.40/hr for a computer systems analyst at a cost of $8.15 (0.083 hr × $103.40/hr). Overall, we estimate 9.083 hr/response (3 hr + 2 hr + 1 hr + 1 hr + 1 hr + 1 hr + 0.083 hr) at a cost of $1,039.54/response [(3 hr × $103.40/hr) + (2 hr × $123.06/hr) + (1 hr × $274.44/hr) + (1 hr × $103.40/hr) + (1 hr × $53.72/hr) + (1 hr × $43.08/hr) + (0.083 hr × $103.40/hr)].

In Table 78, for the CY 2024 performance period/2026 MIPS payment year, in aggregate, we estimate a burden of 159,034 hours [9.083 hr/response × 17,509 responses] at a cost of $18,201,306 (17,509 responses × $1,039.54/response).

TABLE 78: Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

Burden and Respondent Descriptions	Burden Estimate
# of clinicians submitting as individuals (a)	11,197
# of groups submitting via QCDR or MIPS CQM on behalf of individual clinicians (b)	6,312
Total # of Respondents (c) = (a) + (b)	**17,509**
Hours Per Respondent to Report Quality Data (d)	3
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1
# of Hours LPN Review Measure Specifications (g)	1
# of Hours Billing Clerk Review Measure Specifications (h)	1
# of Hours Physician Review Measure Specifications (i)	1
# of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf (j)	0.083
Annual Hours Per Respondent (k)= (d) + (e) + (f) + (g) + (h) + (i) + (j)	9.083
Total Annual Hours (l) = (c)*(k)	**159,034**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $103.40/hr) (m)	$310.20
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $123.06/hr) (n)	$246.12
Cost Computer System's Analyst Review Measure Specifications (@ computer systems analyst's labor rate of $103.40/hr) (o)	$103.40
Cost LPN Review Measure Specifications (@ LPN's labor rate of $53.72/hr) (p)	$53.72
Cost Billing Clerk Review Measure Specifications (@ clerk's labor rate of $43.08/hr) (q)	$43.08
Cost Physician Review Measure Specifications (@ physician's labor rate of $274.44/hr) (r)	$274.44
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (@ computer systems analyst's labor rate of $103.40/hr) (s)	$8.58
Total Annual Cost Per Respondent (t) = (m) + (n) + (o) + (p) + (q) + (r) + (s)	$1,039.54
Total Annual Cost (u) = (c) * (t)	**$18,201,306**

In Table 79, we calculated the net change in estimated burden for quality performance category submissions using the MIPS CQM and QCDR collection type by using the currently approved burden in the CY 2023 PFS final rule (87 FR 70151 through 70153). In aggregate, using the unchanged currently approved time per response estimate, the decrease of 407 respondents from 17,916 to 17,509 for the CY 2024 performance period/2026 MIPS payment year results in a decrease of 3,697 hours (-407 responses $\times$ 9.083 hr/response) at a cost of $-$$423,093 (-407 responses $\times$ $1,039.54/response).

TABLE 79: Burden Adjustments for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	162,731
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (see Table 78, row (l))	159,034
Difference (c) = (b) - (a)	**-3,697**
Total Currently Approved Annual Cost (d)	$18,624,399
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (see Table 78, row (u))	$18,201,306
Difference (f) = (e) - (d)	**-423,093**

(6) Quality Data Submission by Clinicians and Groups: eCQM Collection Type

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77505 through 77506 and 82 FR 53914 through 53915), CY 2019 PFS final rule (83 FR 60006 through 60007), CY 2020 PFS final rule (84 FR 63128 through 63130), CY 2021 PFS final rule (85 FR 84979 through 84980), the CY 2022 PFS final rule (86 FR 65586 through 65588), and the CY 2023 PFS final rule (87 FR 70153 through 70154) for our previously finalized requirements and burden for quality data submission via the eCQM collection types. For the change in associated burden for quality data submission related to the provisions introducing MVP and subgroup reporting beginning in the CY 2024 performance period/2026 MIPS payment year, we refer readers to Table 84.

Based on updated data from the CY 2022 performance period/2024 MIPS payment year data, we assume that 23,346 clinicians will submit quality data using the eCQM collection type for the CY 2024 performance period/2026 MIPS payment year. This is a decrease of 543 clinicians from the estimate of 23,889 clinicians provided in the CY 2023 PFS final rule (87 FR 70153). We assume 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 certified EHR technology (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 $103.40/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 $123.06/hr for a medical and health services manager, 1 hour at $274.44/hr for a physician, 1 hour at $103.40/hr for a computer systems analyst, 1 hour at $53.72/hr for an LPN, and 1 hour at $43.08/hr for a billing clerk. Overall, we estimate a cost of $927.56/response [(2 hr × $103.40/hr) + (2 hr × $123.06/hr) + (1 hr × $274.44/hr) + (1 hr × $103.40/hr) + (1 hr × $53.72/hr) + (1 hr × $43.08/hr)].

In Table 80, for the CY 2024 performance period/2026 MIPS payment year, in aggregate, we estimate a burden of 186,768 hours [8 hr × 23,346 responses] at a cost of $21,654,816 (23,346 responses × $927.56/response).

TABLE 80: Estimated Burden for Quality Performance Category: Clinicians (Submitting Individually or as Part of a Group) Using the eCQM Collection Type

Burden and Respondent Descriptions	Burden Estimate
# of clinicians submitting as individuals (a)	17,944
# of Groups submitting via EHR on behalf of individual clinicians (b)	5,402
Total # of Respondents (c)=(a)+(b)	**23,346**
Hours Per Respondent to Submit MIPS Quality Data File to CMS (d)	2
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1
# of Hours LPN Review Measure Specifications (g)	1
# of Hours Billing Clerk Review Measure Specifications (h)	1
# of Hours Physicians Review Measure Specifications (i)	1
Annual Hours Per Respondent (j) = (d) + (e) + (f) + (g) + (h) + (i)	8
Total Annual Hours (k) = (c) * (j)	**186,768**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $103.40/hr) (l)	$206.80
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $123.06/hr) (m)	$246.12
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $103.40/hr) (n)	$103.40
Cost to Review Measure Specifications (@ LPN's labor rate of $53.72/hr) (o)	$53.72
Cost to Review Measure Specifications (@ clerk's labor rate of $43.08/hr) (p)	$43.08
Cost to Review Measure Specifications (@ physician's labor rate of $274.44/hr) (q)	$274.44
Total Cost Per Respondent (r)=(l)+(m)+(n)+(o)+(p)+(q)	$927.56
Total Annual Cost (s) = (c) * (r)	**$21,654,816**

In Table 81, we illustrate the net change in burden for submissions in the quality performance category using the eCQM collection type from the currently approved burden in the CY 2023 PFS final rule (87 FR 70153 through 70154). In aggregate, using our currently approved time per response burden estimate, the decrease of 543 respondents from 23,889 to 23,347 for the CY 2024 performance period/2026 MIPS payment year results in a decrease of 4,344 hours (−543 responses × 8 hr/response) at a cost of −$503,665 (−543 responses × $927.56/response).

TABLE 81: Burden Adjustments for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the eCQM Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	191,112
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (see Table 80, row (k))	186,768
Difference (c) = (b) - (a)	**-4,344**
Total Currently Approved Annual Cost (d)	$22,158,481
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (see Table 80, row (s))	$21,654,816
Difference (f) = (e) - (d)	**-$503,665**

(7) ICRs Regarding Burden for MVP Reporting

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

(a) Burden for MVP Reporting Requirements

In the CY 2022 PFS final rule, we finalized an option for clinicians choosing to report MVPs to participate through subgroups beginning with the CY 2023 performance period/2025 MIPS payment year (86 FR 65392 through 65394). We refer readers to the CY 2022 and CY 2023 PFS final rules for our previously finalized burden assumptions and requirements for submission data for the MVP performance category, and for the estimated number of clinicians participating as subgroups in the CY

2023 performance period/2025 MIPS payment year (86 FR 65590 through 65592 and 87 FR 70155).

In section IV.A.4.b. of this rule, we are proposing to add five new MVPs to the MVP Inventory. Additionally, we are proposing to consolidate the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single consolidated primary care MVP titled Value in Primary Care MVP. Therefore, MVP participants will have a total of sixteen MVPs available for the CY 2024 performance period/2026 MIPS payment year. Due to the availability of new MVPs, we expect an increase in the projected number of MVP participants. For each newly proposed MVP, we calculated the average quality measure submission rate across the measures available in each MVP for the CY 2021 performance period/2023 MIPS payment year. The total of these average quality measure submissions for each MVP was equivalent to about 2 percent of total quality measure submissions in the CY 2021 performance period/2023 MIPS payment year. We assume there would not be any changes to MVP submissions due to the proposed consolidation of the measures in the Promoting Wellness and Optimizing Chronic Disease Management MVPs into a Value in Primary Care MVP, discussed in section IV.A.4.b. of this rule. That is, we assume clinicians who would have submitted the Optimizing Chronic Disease Management MVP or the Promoting Wellness MVP would instead submit the Value in Primary Care MVP. Therefore, we estimate that 14 percent of the clinicians will participate in MVP reporting in the CY 2024 performance period/2026 MIPS payment year. This is an increase of 2 percentage points from the currently approved estimate of 12 percent in the CY 2023 PFS final rule (87 FR 70155). We refer readers to Appendix 3: MVP Inventory of this proposed rule for additional details on the MVPs proposed for the CY 2024 performance period/2026 MIPS payment year.

We assume the changes to the existing MVPs and the addition of new MVPs will not impact the currently approved number of subgroups. We expect clinician participation in subgroups will be relatively low for the CY 2024 performance period/2026 MIPS payment year due the voluntary subgroup reporting option and the additional burden involved for groups to organize clinicians into subgroups. Therefore, we did not make any adjustments to our previously finalized assumption in the CY 2023 PFS final rule (87 FR 70155) of 20 subgroups that will participate in MVP reporting.

(i) Burden for MVP Registration: Individuals, Groups and APM Entities

We refer readers to the CY 2023 PFS final rule (87 FR 70155 through 70156) for our previously finalized burden relevant to MVP registration for clinicians participating as an individual and/or group for MVP reporting.

As previously discussed, we estimate that approximately 14 percent of the clinicians that currently participate in MIPS will submit data for the measures and activities in an MVP. For the CY 2024 performance period/2026 MIPS payment year, we assume that the total number of individual clinicians, groups, subgroups and APM Entities that will complete the MVP registration process is 9,015. In Table 82, we estimate that it will take 2,254 hours (9,015 responses × 0.25 hr/response) at a cost of $233,038 (9,015 registrations × $25.85/registration) for individual clinicians, groups and APM Entities to register for MVPs in the CY 2024 performance period/2026 MIPS payment year.

TABLE 82: Estimated Burden for MVP Registration (Individual clinicians, Groups, Subgroups and APM Entities)

Burden and Respondent Descriptions	Burden Estimate
Estimated # of Individual clinicians, groups, subgroups and APM Entities Registering (a)	9,015
Estimated Time Per Registration (hr) (b)	0.25
Estimated Total Annual Time (hr) for MVP Registration (c) = (a) * (b)	**2,254**
Computer systems analyst's labor rate ($/hr). (d)	103.40
Estimated Cost Per Registration (e) = (d) * (b)	25.85
Estimated Total Annual Cost for MVP Registration (f) = (a) * (e)	**$233,038**

In Table 83, we illustrate the net change in burden for MVP registration using the currently approved burden in the CY 2023 PFS final rule (87 FR 70155 through 70156). In aggregate, for the CY 2024 performance period/2026 MIPS payment year, the adjustment in the number of respondents expected to register for MVP reporting from 7,731 to 9,015 results in an increase of 1,284 responses. In aggregate, when combined with the currently approved per response time estimate, this will result in an increase of 321 hours (2,254 hours − 1,933 hours) at a cost of $33,192 ($233,038 − $199,846).

TABLE 83: Burden Adjustment for MVP Registration: Individuals, Groups, and APM Entities

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	1,933
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (See Table 82, row (c))	2,254
Difference (c) = (b) - (a)	**321**
Total Currently Approved Annual Cost (d)	$199,846
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 82, row (e))	$233,038
Difference (f) = (e) - (d)	**$33,192**

(ii) Burden for Subgroup Registration

We are not proposing any changes to our previously finalized subgroup registration burden. We note that the proposed subgroup policies in section IV.A.4.d. of this rule do not impact the currently approved burden for subgroup registration. We discuss in detail below, the proposed policies and our reasons for not changing the currently approved burden for subgroup registration. The burden relevant to the subgroup registration requirement is currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes pertaining to subgroup registration under that control number.

In section IV.A.4.d.(2) of this rule, we are proposing to modify § 414.1365(e)(2)(ii) to read that, an MVP Participant that is a subgroup will receive the same reweighting that is applied to its affiliated group, but that for the CY 2023 MIPS performance period/2025 MIPS payment year, if reweighting is not applied to the affiliated group, the subgroup may receive reweighting in the circumstances independent of the affiliated group as described in § 414.1365(e)(2)(ii)(A) and (B). We believe that the proposed modification to the subgroup reweighting policy would not impact the currently approved burden for subgroup registration because it would not change any requirements related to subgroup registration.

In section IV.A.4.d.(3) of this rule, we are proposing to modify the text at § 414.1365(e)(3) to read that if an MVP Participant, that is not an APM Entity or a subgroup, is eligible for facility-based scoring, a facility-based score will also be calculated in accordance with § 414.1380(e). Additionally, we are proposing to add § 414.1365(e)(4)(i) to read that for subgroups, the affiliated group's complex patient bonus will be added to the final score. The proposed revisions would not impact the currently approved burden for subgroup registration since these changes only modify the regulatory text relevant to subgroup scoring policies.

In section IV.A.4.d.(4) of this rule, we are proposing to modify § 414.1385(a)(1) to read that a MIPS eligible clinician, subgroup, or group (including their designated support staff), or a third-party intermediary as defined at § 414.1305, may submit a request for a targeted review. The proposed change would not impact the currently approved burden for subgroup registration since the addition of subgroups to the targeted review language only modifies the regulatory text relevant to the targeted review process and does not change the subgroup registration requirements. We finalized in the CY 2017 Quality Payment Program final rule that a MIPS eligible clinician or group may request a targeted review of the calculation of the MIPS payment adjustment factor under section 1848(q)(6)(A) of the Act and, as applicable, the calculation of the additional MIPS payment adjustment factor under section 1848(q)(6)(C) of the Act (collectively referred to as the MIPS payment adjustment factors) applicable to such MIPS eligible clinician or group for a year (81 FR 77546). We note that information collection requirements, such as targeted reviews, that are imposed after an administrative action are not subject to the PRA under 5 CFR 1320.4(a)(2). Therefore, we are not making any adjustments to the currently approved subgroup registration burden because of the proposal to add subgroups to the targeted review regulation text.

(iii) Burden for MVP Quality Performance Category Submission.

In the CY 2022 PFS final rule (86 FR 65411 through 65415), we previously finalized the reporting requirements for the MVP quality performance category at § 414.1365(c)(1)(i). As discussed in section V.B.11.e. of this rule, we did not propose new requirements to submit data for the quality performance category of MVPs. Therefore, we did not propose any changes to our currently approved per response time estimates for submitting the MVP quality performance category data.

As described in section V.B.11.e.(7)(a) of this proposed rule, we estimate that 14 percent of the clinicians who participated in MIPS for the CY 2021 performance period/2023 MIPS payment year will submit data for the quality performance category of MVP in the CY 2024 performance period/2026 MIPS payment year. We also estimate there will be 20 subgroup reporters in the CY 2024 performance period/2026 MIPS payment year. In Table 84, we estimate that 3,801 clinicians and 10 subgroups will submit data using eCQMs collection type at $614.45/response (see line q for eCQMs); 2,850 clinicians and 10 subgroups will submit data using MIPS CQM and QCDR collection type at $683.73/response (see line q for CQM and QCDRs); and 2,344 clinicians and 0 subgroups will submit data for the MVP quality performance category using the Medicare Part B claims collection type at $1,055.70/response (see line q for claims). For the CY 2024 performance period/2026 MIPS payment year, using our currently approved per response time estimates for the clinicians and subgroups submitting data for the MVP quality performance category, we estimate a burden of 20,198 hours [5.3 hr × 3,811 (3,801 +10) responses] at a cost of $2,341,669 (3,811 responses × $614.45/response) for the eCQM collection type, 17,074 hours [5.97 hr × 2,860 (2,443 +10)] at a cost of $1,955,468 (2,860 responses × $683.73/responses) for the

MIPS CQM and QCDR collection type, and 18,974 hours (9.44 hr × 2,344 clinician responses) at a cost of $2,474,561 (2,344 responses × $1,055.70/response) for the Medicare Part B claims collection type.

TABLE 84: Estimated Burden for MVP Quality Performance Category Submission

Burden and Respondent Descriptions	eCQM Collection Type	CQM and QCDR Collection Type	Claims Collection Type
# of Submissions from pre-existing collection types (a)	3,801	2,850	2,344
# of Subgroup reporters (b)	10	10	0
Total MVP participants (c) = (a) + (b)	3,811	2,860	2,344
Hours Per Computer Systems Analyst to Submit Quality Data (d)	1.33	2	4.8
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	1.33	1.33	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	0.66	0.66	0.66
# of Hours LPN Review Measure Specifications (g)	0.66	0.66	0.66
# of Hours Billing Clerk Review Measure Specifications (h)	0.66	0.66	0.66
# of Hours Physician Review Measure Specifications (i)	0.66	0.66	0.66
Annual Hours per Clinician Submitting Data for MVPs (j) = (d) + (e) + (f) + (g) + (h) + (i)	5.3	5.97	9.44
Total Annual Hours (k) = (c) * (j)	**20,198**	**17,074**	**22,127**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $103.40/hr @ varying times) (k)	$137.52	$206.80	$496.32
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $123.06/hr) (l)	$163.67	$163.67	$246.12
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $103.40/hr) (m)	$68.24	$68.24	$68.24
Cost to Review Measure Specifications (@ LPN's labor rate of $53.72/hr) (n)	$35.46	$35.46	$35.46
Cost to Review Measure Specifications (@ billing clerk's labor rate of $43.08/hr) (o)	$28.43	$28.43	$28.43
Cost to Review Measure Specifications (@ physician's labor rate of $274.44/hr) (p)	$181.13	$181.13	$181.13
*Total Annual Cost Per Submission (q) = (k) + (l) + (m) + (n) + (o) + (p)	$614.45	$683.73	$1,055.70
***Total Annual Cost (r) = (c) * (q)**	**$2,341,669**	**$1,955,468**	**$2,474,561**

Table 85 illustrates the proposed changes in estimated burden for clinicians who will submit the MVP quality performance category utilizing the eCQM, MIPS CQM and QCDR, and claims collection types in the CY 2024 performance period/2026 MIPS payment year. We note we used the currently approved burden in the CY 2023 PFS final rule (87 FR 70157 through 70159) as the baseline to determine the net change in burden. In aggregate, when combined with our currently approved per response time estimate, the increase in 1,284 respondents who will submit data for the MVP quality performance category will result in an increase of 2,878 hours and $333,633 for the eCQM collection type, an increase of 2,430 hours and $278,273 for the CQM and QCDR collection type, and an increase of 3,153 hours and $352,599 for the claims collection type.

TABLE 85: Burden Adjustments for MVP Quality Performance Category Submission

Burden and Respondent Descriptions	eCQM Collection Type	CQM and QCDR Collection Type	Claims Collection Type
Total Currently Approved Annual Hours (a)	17,320	14,644	18,974
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (See Table 84, row (k))	20,198	17,074	22,127
Difference (c) = (b) - (a)	**2,878**	**2,430**	**3,153**
Total Currently Approved Annual Cost (d)	$2,008,036	$1,677,195	$2,121,962
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 84, row (r))	$2,341,669	$1,955,468	$2,474,561
Difference (f) = (e) - (d)	**$333,633**	**$278,273**	**$352,599**

(8) Beneficiary Responses to CAHPS for MIPS Survey

The following proposed changes associated with CAHPS survey vendors to submit data for eligible clinicians will be submitted to OMB for review under control number 0938–1222 (CMS–10450). We note that the associated burden will be made available for public review and comment under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices.

We refer readers to the CY 2021 Quality Payment Program final rule (85 FR 84982 through 84983) for our previously finalized estimated burden associated with beneficiary responses to the CAHPS for MIPS Survey.

In section IV.A.4.f.(1)(c)(ii) of this proposed rule, we are proposing to require Spanish language administration of the CAHPS for MIPS Survey. Specifically, we are proposing to require organizations to contract with a CMS-approved survey vendor that, in addition to administering the survey in English, will administer the Spanish survey translation to Spanish-preferring patients using the procedures detailed in the CAHPS for MIPS Quality Assurance Guidelines. For requirements and burden, we estimate an average administration time of 13.1 minutes (or 0.2183 hr) at a pace of 4.5 items per minute for the English version of the survey. For the Spanish version, we estimate an average administration time of 15.7 minutes (assuming 20 percent more words in the Spanish translation). However, since less than 1 percent of surveys were administered in Spanish for the CY 2022 performance period, we are not updating our burden estimates to include the time associated with the Spanish version at this time.

In this rule, we are adjusting the estimated number of beneficiaries that will respond to the CAHPS for MIPS survey from the previously approved number of beneficiaries in the CY 2021 PFS final rule (85 FR 84982 through 84983). For the CY 2024 performance period/2026 MIPS payment year, we are estimating that 100 groups will elect to report on the CAHPS for MIPS survey. Based on the number of complete and partially complete surveys for groups participating in CAHPS for MIPS survey administration for the CY 2022 performance period/2024 MIPS payment year, we estimate that an average of 255 beneficiaries will respond per group for the CY 2024 performance period/2026 MIPS payment year. Therefore, we estimate that the CAHPS for MIPS survey will be administered to approximately 25,500 beneficiaries for the CY 2024 performance period/2026 MIPS payment year. This adjustment will result in a decrease of 4,452 beneficiary respondents from our currently approved estimate of 29,952 beneficiary respondents in the CY 2021 PFS final rule (85 FR 84982). As shown in Table 86, for the CY 2024 performance period/2026 MIPS payment year, we continue to estimate that the per response time to administer the survey is 0.2183 hours. This will result in an estimated annual burden of 5,567 hours at a cost of $165,750.

TABLE 86: Estimated Burden for Beneficiary Response Requirements

Burden and Respondent Descriptions	Burden Estimate
# of Groups Practices Administering CAHPS for MIPS Survey (a)	100
# of Beneficiaries Per Group Responding to Survey (b)	255
# of Total Beneficiaries Reporting (c)=(a)*(b)	25,500
# of Hours Per Beneficiary Respondent (d)	0.2183
Total Annual Hours (e) = (c) * (d)	**5,567**
Cost for Beneficiary to Respond to CAHPS for MIPS Survey @ labor rate of $29.76/hr (f) = (d) *$29.76/hr	$6.50
Total Annual Cost (g) = (e) * (f)	**$165,750**

In Table 87, we illustrate the net change in estimated burden for beneficiary response requirements using the currently approved burden in the CY 2021 PFS final rule (85 FR 84982 through 84983). In aggregate, using our

currently approved per response time estimate, the decrease in the number of respondents submitting responses for the CAHPS for MIPS survey results in a total annual adjustment of −972 hours at a cost of −$28,938 for the CY 2024 performance period/2026 MIPS payment year.

TABLE 87: Change in Estimated Burden for Beneficiary Response Requirements

Burden and Respondent Descriptions	CY 2024 Performance Period
Total Currently Approved Annual Hours (a)	6,539
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (See Table 81, row (e))	5,567
Difference (c) = (b) - (a)	**-972**
Total Currently Approved Annual Cost (d)	$194,688
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 81, row (g))	$165,750
Difference (f) = (e) - (d)	**-$28,938**

(9) Group Registration for CAHPS for MIPS Survey

The following proposed changes will be submitted to OMB for review under control number 0938–1222 (CMS–10450). We note that the associated burden will be made available for public review and comment under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices.

We refer readers to CY 2019 PFS final rule (83 FR 60009 through 60010) for the previously approved requirements and burden for group registration for the CAHPS for MIPS Survey.

In this rule, we are adjusting the estimated number of groups registering for the CAHPS for MIPS Survey that were previously approved in the CY 2019 PFS final rule (83 FR 60009 through 60010) based on updated data from the CY 2022 performance period/2024 MIPS payment year. We estimate that 266 groups will register for the CAHPS for MIPS Survey for the CY 2024 performance period/2026 MIPS payment year. This adjustment will result in a decrease of 16 group registrations from our currently approved estimate of 282 groups in the CY 2019 PFS final rule (83 FR 60010). In Table 88, for the CY 2024 performance period/2026 MIPS payment year, we continue to estimate that the per response time is 0.75 hours. This will result in an estimated annual burden of 200 hours (266 groups × 0.75 hr/registration) at a cost of $20,628 (266 registrations × $77.55/registration) for a computer systems analyst).

TABLE 88: Estimated Burden for Group Registration for the CAHPS for MIPS Survey

Burden and Respondent Descriptions	Burden Estimate
# of Groups Registering for the CAHPS for MIPS Survey (a)	266
# of Hours Per Computer Systems Analyst (b)	0.75
Total Annual Hours (c) = (a) * (b)	**200**
Cost to Register a Group for the CAHPS for MIPS Survey (@ computer systems analyst @ $103.40/hr) (d) = (b) *$103.40/hr	$77.55
Total Annual Cost (e) = (c) * (d)	**$20,628**

In Table 89, we illustrate the net change in estimated burden for groups registering for the CAHPS for MIPS Survey using the currently approved burden in the CY 2019 PFS final rule (83 FR 60009 through 60010). In aggregate, using our currently approved per response time estimate, the decrease in the number of respondents registering for the CAHPS for MIPS Survey from 282 to 266 results in a total annual adjustment of −12 hours (−16 responses × 0.75 hr/nomination) at a cost of −$1,241 for the CY 2024 performance period/2026 MIPS payment year.

TABLE 89: Change in Estimated Burden for Group Registration for the CAHPS for MIPS Survey

Burden and Respondent Descriptions	CY 2024 Performance Period
Total Currently Approved Annual Hours (a)	212
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (See Table 88, row (c))	200
Difference (c) = (b) - (a)	**-12**
Total Currently Approved Annual Cost (d)	$21,869
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 88, row (i))	$20,628
Difference (f) = (e) - (d)	**-$1,241**

f. ICRs Regarding the Call for MIPS Quality Measures

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

This rule does not propose any new or revised collection of information requirements or burden related to the call for MIPS quality measures. However, based on the actual number of quality measure submissions received for CMS consideration during the 2023 Annual Call for Quality Measures, we are adjusting our burden estimates for the CY 2024 performance period/2026 MIPS payment year.

In this rule, we estimate we will receive 31 quality measure submissions during the 2023 Annual Call for Quality Measures, an increase of 2 from the currently approved number of quality measure submissions for consideration (87 FR 70159 through 70160). We are not proposing any changes to the 5.5 hour (2.4 hr for practice administrator + 3.1 hr for clinician) per response time estimate for quality measure submissions.

In Table 90, we estimate an annual burden of 171 hours (31 measure submissions × 5.5 hr/measure) at a cost of $35,529 (31 measure submissions × $1,146.11/submission for the CY 2024 performance period/2026 MIPS payment year.

TABLE 90: Estimated Burden for Call for Quality Measures

Burden and Respondent Descriptions	Burden estimate
# of New Quality Measures Submitted for Consideration (a)	31
# of Hours per Practice Administrator to Identify, Propose and Link Measure (b)	2.4
# of Hours per Clinician to Identify and Link Measure (c)	1.1
# of Hours per Clinician to Complete Peer Review Article Form (d)	2
Annual Hours Per Response (e) = (b) + (c) + (d)	5.5
Total Annual Hours (f)=(a)*(e)	**171**
Cost to Identify and Submit Measure (@ practice administrator's labor rate of $123.06/hr) * 2.4 hr = (g)	$295.34
Cost to Identify Quality Measure and Complete Peer Review Article Form (@ clinician's labor rate of $274.44/hr) * 3.1 hr = (h)	$850.77
Total Annual Cost Per Submitted Measure (i) = (g) + (h)	$1,146.11
***Total Annual Cost (j)=(a)*(i)**	**$35,529**

In Table 91, we illustrate the net change in estimated burden for the call for quality measures using the currently approved burden in the CY 2023 PFS final rule (87 FR 70159 through 70160). In aggregate, the estimated increase in the number of quality measure submissions will result in an adjustment of +11 hours (+2 measure submissions × 5.5 hr/measure submission) at a cost of $2,292 (+2 measure submissions × $1,146.11/measure submission) for the CY 2024 performance period/2026 MIPS payment year.

TABLE 91: Burden Adjustments for Call for Quality Measures

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours for Respondents (a)	160
Total Annual Hours for Respondents in CY 2023 PFS Final Rule (b) (See Table 85, row (f))	171
Difference (c) = (b) - (a)	**+11**
Total Currently Approved Annual Cost for Respondents (d)	$33,237
Total Annual Cost for Respondents in CY 2024 PFS Proposed Rule (e) (See Table 85, row (j))	$35,529
Difference (f) = (e) - (d)	**+$2,292**

g. ICRs Regarding Promoting Interoperability Data (§§ 414.1375 and 414.1380)

(1) Background

For the CY 2024 performance period/2026 MIPS payment year, MIPS eligible clinicians, groups, subgroups, and APM Entities can submit Promoting Interoperability performance category data through direct log in and upload, or log in and attest submission types. We note that the log in and attest submission type is only available for the Promoting Interoperability performance category and is not available for the quality performance category. With the exception of submitters who elect to use the log in and attest submission type for the Promoting Interoperability performance category, we anticipate that MIPS eligible individual clinicians, groups, subgroups, and APM Entities will use the same data submission type for both the quality and Promoting Interoperability 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. We note that this analysis assesses burden by performance category and submission type and emphasizes that MIPS is a consolidated program. We analyze data submitted by MIPS eligible clinicians, groups, subgroups and APM Entities, and assesses clinician performance based on all the four MIPS performance categories, as applicable.

(2) Reweighting Applications for Promoting Interoperability and Other Performance Categories

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77240 through 77243), CY 2018 Quality Payment Program final rule (82 FR 53918 through 53919), and the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 60011 through 60012, 84 FR 63134 through 63135, 85 FR 84984 through 84985, 86 FR 65596 through 65598, and 87 FR 70160 through 70162, respectively) for our previously finalized requirements for, and our analysis of the information collection and reporting burden associated with, 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 may submit an application requesting reweighting to zero percent for the Promoting Interoperability, quality, cost, and/or improvement activities performance categories under specific circumstances as set forth in § 414.1380(c)(2), including, but not limited to, extreme and uncontrollable circumstances and significant hardship or other type of exception (81 FR 77240 through 77243, 82 FR 53680 through 53686, and 82 FR 53783 through 53785). Table 92 summarizes our analysis of the estimated burden for MIPS eligible clinicians to apply for reweighting of the Promoting Interoperability performance category to zero percent due to a significant hardship or other exception as provided in § 414.1380(c)(2)(i)(C).

Respondents (MIPS eligible individual clinicians, groups, or APM Entities) who apply for a reweighting of the quality, cost, and/or improvement activities performance categories have the option of applying for reweighting of the Promoting Interoperability performance category on the same online form. We assume respondents applying for a reweighting of the Promoting Interoperability performance category due to extreme and uncontrollable circumstances (for example, PHE for COVID–19, vendor issues, etc.) will also request a reweighting of at least one of the other performance categories simultaneously and not submit multiple reweighting applications.

In section IV.A.4.f.(4)(f) of this rule, we are proposing to continue the existing policy of reweighting the Promoting Interoperability performance category for clinical social workers for the CY 2024 performance period/2026 MIPS payment year and making the corresponding revisions to the regulatory text at § 414.1380(c)(2)(i)(A)(*4*)(*iii*). In our analysis of the information collection and reporting burden, we are not adjusting our estimated number of respondents submitting reweighting applications due to this proposal because these proposed changes only modify the regulatory text and do not change the existing reweighting policy for these clinician types participating in MIPS in the CY 2024 performance period/2026 MIPS payment year. To further clarify, these clinician types are automatically reweighted for the Promoting Interoperability performance category and do not need to submit a reweighting application, and therefore do not impact our information collection and reporting burden analysis.

Based on the number of reweighting applications received at the time of the publication of this rule for the CY 2022 performance period/2024 MIPS payment year, we are adjusting our burden estimates relevant to this ICR. In this proposed rule, we estimate that we will receive a total of 29,227 applications to request reweighting for any or all the four MIPS performance categories for the CY 2024 performance

period/2026 MIPS payment year. Out of the 29,227, we estimate that 2,706 respondents will submit a request to reweight the Promoting Interoperability performance category to zero percent due to a significant hardship or other exception as provided in § 414.1380(c)(2)(i)(C). We estimate the remaining 26,510 respondents will submit a request to reweight one or more of the quality, cost, Promoting Interoperability, or improvement activities performance categories due to an extreme or uncontrollable circumstance. Additionally, we estimate 11 APM Entities will submit an extreme and uncontrollable circumstances exception application for the CY 2024 performance period/2026 MIPS payment year. This adjustment results in an increase of 23,788 respondents compared to our currently approved estimate of 5,439 respondents (87 FR 70161). This increase is based on the actual number of reweighting applications submitted for the CY 2022 performance period/2024 MIPS payment year. We note this estimate reflects the significant increase in the number of submitted applications due to extending the deadline, as a result of the ongoing PHE for COVID–19 at the time, for submitting the reweighting applications for the CY 2022 performance period/2024 MIPS payment year to March 3rd, 2023.

Consistent with our assumptions in the CY 2023 PFS final rule (87 FR 70160 through 70162), we continue to estimate it will take 0.25 hours for a computer system analyst to complete and submit the reweighting application. In Table 92, we estimate an annual burden of 7,307 hours (29,227 applications × 0.25 hr/application) at a cost of $755,518 (29,227 applications × $25.85/application).

TABLE 92: Estimated Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

Burden and Respondent Descriptions	Burden Estimate
# of Eligible Clinicians or Groups Applying Due to Significant Hardship and Other Exceptions or Extreme and Uncontrollable Circumstances (a)	29,216
# APM Entities requesting Extreme and Uncontrollable Circumstances exception (b)	11
Total Applications Submitted (c)	**29,227**
Annual Hours Per Applicant per Application Submission (d)	0.25
Total Annual Hours (e) = (c) * (d)	**7,307**
Cost to Submit a Reweighting Application @ computer systems analyst's labor rate of $103.40/hr (f) = (d) *$103.40/hr	$25.85
Total Annual Cost (g) = (e) * (f)	**$755,518**

In Table 93, we illustrate the proposed net change in estimated burden for submission of reweighting applications for Promoting Interoperability and other performance categories using the currently approved burden in the CY 2023 PFS final rule (87 FR 70160 through 70162). The proposed adjustment in the estimated number of respondents, from 5,439 to 29,227 respondents, results in an increase of 23,788 respondents. In aggregate, using our currently approved per response time estimate, as shown in Table 93, the proposed increase in 23,788 respondents results in an increase of 5,947 hours (+23,788 responses × 0.25 hr/response) and $614,920 (+5,947 hr × $103.40/hr) for the CY 2024 performance period/2026 MIPS payment year.

TABLE 93: Change in Estimated Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours in CY 2023 PFS final rule (a)	1,360
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (See Table 92, row (c))	7,307
Difference (c) = (b) - (a)	**+5,947**
Total Currently Approved Annual Cost in CY 2023 PFS final rule (d)	$140,598
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 92, row (e))	$755,518
Difference (f) = (e) - (d)	**+$614,920**

(3) Submitting Promoting Interoperability Data

We are not proposing any new or revised collection of information requirements or burden related to the submission of Promoting Interoperability performance category data. We note the policy proposals in section IV.A.4.f.(4) of this rule related to the submission of Promoting Interoperability data do not impact the currently approved estimated burden for

this ICR. We discuss in detail below the proposed policies and our reasons for not changing our currently approved burden for submission of Promoting Interoperability data. The submission of Promoting Interoperability data requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any submission of Promoting Interoperability changes under that control number.

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77509 through 77511, and 82 FR 53919 through 53920, respectively), and the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 60013 through 60014, 84 FR 63135 through 63137, 85 FR 84985 through 84987, 86 FR 65598 through 65600, and 87 FR 70162 through 70164, respectively) for our previously finalized requirements and burden for submission of data for the Promoting Interoperability performance category.

In section IV.A.4.f.(4)(b)of this proposed rule, we are proposing that for the CY 2026 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of any continuous 180-day period within CY 2024, up to and including the full CY 2024 (January 1, 2024, through December 31, 2024). We are proposing to modify the Promoting Interoperability performance category performance period that we established under § 414.1320(h)(1) to remove subsequent years, include the 2025 MIPS payment year, and add § 414.1320(i)(1) to reflect our proposal. We assume MIPS eligible clinicians and groups that currently submit data for the Promoting Interoperability performance category would utilize the CEHRT for an entire calendar year performance period and therefore, the proposed increase in the length of the performance period for the Promoting Interoperability performance category from 90 to 180 days would not create additional burden for MIPS eligible clinicians and groups that would submit data for the Promoting Interoperability performance category. We note that this is consistent with the discussion of burden for the above policy in the FY 2022 IPPS final rule (86 FR 45515).

In section IV.A.4.f.(4)(d)(i)of this rule, we are proposing changes to the Query of Prescription Drug Monitoring Program Measure under the Electronic Prescribing Objective. Specifically, we are proposing to modify the second exclusion criterion to state that any MIPS eligible clinician who does not electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period can claim the second exclusion. The proposed changes would not affect the requirements for MIPS eligible clinicians and groups that submit data for the Promoting Interoperability performance category since the revision is meant to revise the previously finalized second exclusion in the CY 2018 Quality Payment Program final rule (82 FR 53679). Therefore, we are not making any adjustments to our currently approved estimated burden for this ICR.

In section IV.A.4.f.(4)(d)(ii) of this rule, we are proposing to revise the e-Prescribing measure description in Table 45 to read ''At least one permissible prescription written by the MIPS eligible clinician is transmitted electronically using CEHRT'' and the numerator will be updated to read to indicate ''Number of prescriptions in the denominator generated and transmitted electronically'' to reflect the removal of the health IT certification criterion ''drug-formulary and preferred drug list checks.'' These proposed revisions would not affect the requirements for MIPS eligible clinicians and groups that submit data for the Promoting Interoperability performance category since these changes provide technical updates to the e-prescribing measure. Therefore, we are not making any adjustments to our currently approved estimated burden for this ICR.

In section IV.A.4.f.(4)(d)(iii)of this rule, we are proposing to modify our requirements for the SAFER Guides measure beginning with the CY 2024 performance period/2026 MIPS payment year and subsequent years, to require MIPS eligible clinicians conduct, and therefore attest ''yes'' an annual self-assessment of the CEHRT using the High Priority Practices SAFER Guide (*available at https://www.healthit.gov/topic/safety/safer-guides*), at any point during the calendar year in which the performance period occurs. We note we have captured the estimated burden for reporting this measure in the CY 2022 PFS final rule (86 FR 65599) and the proposed revision would not affect the data collection and submission requirements for MIPS eligible clinicians and groups that submit data for the Promoting Interoperability performance category. Therefore, we are not making any adjustments to our currently approved estimated burden for this ICR.

h. ICRs Regarding the Nomination of Promoting Interoperability Measures

The following proposed changes associated with the information collection related to the nomination of Promoting Interoperability measures will be submitted to OMB for review to remove the information collection relevant to the nomination of Promoting Interoperability measures under control number 0938–1314 (CMS 10621). This rule does create any new or revised collection of information requirements or burden related to the nomination of Promoting Interoperability performance category measures. Due to a consistent decline in the number of submissions received for the Promoting Interoperability performance category measures, we estimate to receive fewer than 10 responses for this ICR. Therefore, we are proposing to remove the ICR for nomination of Promoting Interoperability performance category measures.

As shown in Table 94, we estimate an annual burden of zero hours at a cost of $0 for the CY 2024 performance period/2026 MIPS payment year.

TABLE 94: Estimated Burden for Call for Promoting Interoperability Measures

Burden and Respondent Descriptions	Burden Estimate
# of Organizations Nominating New Promoting Interoperability Measures (a)	0
# of Hours Per Medical and health services manager to Identify and Propose Measure (b)	0.30
# of Hours Per Clinician to Identify Measure (c)	0.20
Annual Hours Per Respondent (d) = (b) + (c)	0.50
Total Annual Hours (e) = (a) [x] (d)	**0**
Cost to Identify and Submit Measure (@ medical and health services manager's labor rate of $123.06/hr.) (f) = (b) [x] $123.06/hr	$36.92
Cost to Identify Improvement Measure (@ physician's labor rate of $274.44/hr.) (g) = (c) [x] $274.44/hr	$54.89
Total Annual Cost Per Respondent (h) = (f) + (g)	$91.81
Total Annual Cost (i) = (a) [x] (h)	**$0**

In Table 95, we illustrate the proposed net change in estimated burden for nomination of Promoting Interoperability measures using the currently approved burden in the CY 2023 PFS final rule (87 FR 70163). The proposed removal of the ICR for nomination of Promoting Interoperability measures results in a decrease of 5 hours (-10 responses × 0.5 hr/response) and a decrease of $918 for the CY 2024 performance period/2026 MIPS payment year.

TABLE 95: Change in Estimated Burden for Nomination of Promoting Interoperability Measures

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours in CY 2023 PFS final rule (a)	5
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (See Table 94, row (c))	0
Difference (c) = (b) - (a)	**-5**
Total Currently Approved Annual Cost in CY 2023 PFS final rule (d)	$918
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 94, row (e))	0
Difference (f) = (e) - (d)	**-$918**

i. ICRs Regarding Improvement Activities Submission (§§ 414.1305, 414.1355, 414.1360, and 414.1365)

We are not proposing any new or revised collection of information requirements or burden related to the submission of improvement activity data. We note that the policy proposal in section IV.A.4.f.(3) of this proposed rule related to the improvement activities submission does not impact our currently estimated burden for this ICR. We discuss in detail below the proposed policy and reasons that it does not change our currently approved burden for improvement activities submission. The improvement activity submission requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not proposing any improvement activity submission changes under that control number.

In section IV.A.4.f.(3)(b)(ii) of this proposed rule, we are proposing changes to the improvement activities inventory for the CY 2024 performance period/2026 MIPS payment year and future years as follows: adding five new improvement activities; modifying one existing improvement activity; and removing four previously adopted improvement activities. We do not believe the changes will impact our currently approved time for interested parties to submit information because MIPS eligible clinicians are still required to submit the same number of activities and the estimated per response time for each activity is uniform. Therefore, we are not proposing to adjust our currently approved burden for improvement activities submission as a result of this proposal.

j. ICRs Regarding the Nomination of Improvement Activities (§ 414.1360)

The proposed changes associated with data submission will be submitted to OMB for review under control number 0938–1314 (CMS 10621).

In this rule, based on the actual number of respondents that submitted improvement activity nominations, we are proposing to adjust the estimated number of improvement activity nominations that were previously approved in the CY 2022 PFS final rule (86 FR 65603 through 65605). We estimate that we will receive approximately 15 improvement activity nominations for the CY 2024 performance period/2026 MIPS payment year. This adjustment will

result in a decrease of 16 improvement activity nominations from our currently approved estimate of 31 nominations in the CY 2022 PFS final rule (86 FR 65605). In Table 96, for the CY 2024 performance period/2026 MIPS payment year, we continue to estimate that the per response time is 4.4 hours. This will result in an estimated annual burden of 66 hours (15 nominations × 4.4 hr/nomination) at a cost of $11,755 (15 × [(2.8 hr × $123.06/hr for a medical and health services manager) + (1.6 hr × $274.44/hr for a physician)]).

TABLE 96: Estimated Burden for Nomination of Improvement Activities

Burden and Respondent Descriptions	Burden Estimate
# of Nominations of New IAs (a)	15
# of Hours Per Medical and Health Services Manager (b)	2.8
# of Hours Per Physician (c)	1.6
Annual Hours Per Respondent (d)= (b) + (c)	4.4
Total Annual Hours (e) = (a) * (d)	**66**
Cost to Nominate an IA (@ medical and health services manager's labor rate of $123.06/hr) (f) = (b) x $123.06/hr	$344.57
Cost to Nominate an IA (@ physician's labor rate of $274.44/hr) (g) = (c) x $274.44/hr	$439.10
Total Annual Cost Per Respondent (h) = (f) + (g)	$783.67
Total Annual Cost (i) = (a) * (h)	**$11,755**

In Table 97, we illustrate the proposed net change in estimated burden for nomination of improvement activities using the currently approved burden in the CY 2022 PFS final rule (86 FR 65605). In aggregate, using our currently approved per response time estimate, the proposed decrease in the number of respondents submitting improvement activity nominations results in a total annual adjustment of -70 hours (-16 responses × 4.4 hr/nomination) at a cost of -$12,539 (-16 x [(2.8 hr × $123.06/hr) + (1.6 hr × $274.44/hr)]) for the CY 2024 performance period/2026 MIPS payment year.

TABLE 97: Change in Estimated Burden for Nomination of Improvement Activities

Burden and Respondent Descriptions	CY 2024 Performance Period
Total Currently Approved Annual Hours (a)	136
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (See Table 94, row (d))	66
Difference (c) = (b) - (a)	**-70**
Total Currently Approved Annual Cost (d)	$24,294
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 94, row (i))	$11,755
Difference (f) = (e) - (d)	**-$12,539**

k. Nomination of MVPs

This rule does not propose any new or revised collection of information requirements or burden related to the nomination of MVPs. The requirements and burden for nomination of MVPs are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to the nomination of MVPs under that control number.

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 policies in this rule do not result in the need to add or revise or delete any claims data fields. Consequently, we are not making any changes under that control number.

m. ICRs Regarding Partial QP Elections (§§ 414.1310(b) and 414.1430)

This rule is not proposing any new or revised collection of information requirements or burden related to the Partial QP Elections to participate in MIPS as a MIPS eligible clinician. The requirements and burden for Partial QP Elections are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to Partial QP Elections under that control number.

n. ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process (§ 414.1445) and Eligible Clinician-Initiated Process (§ 414.1445)

This rule is not proposing any new or revised collection of information

requirements related to Other Payer Advanced APM determinations.

(1) Payer-Initiated Process (§ 414.1445)

This rule is not proposing any new or revised collection of information requirements related to the Payer-Initiated Process. The requirements and burden associated with this information collection are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to the Payer-Initiated process under that control number.

(2) Eligible Clinician-Initiated Process (§ 414.1445)

This rule is not proposing any new or revised collection of information requirements or burden related to the Eligible Clinician-Initiated Process. The requirements and burden associated with this information collection are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing 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 proposing any new or revised collection of information requirements or burden related to the Submission of Data for QP Determinations under the All-Payer Combination Option. The requirements and burden for the All-Payer Combination option are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes under that control number.

o. ICRs Regarding Voluntary Participants Election To Opt-Out of Performance Data Display on Compare Tools (§ 414.1395)

This rule is not proposing any new or revised collection of information requirements or burden related to the election by voluntary participants to opt-out of public reporting on Compare Tools. The requirements and burden associated with this information collection are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to the election of voluntary participants to opt-out of performance data display on Compare Tools under that control number.

p. Summary of Annual Quality Payment Program Burden Estimates

Table 99 summarizes this proposed rule's total burden estimates for the Quality Payment Program for the CY 2024 performance period/2026 MIPS payment year.

In the CY 2023 PFS final rule, the total estimated burden for the CY 2024 performance period/2026 MIPS payment year (see Table 99, row a) was 710,644 hours at a cost of $75,687,130 (87 FR 70169). Accounting for updated wage rates and the subset of all Quality Payment Program ICRs discussed in this rule compared to the CY 2023 PFS final rule, the total estimated annual burden of continuing policies and information set forth in the CY 2023 PFS final rule into the CY 2024 performance period/2026 MIPS payment year is 626,007 hours at a cost of $70,778,884 (see Table 99, row b). These represent a decrease of 84,637 hours and a decrease of $4,908,246. 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 2023 PFS final rule into the CY 2024 performance period/2026 MIPS payment year. This burden estimate of 630,570 hours at a cost of $71,317,983 (see Table 99, row c) reflects the availability of more accurate data to account for all potential respondents and submissions across all the performance categories and more accurately reflects the exclusion of QPs from all MIPS performance categories, an increase of 4,563 hours and $539,099 (see Table 99, row d). This burden estimate is higher than the burden approved for information collection related to the CY 2023 PFS final rule due to updated data and assumptions. Our total burden estimate for the CY 2024 performance period/2026 MIPS payment year is 626,568 hours and $70,858,430 (see Table 99, row e), which represents an increase of 561 hours and $79,546 from the CY 2023 PFS final rule (see Table 99, row f). The difference of −4,002 hours (561 hours − 4,563 hours) and −$459,553 ($79,546 − $539,099) (see Table 99, row g) between this estimate and the total burden shown in Table 99 is the decrease in burden associated with impacts of the policies for the CY 2024 performance period/2026 MIPS payment year.

TABLE 98: Summary of Burden Estimates and Requirements from the CY 2024 PFS Proposed Rule

CY 2024 Performance Period/2026 MIPS Payment Year		
Burden Estimate Description	**Time (Hours)**	**Cost**
Currently approved burden in CY 2023 PFS Final Rule (a)	710,644	$75,687,130
CY 2023 PFS Final Rule w/ updated wage rates and ICRs (b)	626,007	$70,778,884
CY 2023 PFS Final Rule w/ updated data and assumptions (c)	630,570	$71,317,983
Change in burden due to updated data and assumptions (d) = (c) – (b)	**4,563**	**$539,099**
CY 2024 PFS Proposed Rule Total Burden (e)	626,568	$70,858,430
Total change in burden (as shown in Table D-A43) (f) = (e) – (b)	561	$79,546
Change in burden associated with policies (g) = (f) – (d)	**-4,002**	**-$459,553**

TABLE 99: Summary of Quality Payment Program Burden Estimates and Requirements CMS-10621 (OMB 0938-1314) and CMS-10450 (OMB 0938-1222)

Requirement	Currently Approved Responses	CMS-1784-P Responses	Change in Responses	Currently Approved Total Time (Hours)	CMS-1784-P Total Time (Hours)	Change in Total Time (Hours)
§ 414.1400 QCDR simplified self-nomination (see Tables 60 and 61)	0	45	+45	0	365	+365
§ 414.1400 QCDR full self-nomination (see Tables 63 and 63)	63	10	-53	636	101	-535
§ 414.1400 Registry simplified self-nomination (see Tables 64 and 65)	0	89	+89	0	45	+45
§ 414.1400 Registry full self-nomination (see Tables 66 and 67)	132	36	-96	264	72	-192
§ 414.1400 Third Party Intermediary Plan Audits (see Tables 69 and 70)	127	130	+3	585	611	+26
§ 414.1400 Survey Vendor Requirements (see Tables 71 and 72)	15	10	-5	150	100	-50
§§ 414.1325 and 414.1335 (Quality Performance Category) Medicare Part B Claims Collection Type (see Tables 76 and 77)	14,736	14,402	-334	209,251	204,508	-4,743
§§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type (see Tables 78 and 79)	17,916	17,509	-407	162,731	159,034	-3,697
§§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type (see Tables 80 and 81)	23,889	23,346	-543	191,112	186,768	-4,344
§414.1365 MVP Registration (see Tables 82 and 83)	7,731	9,015	+1,284	1,933	2,254	+321
MVP Quality Submission (see Tables 84 and 85)	7,731	9,015	+1,284	50,938	59,399	+8,461
§§ 414.1325 and 414.1335	29,952	25,500	-4,452	6,539	5,567	-972

Requirement	Currently Approved Responses	CMS-1784-P Responses	Change in Responses	Currently Approved Total Time (Hours)	CMS-1784-P Total Time (Hours)	Change in Total Time (Hours)
Beneficiary Responses for CAHPS for MIPS Survey (see Tables 86 and 87)						
Group Registration for CAHPS for MIPS Survey (see Tables 88 and 89)	282	266	-16	212	200	-12
Call for Quality Measures (see Tables 90 and 91)	29	31	+2	160	171	+11
§ 414.1380(c)(2) Reweighting Applications for Promoting Interoperability and Other Performance Categories (see Tables 92 and 93)	5,439	29,227	+23,788	1,360	7,307	+5,947
§ 414.1360 (Improvement Activities Performance Category) Nomination of Improvement Activities (see Tables 94 and 95)	31	15	-16	136	66	-70
TOTAL	108,073	128,646	+20,573	626,007	626,568	+561

Table 100 provides the reasons for changes in the estimated burden for information collections in the Quality Payment Program segment of this proposed rule. We have divided the reasons for our change in burden into those related to proposed policies in the CY 2024 PFS rule and those related to adjustments in burden continued from the CY 2023 PFS final rule policies that reflect updated data and revised methods.

TABLE 100: Reasons for Proposed Change in Burden Compared to the Currently Approved CY 2023 Information Collection Burden

ICR Title	Changes in burden due to CY 2024 proposed rule policies	Adjustments in burden continued from CY 2023 PFS final rule policies due to revised methods or updated data
QCDR Simplified Self-Nomination and other Requirements (See Table 61)	None	Proposed addition of a new ICR.
QCDR Full Self-Nomination and other Requirements (See Table 63)	None	Decrease in number of respondents due to updated assumptions. Decrease in the total number of hours due to restructuring the ICR.
Qualified Registry Simplified Self-Nomination and other Requirements (See Table 65)	None	Proposed addition of a new ICR.
Qualified Registry Full Self-Nomination and other Requirements (See Table 67)	None	Decrease in number of respondents due to updated assumptions. Decrease in the total number of hours due to restructuring the ICR.
Third Party Intermediary Plan Audits (see Table 70)	None	New ICR. Increase in number of respondents and hours due to updated assumptions for the CY 2024 performance period/2026 MIPS payment year.
Survey Vendor Requirements (see Table 72)	None	Decrease in number of respondents due to updated assumptions.
Quality Performance Category: Medicare Part B Claims Collection Type (see Table 77)	Decrease in number of respondents due to the estimated increase in the number of respondents submitting for the MVP quality performance category via the claims collection type.	None
Quality Performance Category: QCDR/ MIPS CQM Collection Type (see Table 79)	Decrease in number of respondents due to the estimated increase in the number of respondents submitting for the MVP quality performance category via the QCDR and MIPS CQM collection type.	None
Quality Performance Category: eCQM Collection Type (see Table 81)	Decrease in number of respondents due to the estimated increase in the number of respondents submitting for the MVP quality performance category via the eCQM collection type.	None
MVP Registration (see Table	Increase in number of	None

ICR Title	Changes in burden due to CY 2024 proposed rule policies	Adjustments in burden continued from CY 2023 PFS final rule policies due to revised methods or updated data
83)	respondents due to finalized addition of 5 new MVPs.	
MVP Quality Submission (see Table 85)	Increase in number of respondents due to finalized addition of 5 new MVPs.	None
Beneficiary Responses for CAHPS for MIPS Survey (see Table 87)	None	Decrease in number of respondents due to updated projections for the CY 2024 performance period/2026 MIPS payment year
Group Registration for CAHPS for MIPS Survey (see Table 89)	None	Decrease in number of respondents due to updated projections for the CY 2024 performance period/2026 MIPS payment year
Call for Quality Measures (see Table 91)	None	Increase in number of respondents due to updated projections for the CY 2024 performance period/2026 MIPS payment year
Promoting Interoperability Performance Category: Reweighting Applications for Promoting Interoperability and Other Performance Categories (see Table 93)	None	Increase in number of respondents due to updated projections for the CY 2024 performance period/2026 MIPS payment year.
Improvement Activities Performance Category: Nomination of Improvement Activities (see Table 95)	None	Decrease in number of respondents due to updated projections for the CY 2024 performance period/2026 MIPS payment year

C. Summary of Annual Burden Estimates for Changes

TABLE 101: Annual Requirements and Burden Estimates

Section(s) Under Title 42 of the CFR	OMB Control Number	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§ 414.940 (Requiring Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts)	0938-1435 (CMS-10835	25 in the initial year; 2 in subsequent years	25 in the initial year, 2 in subsequent years	5	125 in the initial year, 10 in subsequent years	41.74	5,218 in the initial year; 418 in subsequent years
§ 414.94(c)(2) (AUC Program Provider-Led Entity reapplication for qualification)	0938-1288 (CMS-10570)	(10)	(10)	(15)	(150)	(1,714.2)	(17,142)
Placeholder RHC/FQHC CfCs	0938-0344 (CMS-R-38)						
§§ 600.125(a)(1), 600.140(b)(4) through (6), 600.145(a), 600.145(f)(2), and 600.170(a)(2) Basic Health Program (BHP) Provisions	0938-1218 (CMS-10510)	2	varies	varies	356	varies	30,322
§§414.1325 and 414.1335 Quality Payment Program: CAHPS Survey	0938-1222 (CMS-10450)	(4,473)	(4,473)	Varies	(1,034)	Varies	(35,349)
§§ 414.1318, 414.1325 and 414.1335, 414.1360, 414.1365, 414.1375, 414.1380, 414.1395, 414.1400, 414.1430, and 414.1440 Quality Payment Program	0938-1314 (CMS-10621)	+25,036	+25,036	Varies	+1,590	Varies	+113,880
TOTAL				Varies		Varies	

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed in this section, please visit the CMS website at *https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing*, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** section of this proposed rule and identify the rule (CMS–1784–P) the ICR's CFR citation, and OMB control number.

VI. Response to Comments

Because of the large number of public comments, we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Regulatory Impact Analysis

A. Statement of Need

In this proposed rule, we are proposing payment and policy changes under the Medicare PFS and required statutory changes under the Consolidated Appropriations Act, 2021 (CAA, 2021); sections 301, 302, 303, 304, and 305 under the Consolidated Appropriations Act, 2022 (CAA, 2022); sections 2003 and 2005 of the SUPPORT for Patients and Communities Act of 2018, sections 4113, 4114, and 4121 under the Consolidated Appropriations Act of 2023 (CAA, 2023), section 90004 of the Infrastructure Investment and Jobs Act, section 6 of the Sustaining Excellence in Medicaid Act of 2019, and sections 11101, 11402, 11403, 11407 under the Inflation Reduction Act (IRA). Our policies in this rule specifically address: changes to the PFS; other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, the relative value of services, and changes in the statute; updates and refinements to Medicare Shared Savings Program (Shared Savings Program) requirements; updates to the Quality Payment Program; updates to the Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare provider enrollment policies; updates to electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan (section 2003 of the SUPPORT Act); changes to the regulations associated with the Ambulance Fee Schedule and the Medicare Ground Ambulance Data Collection System; and changes to release Medicare Advantage risk adjustment data early for use with Care Compare websites. The policies reflect CMS' stewardship of the Medicare program and overarching policy objectives for ensuring equitable beneficiary access to appropriate and quality medical care.

1. Statutory Provisions

a. Extension of Certain Medicare Telehealth Flexibilities, Under Section 1834(m) of the Act, as Amended by the CAA, 2023

Section II.D.1.e. of this proposed rule implements section 4113, of the CAA, 2023, which extended through CY 2024 several temporary flexibilities for Medicare telehealth services adopted during the PHE for COVID–19. Specifically, section 4113 extended the

temporary inapplicability of geographic and location restrictions, extended the temporary expansion of practitioner types who can be paid for Medicare telehealth services, delayed the in-person visit requirements for mental health services furnished via telehealth, and extended audio-only flexibilities for certain telehealth services. This provision is necessary to fulfill the statutory requirement to implement this extension through December 31, 2024.

b. Drugs and Biological Products Paid Under Medicare Part B

Section III.A.1. of this proposed rule proposes regulations text changes to implement provisions of the Inflation Reduction Act of 2022 that affect payment amounts or patient out-of-pocket costs for certain drugs and biologicals payable under Part B. Two provisions affect payment amounts for biosimilar biological products. Section 11402 of the IRA amends the payment limit for new biosimilars furnished on or after July 1, 2024 during the initial period when ASP data is not available. Section 11403 makes changes to the payment limit for certain biosimilar products with an ASP that is not more than the ASP of the reference biological for a period of 5 years. Two other provisions make statutory changes to patient out-of-pocket costs for certain drugs payable under Medicare Part B. Section 11101 of the IRA requires that beneficiary coinsurance for a Part B rebatable drug is to be based on the inflation-adjusted payment amount if the Medicare payment amount for a calendar quarter exceeds the inflation-adjusted payment amount, beginning on April 1, 2023. Section 11407 makes statutory changes to waive the deductible for insulin that is furnished through a covered item of durable medical equipment (DME) and establishes a $35 cap on cost sharing for a month's supply of insulin furnished through a covered item of DME, both beginning July 1, 2023.

Section III.A.3 of this proposed rule proposes policies to implement section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) (IIJA) which requires drug manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. These provisions are necessary to fulfill the statutory requirement to implement this policy effective January 1, 2023 and reduce unnecessary Medicare spending for discarded drug.

c. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

Section III.B.2. of this proposed rule implements sections 4113, 4121, and 4124 of the CAA, 2023. Section 4113 of the CAA, 2023 amends section 1834(m)(8) of the Act to extend payment for telehealth services furnished by RHCs and FQHCs for the limited period beginning on the first day after the end of the PHE for COVID–19 and ending on December 31, 2024. Section 4113 also delays the in-person requirements under Medicare for mental health visits furnished by RHCs and FQHCs via telecommunications technology until January 1, 2025.

Section 4121 of the CAA, 2023 amends section 1861(aa)(1)(B) of the Act by adding marriage and family therapists (MFT) and mental health counselors (MHC) as eligible practitioners of RHCs and FQHCs beginning January 1, 2024. Section 4121 allows MFTs and MHCs to bill directly and be paid as an RHC and FQHC practitioner under the RHC AIR an FQHC PPS.

Section 4124 of the CAA, 2023 establishes an Intensive Outpatient benefit in RHCs and FQHCs. Proposals related to implementation of IOP for RHCs and FQHCs are discussed in the CY 2024 OPPS proposed rule.

d. Clinical Laboratory Fee Schedule (CLFS)—Proposed Revisions Consistent With Recent Statutory Changes

Section III.D.5. of this rule proposes conforming regulations text changes for CLFS data reporting requirements due to the enactment of section 4114 of the CAA, 2023. For clinical diagnostic laboratory tests (CDLTs) that are not advanced diagnostic laboratory tests (ADLTs), the CAA, 2023 delays the next data reporting period by one year. Instead of taking place from January 1, 2023 through March 31, 2023, data reporting will now take place from January 1, 2024 through March 31, 2024, based on the original data collection period of January 1, 2019 through June 30, 2019. Data reporting for these tests then resumes on a 3-year cycle (2027, 2030, etc.). Additionally, the CAA, 2023 amends the statutory provisions for the phase-in of payment reductions resulting from private payor rate implementation to specify that the applicable percent in CY 2023 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2023 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2022. The CAA, 2023 further amends the statutory phase-in provisions to provide that for CYs 2024 through 2026, the payment amount for a CDLT may not be reduced by more than 15 percent as compared to the payment amount for that test established in the preceding year.

e. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan (Section 2003 of the SUPPORT Act)

In this rule, we are proposing changes to the electronic prescribing for controlled substances (EPCS) requirement specified in section 2003 of the SUPPORT Act (referred to as the CMS EPCS Program). The proposals specify the basis for the evaluation of compliance by describing how prescriptions are calculated, remove the same entity exception while conditioning the electronic prescribing requirement as subject to the exemption in § 423.160(a)(3)(iii), identify non-compliance actions for subsequent measurement years, and update other CMS EPCS Program exceptions. Previously finalized policies did not include actions for non-compliance after the 2024 measurement year, and we need to identify actions for non-compliance in subsequent measurement years.

f. Ambulance Fee Schedule and the Medicare Ground Ambulance Data Collection System

Section 4103 of the CAA amended section 1834(l)(12)(A) and (l)(13) of the Act to extend the payment add-ons set forth in those subsections through December 31, 2024. The ambulance extender provisions are enacted through legislation that is self-implementing. We are proposing only to revise the dates in § 414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to these self-implementing statutory requirements.

Section 1834(l)(17)(A) of the Act requires the Secretary to develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary for providers and suppliers of ground ambulance services. In this proposed rule, we are proposing revisions to the Medicare Ground Ambulance Data Collection Instrument. The changes and clarifications aim to reduce burden on respondents, improve data quality, or both.

g. Quality Payment Program

This proposed rule is also necessary to make changes to the Quality Payment Program to move the program forward to

focus more on measurement efforts, refine how clinicians will be able to participate in a more meaningful way through the Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs), and highlight the value of participating in Advanced Alternative Payment Models (APMs). Authorized by MACRA, the Quality Payment Program is an incentive program that includes two participation tracks, MIPS and Advanced APMs. MIPS eligible clinicians are subject to a MIPS payment adjustment based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. Currently, reporting for traditional MIPS is seen as siloed across the performance categories. These policy proposals are intended to promote better quality reporting to improve patient health outcomes by coordinating reporting for MIPS across performance categories, and make changes to scoring that will provide a better picture of clinicians' performance.

2. Discretionary Provisions

a. Drugs and Biological Products Paid Under Medicare Part B

In section III.A. of this proposed rule, as part of our continued implementation, section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) (IIJA) which amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. We are proposing the date of the initial report to manufacturers, the date for subsequent reports, method of calculation when there are multiple manufacturers for a refundable drug, increased applicable percentages for drugs with unique circumstances, and a future application process by which manufacturers may apply for an increased applicable percentage for a drug.

b. RHCs and FQHCs

In section III.B.2. of this proposed rule, we are proposing to continue to define ''immediate availability'' as including real-time audio and visual interactive telecommunications for the direct supervision of services and supplies furnished incident to a physician's service through December 31, 2024 for RHCs and FQHCs.

In section III.B.3. of this proposed rule, we are proposing to change the required level of supervision for behavioral health services furnished ''incident to'' a physician or non-physician practitioner's services at RHCs and FQHCs to allow general supervision, rather than direct supervision, consistent with the policies finalized under the PFS for CY 2023.

In section III.B.4. of this proposed rule, we are proposing a policy to include Remote Patient Monitoring (RPM), Remote Therapeutic Monitoring (RTM), Community Health Integration (CHI), and Principal Illness Navigation (PIN) services in the general care management HCPCS code G0511 when these services are provided by RHCs and FQHCs. We are proposing to revise the calculation for G0511 to include the weighted average of these services using the CY 2021 PFS non-facility utilization. These provisions are necessary in that we evaluate coding provisions in this rule and their applicability to RHCs and FQHCs.

Also, in section III.B.4. of this proposed rule, we are proposing to remove the direct supervision requirement for obtaining consent for CCM services and virtual communication services furnished in RHCs and FQHCs.

c. Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Expansion of Supervising Practitioners

In section III.E. of this proposed rule, we are proposing revisions to §§ 410.47 (PR) and 410.49 (CR/ICR) to add to the types of practitioners who may supervise PR, CR and ICR programs to also include a physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist (CNS). These provisions are necessary to fulfill the statutory requirement to implement these changes made in section 51008 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018) (BBA of 2018) effective January 1, 2024.

d. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

As discussed in section III.F. of this proposed rule, we are proposing to allow periodic assessments to be furnished via audio-only communication when two-way audio-video communications technology is not available to the beneficiary through the end of CY 2024, to the extent that it is authorized by SAMHSA and DEA at the time the service is furnished and all other applicable requirements are met. We believe this modification is needed because extending these audio-only flexibilities for an additional year may minimize disruptions associated with the conclusion of the PHE, and evidence has shown that Medicare beneficiaries from historically underserved populations are more likely to be offered and use audio-only telemedicine services than audio-video services.[335] Therefore, minimizing disruptions to care for audio-only periodic assessments may further promote health equity and minimize disparities in access to care.

e. Medicare Shared Savings Program

In section III. G. of this proposed rule, we are proposing modifications to the Shared Savings Program to further advance Medicare's overall value-based care strategy of growth, alignment, and equity, and to respond to concerns raised by ACOs and other interested parties. The proposed changes to the Shared Savings Program include the following: modifications to the quality performance standard and reporting requirements under the APP that would continue to move ACOs toward digital measurement of quality and to align with QPP; modifications to the step-wise beneficiary assignment methodology to add a new third step and related changes to how we identify the assignable beneficiary population; updates to the definition of primary care services used for purposes of beneficiary assignment to remain consistent with billing and coding guidelines; refinements to the financial benchmarking methodology for ACOs in agreement periods beginning on January 1, 2024, and in subsequent years to (1) cap the risk score growth in an ACO's regional service area when calculating regional trends used to update the historical benchmark at the time of financial reconciliation for symmetry with the cap on ACO risk score growth, (2) apply the same CMS–HCC risk adjustment methodology applicable to the calendar year corresponding to the performance year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year, (3) further mitigate the impact of the negative regional adjustment on the benchmark to encourage participation by ACOs caring for medically complex, high cost beneficiaries, and (4) specify the circumstances in which CMS would recalculate the prior savings adjustment for changes in values used in benchmark calculations due to compliance action taken to address avoidance of at-risk beneficiaries, or as a result of the issuance of a revised initial determination of financial performance for a previous performance year following a reopening of ACO shared savings and shared losses calculations; refine newly established

[335] *https://pubmed.ncbi.nlm.nih.gov/33471458/.*

AIP policies; make updates to other programmatic areas including the program's eligibility requirements; and make timely technical changes to the regulations for clarity and consistency.

f. Medicare Part B Payment for Preventive Vaccine Administration Services

Section III.H.3 of this proposed rule discusses the implementation of policies that impact the payment amount for administration of preventive vaccines paid under the Part B vaccine benefit, specifically the proposed in-home additional payment for Part B vaccine administration. Section III.H.4. of this proposed rule codifies other amendments to the regulation text for Part B preventive vaccine administration. These provisions are necessary to provide stable payment for preventive vaccine administration and to allow predictability for providers and suppliers to rely on for building and sustaining robust vaccination programs.

g. Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging

In section III.J. of this proposed rule, we are proposing to pause implementation of the AUC program for reevaluation and to rescind the current AUC program regulations at § 414.94. These provisions are necessary because we have exhausted all reasonable options for fully operationalizing the AUC program consistent with the statutory provisions as prescribed in section 1834(q)(B) of the Act directing CMS to require real-time claims-based reporting to collect information on AUC consultation and imaging patterns for advanced diagnostic imaging services to ultimately inform outlier identification and prior authorization.

h. Medicare and Medicaid Provider Enrollment

This proposed rule also proposes several regulatory enhancements to our Medicare and Medicaid provider enrollment policies. These provisions focus on, but are not limited to: (1) expanding the bases for denying or revoking a provider's or supplier's Medicare enrollment; (2) revising the effective dates of certain Medicare revocations; and (3) revising certain policies regarding Medicaid terminations. These changes are necessary to help ensure that payments are made only to qualified providers and suppliers and/or to increase the efficiency of the Medicare and Medicaid provider enrollment processes. We believe that fulfilling these objectives would assist in protecting the Trust Funds and Medicare beneficiaries.

i. Expand Diabetes Screening and Diabetes Definitions

In section III.L. of this proposed rule, we are proposing to (1) expand coverage of diabetes screening tests to include the Hemoglobin A1C test (HbA1c) test, (2) expand and simplify the frequency limitations for diabetes screening, and (3) simplify the regulatory definition of ''diabetes'' for diabetes screening, Medical Nutrition Therapy (MNT) and Diabetes Outpatient Self-Management Training Services (DSMT). Diabetes is a chronic disease that affects how the body turns food into energy and includes three main types: Type 1, Type 2 and gestational diabetes. The Centers for Disease Control and Prevention (CDC) reports that approximately 37.3 million Americans are living with diabetes and an additional 96 million Americans are living with prediabetes.[336] CDC reports that 326,000 persons age 65 years and older are newly diagnosed with diabetes each year. CDC also estimates that among persons age 65 years and older, 21 percent have been diagnosed with diabetes while 5 percent have undiagnosed diabetes.[337] Diabetes is the leading cause of kidney failure and new cases of blindness among adults, and the sixth leading cause of death among adults age 65 years and older in the US.[338] Screening is performed on persons who may not exhibit symptoms to identify persons with either prediabetes or diabetes, who can then be referred for appropriate prevention or treatment, with the intention of improving health outcomes.

j. Basic Health Program Provisions

Section 1331 of the ACA requires the Secretary to establish a BHP, and section 1331(c)(4) of the ACA specifically provides that a State shall coordinate the administration of, and provision of benefits under the BHP with other State programs. Additionally, section 1331(f) of the ACA requires the Secretary to review each State's BHP on an annual basis. These proposed regulations build from previous BHP regulations to provide for options for BHP implementation and operations as well as oversight of the BHP program, beginning with program year 2024.

k. A Social Determinants of Health Risk Assessment in the Annual Wellness Visit

In section III.S. of this proposed rule, we are proposing to exercise our authority in section 1861(hhh)(2)(I) of the Act to add elements to the Annual Wellness Visit (AWV) by adding a new Social Determinants of Health (SDOH) Risk Assessment as an optional, additional element with an additional payment. We propose that the SDOH Risk Assessment be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV. The AWV includes the establishment (or update) of the patient's medical and family history, application of a health risk assessment and the establishment (or update) of a personalized prevention plan. The AWV also provides an optional Advance Care Planning (ACP) service. The AWV is covered for eligible beneficiaries who are no longer within 12 months of the effective date of their first Medicare Part B coverage period and who have not received either an Initial Preventive Physical Examination (IPPE) or AWV within the past 12 months. The goals of AWV are health promotion, disease prevention and detection and include education, counseling, a health risk assessment, referrals for prevention services, and a review of opioid use. Additional information about the AWV can be found on the CMS website at (*https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html*).

B. Overall Impact

We have examined the impacts 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 (January 18, 2011), Executive Order 14094 entitled ''Modernizing Regulatory Review'' (April 6, 2023), 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), and Executive Order 13132 on Federalism (August 4, 1999).

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

[336] CDC Website on diabetes at *https://www.cdc.gov/diabetes/basics/index.html.*

[337] Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2020. Accessed March 9, 2023. *https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.*

[338] Heron M. Deaths: Leading causes for 2019. National Vital Statistics Reports; vol 70 no 9. Hyattsville, MD: National Center for Health Statistics. 2021. DOI: *https://dx.doi.org/10.15620/cdc:107021.*

(including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 entitled ''Modernizing Regulatory Review'' (hereinafter, the Modernizing E.O.) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) ($200 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1)) as measured by the $200 million or more in any 1 year. Accordingly, we have 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 *https://www.sba.gov/document/support-table-size-standards* (refer to the 620000 series)). Individuals and States are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this proposed rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

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 603 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. Medicare does not pay rural hospitals for their services under the PFS; rather, 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 proposed 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 2023, that threshold is approximately $177 million. This 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 rule does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

We prepared the following analysis, which together with the information provided in the rest of this rule, meets all assessment requirements. The analysis explains the rationale for and purposes of this proposed rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we will use to minimize the burden on small entities. As indicated elsewhere in this proposed 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 to implement provisions of the statute. We provide information for each of the policy changes in the relevant sections of this proposed rule. We are unaware of any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives we considered, 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 Medicare Part B 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 2023 with payment rates for CY 2024 using CY 2022 Medicare utilization. The payment impacts described in this proposed rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and will depend on the mix of services they furnish. 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 diagnostic laboratory tests that are paid under the Clinical Laboratory Fee Schedule (CLFS).

The PFS update adjustment factor for CY 2024, as specified in section 1848(d)(19) of the Act, is 0.00 percent before applying other adjustments. In addition, the CAA, 2023 provided a one-time 2.50 percent increase in PFS payment amounts for services furnished on or after January 1, 2023, and a one-time 1.25 percent increase in PFS payment amounts for services furnished on or after January 1, 2024, and required that the supplementary increases shall not be taken into account in determining PFS payment rates for subsequent years.

To calculate the CY 2024 PFS conversion factor (CF), we took the CY 2023 conversion factor without the one-year 2.50 percent payment increase provided by the CAA, 2023 for CY 2023 and multiplied it by the budget neutrality adjustment required as described in the preceding paragraphs and the 1.25 percent PFS payment increase provided by the CAA, 2023 for CY 2024. We estimate the CY 2024 PFS CF to be 32.7476 which reflects the −2.17 percent budget neutrality adjustment under section 1848(c)(2)(B)(ii)(II) of the Act, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and the 1.25 percent payment increase for services furnished in CY 2024, as provided in the CAA, 2023. We estimate the CY 2024 anesthesia CF to be 20.4370 which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE 102: Calculation of the CY 2024 PFS Conversion Factor

CY 2023 Conversion Factor		33.8872
Conversion Factor without the CAA, 2023 (2.5 Percent Increase for CY 2023)		33.0607
CY 2024 RVU Budget Neutrality Adjustment	-2.17 percent (0.9783)	
CY 2024 1.25 Percent Increase Provided by the CAA, 2023	1.25 percent (1.0125)	
CY 2024 Conversion Factor		**32.7476**

TABLE 103: Calculation of the CY 2024 Anesthesia Conversion Factor

CY 2023 National Average Anesthesia Conversion Factor		21.1249
Conversion Factor without the CAA, 2023 (2.5 Percent Increase for CY 2023)		20.6097
CY 2024 RVU Budget Neutrality Adjustment	-2.17 percent (0.9783)	
CY 2024 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.11 percent (1.0011)	
CY 2024 1.25 Percent Increase Provided by the CAA, 2023	1.25 percent (1.0125)	
CY 2024 Conversion Factor		**20.4370**

Table 104 shows the payment impact of the policies contained in this proposed rule on PFS services. 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 104 (CY 2023 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 104.

- 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 2022 utilization and CY 2023 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 2024 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 2024 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 2024 impact on total allowed charges of the changes in the MP RVUs.
- Column F (Combined Impact): This column shows the estimated CY 2024 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

TABLE 104: CY 2024 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	$216	0%	-1%	0%	-1%
ANESTHESIOLOGY	$1,647	-2%	-1%	0%	-2%
AUDIOLOGIST	$69	-1%	-1%	0%	-2%
CARDIAC SURGERY	$174	-1%	-1%	0%	-2%
CARDIOLOGY	$5,989	0%	0%	0%	0%
CHIROPRACTIC	$644	-1%	-1%	0%	-2%
CLINICAL PSYCHOLOGIST	$711	1%	0%	0%	2%
CLINICAL SOCIAL WORKER	$795	2%	0%	0%	2%
COLON AND RECTAL SURGERY	$147	-1%	-1%	0%	-2%
CRITICAL CARE	$331	-1%	0%	0%	-1%
DERMATOLOGY	$3,713	0%	0%	0%	-1%
DIAGNOSTIC TESTING FACILITY	$828	0%	-2%	0%	-2%
EMERGENCY MEDICINE	$2,460	-2%	-1%	0%	-2%
ENDOCRINOLOGY	$507	1%	1%	0%	3%
FAMILY PRACTICE	$5,504	2%	2%	0%	3%
GASTROENTEROLOGY	$1,474	0%	0%	0%	0%
GENERAL PRACTICE	$361	1%	1%	0%	2%
GENERAL SURGERY	$1,614	-1%	-1%	0%	-1%
GERIATRICS	$180	0%	1%	0%	1%
HAND SURGERY	$251	-1%	0%	0%	-1%
HEMATOLOGY/ONCOLOGY	$1,591	1%	0%	0%	2%
INDEPENDENT LABORATORY	$546	-1%	-1%	0%	-1%
INFECTIOUS DISEASE	$573	-1%	0%	0%	-1%
INTERNAL MEDICINE	$9,618	0%	1%	0%	1%
INTERVENTIONAL PAIN MGMT	$849	0%	0%	0%	0%
INTERVENTIONAL RADIOLOGY	$457	-1%	-3%	0%	-4%
MULTISPECIALTY CLINIC/OTHER PHYS	$146	0%	0%	0%	0%
NEPHROLOGY	$1,803	-1%	0%	0%	-1%
NEUROLOGY	$1,323	0%	0%	0%	1%
NEUROSURGERY	$694	-1%	0%	0%	-1%
NUCLEAR MEDICINE	$51	-1%	-2%	0%	-3%
NURSE ANES / ANES ASST	$1,081	-2%	0%	0%	-2%
NURSE PRACTITIONER	$6,260	1%	1%	0%	2%
OBSTETRICS/GYNECOLOGY	$558	0%	1%	0%	1%
OPHTHALMOLOGY	$4,647	0%	0%	0%	-1%
OPTOMETRY	$1,292	-1%	-1%	0%	-2%
ORAL/MAXILLOFACIAL SURGERY	$62	-1%	-1%	0%	-2%
ORTHOPEDIC SURGERY	$3,358	-1%	0%	0%	-1%
OTHER	$55	0%	-1%	0%	0%
OTOLARYNGOLOGY	$1,112	0%	0%	0%	0%
PATHOLOGY	$1,136	-1%	-1%	0%	-2%
PEDIATRICS	$55	0%	1%	0%	1%
PHYSICAL MEDICINE	$1,087	0%	0%	0%	-1%
PHYSICAL/OCCUPATIONAL THERAPY	$5,257	-1%	-2%	0%	-2%
PHYSICIAN ASSISTANT	$3,366	1%	1%	0%	2%
PLASTIC SURGERY	$300	-1%	-1%	0%	-1%

(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
PODIATRY	$1,890	0%	0%	0%	0%
PORTABLE X-RAY SUPPLIER	$75	0%	0%	0%	-1%
PSYCHIATRY	$897	1%	1%	0%	2%
PULMONARY DISEASE	$1,290	0%	0%	0%	0%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	$1,552	0%	-2%	0%	-2%
RADIOLOGY	$4,517	-1%	-2%	0%	-3%
RHEUMATOLOGY	$509	1%	1%	0%	2%
THORACIC SURGERY	$292	-1%	-1%	0%	-2%
UROLOGY	$1,623	0%	0%	0%	1%
VASCULAR SURGERY	$1,009	0%	-3%	0%	-3%
TOTAL	$88,549	0%	0%	0%	0%

* Column F may not equal the sum of columns C, D, and E due to rounding.

In recent years, we have received requests from interested parties for CMS to provide more granular information that separates the specialty-specific impacts by site of service. These interested parties have presented high-level information to CMS suggesting that Medicare payment policies are directly responsible for the consolidation of privately-owned physician practices and freestanding supplier facilities into larger health systems. Their concerns highlight a need to update the information under the PFS to account for current trends in the delivery of health care, especially concerning independent versus facility-based practices. We published an RFI in the CY 2023 PFS proposed rule to gather feedback on this issue and refer readers to the discussion in last year's final rule (87 FR 69429 through 69438). As part of our holistic review of how best to update our data and offer interested parties additional information that addresses some of the concerns raised, we have recently improved our current suite of public use files (PUFs) by including a new file that shows estimated specialty payment impacts at a more granular level, specifically by showing ranges of impact for practitioners within a specialty. This file is available on the CMS website under downloads for the CY 2024 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

For this rulemaking cycle, we are providing an additional impact table that includes a facility/non-facility breakout of payment changes. The following is an explanation of the information represented in Table 105.

- Column A (Specialty): Identifies the specialty for which data are shown.
- Column B (Setting): Identifies the facility or nonfacility setting for which data are shown.
- Column C (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2022 utilization and CY 2023 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 D (Combined Impact): This column shows the estimated CY 2024 combined impact on total allowed charges.

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TABLE 105: CY 2024 PFS Estimated Impact on Total Allowed Charges by Setting

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
ALLERGY/IMMUNOLOGY	*TOTAL*	$216	-1%
	Non-Facility	$209	-1%
	Facility	$7	2%
ANESTHESIOLOGY	*TOTAL*	$1,647	-2%
	Non-Facility	$314	-2%
	Facility	$1,332	-2%
AUDIOLOGIST	*TOTAL*	$69	-2%
	Non-Facility	$67	-2%
	Facility	$3	-2%
CARDIAC SURGERY	*TOTAL*	$174	-2%
	Non-Facility	$34	-2%
	Facility	$141	-2%
CARDIOLOGY	*TOTAL*	$5,989	0%
	Non-Facility	$3,712	1%
	Facility	$2,278	-1%
CHIROPRACTIC	*TOTAL*	$644	-2%
	Non-Facility	$643	-2%
	Facility	$1	-2%
CLINICAL PSYCHOLOGIST	*TOTAL*	$711	2%
	Non-Facility	$567	2%
	Facility	$143	1%
CLINICAL SOCIAL WORKER	*TOTAL*	$795	2%
	Non-Facility	$646	3%
	Facility	$149	2%
COLON AND RECTAL SURGERY	*TOTAL*	$147	-2%
	Non-Facility	$54	-1%
	Facility	$94	-2%
CRITICAL CARE	*TOTAL*	$331	-1%
	Non-Facility	$50	2%
	Facility	$281	-2%
DERMATOLOGY	*TOTAL*	$3,713	-1%
	Non-Facility	$3,575	-1%
	Facility	$137	0%
DIAGNOSTIC TESTING FACILITY	*TOTAL*	$828	-2%
	Non-Facility	$827	-2%
	Facility	$2	-3%
EMERGENCY MEDICINE	*TOTAL*	$2,460	-2%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$193	-1%
	Facility	$2,267	-2%
ENDOCRINOLOGY	*TOTAL*	$507	3%
	Non-Facility	$406	3%
	Facility	$101	1%
FAMILY PRACTICE	*TOTAL*	$5,504	3%
	Non-Facility	$4,373	4%
	Facility	$1,131	1%
GASTROENTEROLOGY	*TOTAL*	$1,474	0%
	Non-Facility	$547	2%
	Facility	$927	-1%
GENERAL PRACTICE	*TOTAL*	$361	2%
	Non-Facility	$285	3%
	Facility	$76	-1%
GENERAL SURGERY	*TOTAL*	$1,614	-1%
	Non-Facility	$468	-1%
	Facility	$1,146	-2%
GERIATRICS	*TOTAL*	$180	1%
	Non-Facility	$105	2%
	Facility	$75	0%
HAND SURGERY	*TOTAL*	$251	-1%
	Non-Facility	$134	0%
	Facility	$118	-1%
HEMATOLOGY/ONCOLOGY	*TOTAL*	$1,591	2%
	Non-Facility	$1,037	1%
	Facility	$554	2%
INDEPENDENT LABORATORY	*TOTAL*	$546	-1%
	Non-Facility	$534	-1%
	Facility	$13	-3%
INFECTIOUS DISEASE	*TOTAL*	$573	-1%
	Non-Facility	$84	2%
	Facility	$489	-2%
INTERNAL MEDICINE	*TOTAL*	$9,618	1%
	Non-Facility	$4,699	3%
	Facility	$4,918	-1%
INTERVENTIONAL PAIN MGMT	*TOTAL*	$849	0%
	Non-Facility	$666	1%
	Facility	$183	-2%
INTERVENTIONAL RADIOLOGY	*TOTAL*	$457	-4%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$292	-5%
	Facility	$166	-3%
MULTISPECIALTY CLINIC/OTHER PHYS	*TOTAL*	$146	0%
	Non-Facility	$72	1%
	Facility	$74	-1%
NEPHROLOGY	*TOTAL*	$1,803	-1%
	Non-Facility	$1,068	0%
	Facility	$735	-2%
NEUROLOGY	*TOTAL*	$1,323	1%
	Non-Facility	$845	2%
	Facility	$477	-1%
NEUROSURGERY	*TOTAL*	$694	-1%
	Non-Facility	$119	0%
	Facility	$575	-2%
NUCLEAR MEDICINE	*TOTAL*	$51	-3%
	Non-Facility	$26	-2%
	Facility	$25	-3%
NURSE ANES / ANES ASST	*TOTAL*	$1,081	-2%
	Non-Facility	$24	-2%
	Facility	$1,057	-2%
NURSE PRACTITIONER	*TOTAL*	$6,260	2%
	Non-Facility	$4,036	3%
	Facility	$2,224	1%
OBSTETRICS/GYNECOLOGY	*TOTAL*	$558	1%
	Non-Facility	$381	2%
	Facility	$177	0%
OPHTHALMOLOGY	*TOTAL*	$4,647	-1%
	Non-Facility	$3,270	0%
	Facility	$1,377	-1%
OPTOMETRY	*TOTAL*	$1,292	-2%
	Non-Facility	$1,227	-2%
	Facility	$65	-1%
ORAL/MAXILLOFACIAL SURGERY	*TOTAL*	$62	-2%
	Non-Facility	$51	-2%
	Facility	$11	-2%
ORTHOPEDIC SURGERY	*TOTAL*	$3,358	-1%
	Non-Facility	$1,480	0%
	Facility	$1,878	-1%
OTHER	*TOTAL*	$55	0%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$43	0%
	Facility	$12	-1%
OTOLARYNGOLOGY	*TOTAL*	$1,112	0%
	Non-Facility	$883	1%
	Facility	$230	-1%
PATHOLOGY	*TOTAL*	$1,136	-2%
	Non-Facility	$589	-1%
	Facility	$546	-3%
PEDIATRICS	*TOTAL*	$55	1%
	Non-Facility	$34	2%
	Facility	$21	-1%
PHYSICAL MEDICINE	*TOTAL*	$1,087	-1%
	Non-Facility	$535	1%
	Facility	$552	-2%
PHYSICAL/OCCUPATIONAL THERAPY	*TOTAL*	$5,257	-2%
	Non-Facility	$5,257	-2%
	Facility	$	0%
PHYSICIAN ASSISTANT	*TOTAL*	$3,366	2%
	Non-Facility	$2,257	3%
	Facility	$1,109	0%
PLASTIC SURGERY	*TOTAL*	$300	-1%
	Non-Facility	$133	-1%
	Facility	$167	-2%
PODIATRY	*TOTAL*	$1,890	0%
	Non-Facility	$1,682	0%
	Facility	$208	0%
PORTABLE X-RAY SUPPLIER	*TOTAL*	$75	-1%
	Non-Facility	$72	-1%
	Facility	$3	-2%
PSYCHIATRY	*TOTAL*	$897	2%
	Non-Facility	$496	3%
	Facility	$401	0%
PULMONARY DISEASE	*TOTAL*	$1,290	0%
	Non-Facility	$532	3%
	Facility	$758	-2%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	*TOTAL*	$1,552	-2%
	Non-Facility	$1,076	-2%
	Facility	$476	-2%
RADIOLOGY	*TOTAL*	$4,517	-3%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$1,977	-3%
	Facility	$2,540	-3%
RHEUMATOLOGY	*TOTAL*	$509	2%
	Non-Facility	$457	2%
	Facility	$52	3%
THORACIC SURGERY	*TOTAL*	$292	-2%
	Non-Facility	$57	-5%
	Facility	$235	-2%
UROLOGY	*TOTAL*	$1,623	1%
	Non-Facility	$1,150	1%
	Facility	$474	0%
VASCULAR SURGERY	*TOTAL*	$1,009	-3%
	Non-Facility	$724	-4%
	Facility	$284	-2%
TOTAL	***TOTAL***	$88,549	0%
	Non-Facility	$55,071	1%
	Facility	$33,478	-1%

2. CY 2024 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 family practice, endocrinology, nurse practitioner, physician assistant, clinical social worker, psychiatry, clinical psychologist, and general practice, reflect increases relative to other physician specialties. These increases can largely be attributed to proposed implementation of the separate payment for the O/O E/M visit inherent complexity add-on code, the Year 3 update to clinical labor pricing, and/or the proposed adjustment to certain behavioral health services. Approximately 90 percent of the budget neutrality adjustment is attributable to the O/O E/M visit inherent complexity add-on code with all other proposed valuation changes making up the other 10 percent. The services that make up these specialties rely primarily on E/M services, behavioral health care, or on clinical labor for their practice expense costs. These increases are also due to increases in value for particular services after considering the recommendations from the American Medical Association's (AMA) Relative Value Scale Update Committee (RUC) and CMS review, and increased payments resulting from updates to supply and equipment pricing.

The estimated impacts for several specialties, including anesthesiology, interventional radiology, radiology, vascular and thoracic surgery, physical/occupational therapy, and audiologists reflect decreases in payments relative to payment to other physician specialties, largely resulting from the redistributive effects of the implementation of separate payment for the O/O E/M visit inherent complexity add-on code, the Year 3 update to clinical labor pricing, and/or the proposed adjustment to certain behavioral health services. The services that make up these specialties were negatively affected by the redistributive effects of increases in work RVUs for other codes, and/or rely primarily on supply/equipment items for their practice expense costs and therefore were affected negatively by the updated Year 3 clinical labor pricing under budget neutrality. These decreases are also due to the revaluation of individual procedures based on reviews, including consideration of AMA RUC review and recommendations, as well as decreases resulting from the continued phase-in implementation of the previously finalized updates to supply and equipment pricing. The estimated impacts also reflect decreases due to continued implementation of previously finalized code-level reductions that are being phased in over several years. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the CLFS.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table (Table 104), including comments received in response to the valuations. We remind interested parties 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 percentage changes in Table 104 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.

As discussed above, we have reviewed our suite of public use files and have worked on new ways to offer interested parties additional information that addresses some of the concerns raised about lack of granularity in our impact tables. To illustrate how impacts can vary within specialties, we created a public use file that models the expected percentage change in total RVUs per practitioner. Using CY 2022 utilization data, Total RVUs change between −1 percent and 1 percent for more than 15 percent of practitioners, representing approximately 26 percent of the changes in Total RVUs for all practitioners, with variation by specialty. Specialties, such as gastroenterology, exhibit little variation in changes in total RVUs per practitioner. Table 104 (CY 2024 PFS Estimated Impact on Total Allowed Charges by Specialty) indicates an overall change of 0 percent for this specialty, and the practitioner-level distribution shows that 89 percent of these practitioners will experience a change in Total RVUs between −2 percent and 2 percent. The specific service mix within a specialty may vary by practitioner, so individual practitioners may experience different changes in total RVUs. For example, Table 104 indicates a 1 percent increase in RVUs for the internal medicine specialty as a whole, however, 49 percent of internal medicine specialty practitioners—representing over 41 percent of Total RVUs for the specialty—will experience a 1 percent or more decrease in Total RVUs. Meanwhile, 40 percent of internal medicine specialty practitioners will experience 2 percent or more increases in Total RVUs, and these practitioners account for a similar 41 of Total RVUs for this specialty. We also note the code level RVU changes are available in the Addendum B public use file that we make available with each rule.

The specialty impacts displayed in Table 104 reflect changes that take place within the pool of total RVUs. The specialty impacts table therefore includes any changes in spending which result from finalized policies within BN (such as the updated proposals associated with the complexity add-on code G2211 in CY 2024 or the clinical labor pricing update that began in CY 2022) but does not include any changes in spending which result from finalized policies that are not subject to BN adjustment, and therefore, have a neutral impact across all specialties. The 2.50 and 1.25 percent payment supplements for CY 2023 and CY 2024, respectively, are statutory changes that take place outside of BN, and therefore, are not captured in the specialty impacts displayed in Table 104.

b. Impact

Column F of Table 104 displays the estimated CY 2024 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 2024 PFS proposed rule website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/.* We selected these procedures for sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/.*

3. Health Equity

Advancing health equity is the first pillar of CMS's 2022 Strategic Framework.[339] As part of our efforts to gain insight into how the PFS policies could affect health equity, we are considering adding elements to our impact analysis which would detail how policies impact particular patient populations. Patient populations that have been disadvantaged or underserved by the healthcare system may include patients with the following characteristics, among others: members of racial and ethnic minorities; members of federally recognized Tribes, people with disabilities; members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency, members of rural communities, and persons otherwise adversely affected by persistent poverty or inequality.

In the FY 2024 IPPS/LTCH PPS proposed rule, (88 FR 27261 through 27266), we included a table that details providers in terms of the beneficiaries they serve, as well as differences in estimated average payments per case and changes in estimated average payments per case relative to other providers. Because we do not have data for all characteristics that may identify disadvantaged or underserved patient populations, we use several proxies to capture these characteristics, including elements from claims data and Medicare enrollment data. The characteristics included in the table in the IPPS/LTCH PPS proposed rule, described in further detail below, include race/ethnicity, dual eligibility for Medicaid and Medicare, Medicare low income subsidy (LIS) enrollment, a joint indicator for dual or LIS enrollment, presence of an ICD–10–CM Z code indicating a ''social determinant of health'' (SDOH), presence of a behavioral health diagnosis code, receiving end-stage renal disease (ESRD) Medicare coverage, qualifying for Medicare due to disability, living in a rural area, and living in an area with an area deprivation index (ADI) greater than or equal to 85.

a. Race and Ethnicity

The first health equity-relevant grouping is race/ethnicity. To assign the race/ethnicity variables, we utilized the Medicare Bayesian Improved Surname Geocoding (MBISG) data in conjunction with the claims data. The method used to develop the MBISG data involves estimating a set of six racial and ethnic probabilities (White, Black, Hispanic, American Indian or Alaska Native, Asian or Pacific Islander, and multiracial) from the surname and address of beneficiaries by using previous self-reported data from a national survey of Medicare beneficiaries, post-stratified to CMS enrollment files. The MBISG method is used by the CMS Office of Minority Health in its reports analyzing Medicare Advantage plan performance on Healthcare Effectiveness Data and Information Set (HEDIS) measures, and is being considered by CMS for use in other CMS programs. In the 2024 IPPS/LTCH proposed rule (88 FR 27261 through 27266), we estimated the percentage of discharges for each specified racial/ethnic category for each hospital by taking, the sum of the probabilities for that category for that hospital and dividing by the hospital's total number of discharges.

b. Income

The two main proxies for income available in the Medicare claims and enrollment data are dual eligibility for Medicare and Medicaid and Medicare LIS status. Dual-enrollment status is a powerful predictor of poor outcomes on

[339] Available at *https://www.cms.gov/files/document/2022-cms-strategic-framework.pdf.*

some quality and resource use measures even after accounting for additional social and functional risk factors.[340] Medicare LIS enrollment refers to a beneficiary's enrollment in the low-income subsidy program for the Part D prescription drug benefit. This program covers all or part of the Part D premium for qualifying Medicare beneficiaries and gives them access to reduced copays for Part D drugs. (We note that beginning on January 1, 2024, eligibility for the full low-income subsidy will be expanded to include individuals currently eligible for the partial low-income subsidy.) Because Medicaid eligibility rules and benefits vary by State/territory, Medicare LIS enrollment identifies beneficiaries who are likely to have low income but may not be eligible for Medicaid. Not all beneficiaries who qualify for the duals or LIS programs actually enroll. Due to differences in the dual eligibility and LIS qualification criteria and less than complete participation in these programs, sometimes beneficiaries were flagged as dual but not LIS or vice versa. Hence this analysis also used a ''dual or LIS'' flag as a third proxy for low income. The dual and LIS flags were constructed based on enrollment/eligibility status in the CMS Chronic Conditions Data Warehouse (CCW) during the month of the hospital discharge.

c. Social Determinants of Health (SDOH)

Social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.[341] These circumstances or determinants influence an individual's health status and can contribute to wide health disparities and inequities. ICD–10–CM contains Z-codes that describe a range of issues related—but not limited—to education and literacy, employment, housing, ability to obtain adequate amounts of food or safe drinking water, and occupational exposure to toxic agents, dust, or radiation. The presence of ICD–10–CM Z-codes in the range Z55–Z65 identifies beneficiaries with these SDOH characteristics. The SDOH flag used for this analysis was turned on if one of these Z-codes was recorded on the claim for the physician service itself (that is, the beneficiary's prior claims were not examined for additional Z-codes). Analysis of Z-codes in Medicare claims data from 2019 suggests that Z-codes are used inconsistently across provider types and population groups, and are generally underreported.[342] Therefore, we believe Z-codes do not reflect the actual rates of SDOH.

d. Behavioral Health

Beneficiaries with behavioral health diagnoses often face co-occurring physical illnesses, but often experience difficulty accessing care.[343] The combination of physical and behavioral health conditions can exacerbate both conditions and result in poorer outcomes than one condition alone.[344] Additionally, the intersection of behavioral health and health inequities is a core aspect of CMS' Behavioral Health Strategy.[345] We used the presence of one or more ICD–10–CM codes in the range of F01–F99 to identify beneficiaries with a behavioral health diagnosis.

e. Disability

Individuals under age 65 who are determined eligible for Social Security disability benefits may also be eligible for Medicare coverage.[346] Individuals may qualify for Social Security disability benefits on the basis of a medically determinable physical or mental impairment(s) that has lasted or is expected to last for a continuous period of at least 12 months or is expected to result in death.[347] Disabled beneficiaries often have complex healthcare needs and difficulty accessing care. Compared to people without disabilities, people with disabilities generally have less access to health care, have more depression and anxiety, engage more often in risky health behaviors such as smoking, and are less physically active.[348] Beneficiaries were classified as disabled for the purposes of this analysis if their original reason for qualifying for Medicare was disability; this information was obtained from Medicare's CCW enrollment data. We note that this is likely an underestimation of disability, because it does not account for beneficiaries who became disabled after becoming entitled to Medicare.

f. End-Stage Renal Disease (ESRD)

Beneficiaries with ESRD have high healthcare needs and high medical spending, and often experience comorbid conditions and poor mental health. Beneficiaries with ESRD also experience significant disparities, such as a limited life expectancy.[349] Beneficiaries were classified as ESRD for the purposes of this analysis if they were receiving Medicare ESRD coverage during the month of the discharge; this information was obtained from the CCW enrollment data.

g. Geography

Beneficiaries in some geographic areas—particularly rural areas or areas with concentrated poverty—often have difficulty accessing care. [350] [351] For this analysis, beneficiaries were classified on two dimensions: from a rural area and from an area with an area deprivation index (ADI) greater than or equal to 85.

Rural status is defined for purposes of this analysis using the primary Rural-Urban Commuting Area (RUCA) codes 4–10 (including micropolitan, small town, and rural areas) corresponding to each beneficiary's zip code. RUCA codes are defined at the census tract level based on measures of population density, urbanization, and daily commuting. The ADI is obtained from a publicly available dataset designed to capture socioeconomic disadvantage at the neighborhood level.[352] It utilizes data on income, education,

[340] *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195046/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report-Executive-Summary.pdf.*

[341] *Available at: https://health.gov/healthypeople/priority-areas/social-determinants-health.*

[342] Maksut JL, Hodge C, Van CD, Razmi, A, & Khau MT. Utilization of Z Codes for Social Determinants of Health among Medicare Fee-For-Service Beneficiaries, 2019. Office of Minority Health (OMH) Data Highlight No. 24. Centers for Medicare and Medicaid Services (CMS), Baltimore, MD, 2021. Available at *https://www.cms.gov/files/document/z-codes-data-highlight.pdf.*

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[345] *https://www.cms.gov/cms-behavioral-health-strategy.*

[346] Medicare eligibility on the basis of disability is discussed in 42 CFR 406.12.

[347] *https://www.ssa.gov/disability/professionals/bluebook/general-info.htm.*

[348] *https://www.cdc.gov/ncbddd/humandevelopment/health-equity.html#ref.*

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[352] *https://www.neighborhoodatlas.medicine.wisc.edu/.*

employment, housing quality, and 13 other factors from the American Community Survey (ACS) and combines them into a single raw score, which is then used to rank neighborhoods (defined at various levels), with higher scores reflecting greater deprivation. The version of the ADI used for this analysis is at the Census Block Group level and the ADI corresponds to the Census Block Group's percentile nationally. Living in an area with an ADI score of 85 or above, a validated measure of neighborhood disadvantage, is shown to be a predictor of 30-day readmission rates, lower rates of cancer survival, poor end of life care for patients with heart failure, and longer lengths of stay and fewer home discharges post-knee surgery even after accounting for individual social and economic risk factors.[353] [354] [355] [356] [357] The MedPAR discharge data was linked to the ADI data available in the CCW. Beneficiaries with no recorded ADI were treated as being from an urban area and as having an ADI less than 85.

In examining how we might expand our PFS impact analysis, we considered what framework might accurately provide insight into the relationship between PFS policies and health equity. Rather than examining changes in estimated average payments, we believe that illuminating the baseline is a necessary first step toward advancing our goal of measuring the impact of PFS policies on health equity. Table 107 displays the share of utilization for each of the health-equity relevant characteristics listed above. First, we list the share of enrollees with each characteristic. Next, we list the share of utilization by beneficiaries (that is, enrollees with at least one claim for a physician service in CY 2022) with each characteristic by provider specialty. The information contained in Table 107 is provided solely to demonstrate beneficiary utilization of services by provider specialty impact across a number of health equity dimensions and does not form the basis or rationale for the proposed policies.

In consideration of the differences between IPPS/LTCH and the PFS discussed below, we are seeking comment from interested parties about how we might structure a PFS impact analysis that addresses these and other considerations to examine how changes in the PFS would impact beneficiaries of particular groups. We are also seeking comment about how such a framework would allow us to consider developing policies that enhance health equity under our existing statutory authority. We welcome suggestions about alternative measures of health equity in our impact analysis, in particular with regard to the ADI as a proxy for disparities related to geographic variation. Finally, we seek feedback about additional categories beyond those described previously that should be considered in our analysis, along with potential data sources.

Nature of a service. In the table that details providers in terms of the beneficiaries they serve in the IPPS/LTCH PPS proposed rule, the unit of measurement we used was a hospital discharge. A discharge includes all resources involved in the hospital's caring for a beneficiary during the hospital stay. There is no parallel construct under the PFS. While the resources involved in furnishing a given discharge can and do vary under the IPPS, a discharge consists of a somewhat predictable set of resources that occur across a number of cost centers. On the other hand, a service unit under the PFS can range from very discrete services, such as a single pulse oximetry measurement (CPT code 94760) with total RVUs of 0.07 to complex services that include several visits during a global period, such as a liver transplant (CPT code 47135) with total RVUs of 160.44. As an illustration, based on the MS–DRGs reported in the claims data, the standard deviation of the mean IPPS relative weight is of similar magnitude to the mean. In contrast, based on the PFS services reported in the claims data, the standard deviation of the mean PFS RVU service is vastly larger than the mean.

TABLE 106: Differences in Claim-level Relative Weights between IPPS and PFS

	IPPS Relative Weight[358] on claim	PFS RVU on claim
Mean	1.95	2.62
Standard Deviation	1.72	1,241

In addition, under the PFS, some services furnished during a single encounter are billed in multiple units. These services could range from allergy testing (CPT codes 95004 through 95078) to anesthesia services (CPT codes 00100 through 01860). The average total RVUs for services billed in multiple units are not comparable to services billed in a single unit per encounter.

Number of practitioners serving a beneficiary and associated spending. Under the IPPS, most beneficiaries who had one or more IPPS claims during fiscal year 2022 were served by 1 or 2 providers, which accounts for most of the spending under the IPPS. The share of beneficiaries served by a given number of providers is consistent with the share of spending incurred for these discharges. Less than 10 percent of beneficiaries were served by 5 or more providers. Under the PFS, during CY

[353] 7 U.S. Department of Health & Human Services, ''Executive Summary: Report to Congress: Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program,'' Office of the Assistant Secretary for Planning and Evaluation, March 2020. Available at *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195046/Social-Risk-inMedicare%E2%80%99s-VBP-2nd-Report-Executive-Summary.pdf.*

[354] Kind AJ, et al., ''Neighborhood socioeconomic disadvantage and 30-day rehospitalization: a retrospective cohort study.'' Annals of Internal Medicine. No. 161(11), pp 765–74, doi: 10.7326/M13–2946 (December 2, 2014), available at *https://www.acpjournals.org/doi/epdf/10.7326/M13-2946.*

[355] Jencks SF, et al., ''Safety-Net Hospitals, Neighborhood Disadvantage, and Readmissions Under Maryland's All-Payer Program.'' Annals of Internal Medicine. No. 171, pp 91–98, doi:10.7326/M16–2671 (July 16, 2019), available at *https://www.acpjournals.org/doi/epdf/10.7326/M16-2671.*

[356] Cheng E, et al., ''Neighborhood and Individual Socioeconomic Disadvantage and Survival Among Patients With Nonmetastatic Common Cancers.'' JAMA Network Open Oncology. No. 4(12), pp 1–17, doi: 10.1001/jamanetworkopen.2021.39593 (December 17, 2021), available at *https://onlinelibrary.wiley.com/doi/epdf/10.1111/jrh.12597.*

[357] Khlopas A, et al., ''Neighborhood Socioeconomic Disadvantages Associated With Prolonged Lengths of Stay, Nonhome Discharges, and 90-Day Readmissions After Total Knee Arthroplasty.'' The Journal of Arthroplasty. No. 37(6), pp S37–S43, doi: 10.1016/j.arth.2022.01.032 (June 2022), available at *https://www.sciencedirect.com/science/article/pii/S0883540322000493.*

[358] The IPPS relative weights are not fully comparable to PFS RVUs because IPPS payments may include outliers. Even considering outliers, however, the standard deviation on IPPS payments is only slightly higher relative to the mean ($17,104+/−$21,825).

2022, most beneficiaries with one or more PFS claims saw 5 or more practitioners. In contrast to the pattern under the IPPS, PFS spending for beneficiaries who saw 10 or more practitioners accounted for a disproportionate share of total spending. Under the IPPS, examining providers in terms of beneficiary characteristics reflects the care of most beneficiaries with one or more discharges under the IPPS. Under the PFS, the same framework would be mostly describing the forty percent of beneficiaries with one or more PFS services who account for close to 80 percent of total spending.

Utilization of services by beneficiary characteristic. As shown in Table 107, the specialty-level services utilized by beneficiaries with particular characteristics varies widely. Beneficiaries with the characteristics in Table 107 do not access services consistent with the share of enrollees with that characteristic. As a result, comparing across deciles, for example, of practitioners serving beneficiaries of one race, would often be comparing very different service mixes. How discrete a service is, the setting it is furnished in, and the associated inputs may result in services that have very different baseline allowed charges.

A significant body of literature has examined the reasons for differential access to physician services by beneficiary characteristic. Some of the explanations of the differential utilization of services include:

- Patient preferences and willingness to undergo procedures, such as due to decreased belief in treatment efficacy and concerns about surgical risks[359] [360] [361] [362]
- Geographic location: specialists and sub-specialists are sometimes clustered in urban areas due to higher demand for services [363]
- Differences in referral patterns [364] from primary care physicians and following hospitalizations
- Differences in providers who can speak the language of beneficiaries with Limited English Proficiency [365]

The information contained in Table 107 is provided solely to demonstrate beneficiary utilization by provider specialty impact across a number of health equity dimensions. This does not form the basis or rationale for the proposed policies in this proposed rule.

[359] Ibrahim SA, Siminoff LA, Burant CJ, et al. Differences in expectations of outcome mediate African American/white patient differences in ''willingness'' to consider joint replacement. *Arthritis Rheum.* 2002;46:2429–2435.

[360] Vina ER, Cloonan YK, Ibrahim SA, et al. Race, sex, and total knee replacement consideration: role of social support. *Arthritis Care Res (Hoboken)* 2013;65:1103–1111.

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[362] Hausmann LR, Mor M, Hanusa BH, et al. The effect of patient race on total joint replacement recommendations and utilization in the orthopedic setting. *J Gen Intern Med.* 2010;25:982–988.

[363] Cyr, M.E., Etchin, A.G., Guthrie, B.J. et al. Access to specialty healthcare in urban versus rural US populations: a systematic literature review. BMC Health Serv Res 19, 974 (2019). *https://doi.org/10.1186/s12913-019-4815-5.*

[364] Landon BE, Onnela J, Meneades L, O'Malley AJ, Keating NL. Assessment of Racial Disparities in Primary Care Physician Specialty Referrals. JAMA Netw Open. 2021;4(1):e2029238. doi:10.1001/jamanetworkopen.2020.29238.

[365] Berdahl TA, Kirby JB. Patient-Provider Communication Disparities by Limited English Proficiency (LEP): Trends from the US Medical Expenditure Panel Survey, 2006–2015. J Gen Intern Med. 2019 Aug;34(8):1434–1440. doi: 10.1007/s11606–018–4757–3. Epub 2018 Dec 3. PMID: 30511285; PMCID: PMC6667581.

TABLE 107: Beneficiary Service Utilization by Payment Impact Specialty Across Demographic and Equity Characteristics, CY 2022

	All	White	Black	Hispanic	AAPI[366]	AIAN[367]	SDOH	Behavioral Health	ESRD	ADI	LIS Ever	Dual Ever	LIS/Dual Ever	Non-Metro	Disability
	Total # of Enrollees	% Enrollees													
All Enrollees	28,285,281	79.8 %	7.4 %	5.8 %	3.2 %	0.5 %	0.9 %	31.5 %	0.9 %	7.7 %	17.7 %	16.6 %	18.0 %	22.6 %	18.6 %
	Total Services	% Services													
All Users	2,504,984,961	81.8 %	7.2 %	5.1 %	2.4 %	0.4 %	0.0 %	3.7 %	1.9 %	6.7 %	18.8 %	17.7 %	19.0 %	16.3 %	23.7 %
ALLERGY/IMMUNOLOGY	20,089,081	84.0 %	5.5 %	4.1 %	2.5 %	0.1 %	0.0 %	0.5 %	0.3 %	4.4 %	8.6 %	7.8 %	8.6 %	11.7 %	16.3 %
ANESTHESIOLOGY	9,563,100	82.9 %	6.4 %	5.4 %	2.1 %	0.5 %	0.0 %	6.2 %	1.2 %	6.9 %	19.5 %	17.7 %	19.6 %	16.8 %	30.7 %
CARDIAC SURGERY	457,226	82.7 %	5.9 %	5.8 %	2.1 %	0.5 %	0.0 %	2.1 %	4.3 %	8.0 %	16.6 %	15.5 %	16.8 %	22.7 %	16.7 %
CARDIOLOGY	71,347,515	81.5 %	7.2 %	5.3 %	2.8 %	0.3 %	0.0 %	1.8 %	2.4 %	7.3 %	15.8 %	14.6 %	15.9 %	17.4 %	16.4 %
COLON AND RECTAL SURGERY	724,904	83.7 %	5.6 %	4.7 %	2.5 %	0.2 %	0.0 %	0.7 %	1.3 %	5.7 %	13.6 %	12.6 %	13.8 %	12.8 %	19.9 %

[366] American Asian and Pacific Islander .
[367] American Indian and Alaskan Native.

	All	Total # of Enrollees	% Enrollees												
			White	Black	Hispanic	AAPI[366]	AIAN[367]	SDOH	Behavioral Health	ESRD	ADI	LIS Eyer	Dual Eyer	LIS/Dual Eyer	Non-Metro	Disability
CRITICAL CARE	1,867,947		76.1 %	10.3 %	6.9 %	3.4 %	0.4 %	0.1 %	5.3 %	5.2 %	7.4 %	28.8 %	27.6 %	29.2 %	13.0 %	27.1 %
DERMATOLOGY	49,298,654		93.2 %	0.9 %	1.6 %	0.7 %	0.1 %	0.0 %	0.6 %	0.5 %	3.7 %	4.2 %	3.8 %	4.3 %	15.4 %	7.4 %
EMERGENCY MEDICINE	21,952,901		78.7 %	9.6 %	6.0 %	2.4 %	0.6 %	0.2 %	5.3 %	3.1 %	7.8 %	25.1 %	23.8 %	25.4 %	17.3 %	24.8 %
ENDOCRINOLOGY	13,439,562		82.9 %	5.2 %	4.2 %	3.7 %	0.2 %	0.0 %	1.1 %	1.4 %	4.2 %	11.2 %	10.2 %	11.3 %	9.1 %	16.4 %
FAMILY PRACTICE	99,140,616		84.0 %	5.8 %	4.3 %	2.3 %	0.5 %	0.2 %	11.6 %	0.9 %	8.0 %	16.3 %	15.1 %	16.5 %	22.0 %	19.4 %
GASTROENTEROLOGY	25,248,189		84.4 %	5.7 %	4.0 %	2.0 %	0.2 %	0.0 %	0.6 %	1.1 %	5.3 %	11.2 %	10.4 %	11.3 %	12.9 %	17.9 %
GENERAL PRACTICE	5,342,814		73.9 %	8.4 %	9.8 %	3.9 %	0.5 %	0.1 %	12.5 %	1.3 %	7.2 %	28.6 %	27.6 %	28.8 %	16.5 %	23.2 %
GENERAL SURGERY	9,166,757		80.9 %	8.2 %	5.8 %	1.9 %	0.5 %	0.0 %	3.7 %	5.2 %	8.8 %	23.0 %	21.9 %	23.3 %	21.9 %	28.9 %
GERIATRICS	1,625,353		76.7 %	9.3 %	5.8 %	5.1 %	0.4 %	0.6 %	30.1 %	1.6 %	5.1 %	30.8 %	30.2 %	31.3 %	9.1 %	17.2 %
HAND SURGERY	3,013,821		87.6 %	3.7 %	3.0 %	1.7 %	0.2 %	0.0 %	0.1 %	0.5 %	3.8 %	7.4 %	6.7 %	7.5 %	11.4 %	13.2 %

	All	Total # of Enrollees	% Enrollees												
			White	Black	Hispanic	AAPI[366]	AIAN[367]	SDOH	Behavioral Health	ESRD	ADI	LIS Eyer	Dual Eyer	LIS/Dual Eyer	Non-Metro	Disability
HEMATOLOGY/ONCOLOGY	458,304,885		81.4 %	8.1 %	4.8 %	2.4 %	0.3 %	0.0 %	1.0 %	1.2 %	7.4 %	13.9 %	12.9 %	14.0 %	14.5 %	18.2 %
INFECTIOUS DISEASE	48,318,745		86.6 %	4.9 %	4.2 %	1.1 %	0.2 %	0.0 %	0.4 %	3.3 %	6.7 %	12.8 %	11.4 %	12.9 %	5.4 %	24.5 %
INTERNAL MEDICINE	142,667,884		80.0 %	8.2 %	5.2 %	3.3 %	0.4 %	0.1 %	10.0 %	2.4 %	6.6 %	19.9 %	18.9 %	20.1 %	15.1 %	21.0 %
INTERVENTIONAL PAIN MGMT	15,783,928		83.7 %	6.3 %	5.4 %	1.7 %	0.4 %	0.0 %	3.7 %	0.6 %	7.2 %	18.3 %	16.5 %	18.4 %	15.3 %	32.5 %
INTERVENTIONAL RADIOLOGY	6,371,060		75.5 %	10.3 %	7.1 %	3.6 %	0.3 %	0.0 %	0.6 %	11.3 %	7.0 %	21.3 %	20.1 %	21.5 %	14.6 %	20.5 %
MULTISPECIALTY CLINIC/OTHER PHYS	1,874,372		81.5 %	6.6 %	4.6 %	3.2 %	0.7 %	0.2 %	6.7 %	1.9 %	5.9 %	19.3 %	18.3 %	19.4 %	15.8 %	20.7 %
NEPHROLOGY	15,193,786		61.7 %	19.2 %	10.8 %	4.7 %	0.8 %	0.0 %	1.5 %	35.1 %	10.2 %	31.4 %	29.3 %	31.8 %	14.4 %	26.1 %
NEUROLOGY	49,770,374		83.8 %	5.6 %	5.0 %	2.0 %	0.3 %	0.0 %	4.2 %	0.7 %	5.3 %	20.4 %	19.2 %	20.6 %	12.9 %	40.7 %
NEUROSURGERY	2,430,012		83.7 %	6.3 %	4.3 %	2.0 %	0.4 %	0.0 %	1.0 %	0.9 %	8.1 %	17.0 %	15.8 %	17.2 %	20.6 %	25.8 %
NUCLEAR MEDICINE	1,840,191		82.2 %	6.1 %	5.4 %	2.6 %	0.1 %	0.0 %	0.6 %	1.0 %	6.0 %	14.6 %	13.7 %	14.7 %	9.0 %	15.4 %

	All	% Enrollees														
	Total # of Enrollees	White	Black	Hispanic	AAPI[366]	AIAN[367]	SDOH	Behavioral Health	ESRD	ADI	LIS Ever	Dual Ever	LIS/Dual Ever	Non-Metro	Disability
OBSTETRICS/GYNECOLOGY	11,867,340	81.2 %	8.6 %	4.6 %	2.2 %	0.5 %	0.0 %	1.1 %	0.6 %	6.8 %	14.2 %	13.4 %	14.3 %	15.7 %	18.3 %
OPHTHALMOLOGY	55,861,861	83.3 %	5.2 %	4.7 %	3.5 %	0.3 %	0.0 %	0.1 %	1.4 %	5.6 %	10.9 %	10.0 %	11.0 %	17.4 %	9.8 %
ORTHOPEDIC SURGERY	48,700,496	85.2 %	5.4 %	4.0 %	2.1 %	0.3 %	0.0 %	0.3 %	0.5 %	6.0 %	9.7 %	8.7 %	9.7 %	17.4 %	13.8 %
OTOLARYNGOLOGY	13,168,571	84.1 %	5.8 %	4.2 %	2.4 %	0.2 %	0.0 %	0.8 %	0.5 %	5.7 %	11.8 %	10.9 %	11.8 %	16.9 %	16.0 %
PATHOLOGY	22,251,357	83.3 %	6.1 %	4.3 %	2.4 %	0.3 %	0.0 %	0.5 %	2.1 %	6.2 %	13.2 %	12.2 %	13.3 %	18.1 %	15.6 %
PEDIATRICS	2,097,101	78.4 %	7.1 %	8.9 %	1.4 %	0.3 %	0.1 %	3.9 %	1.9 %	9.4 %	19.3 %	18.2 %	19.4 %	12.4 %	29.8 %
PHYSICAL MEDICINE	24,542,987	80.2 %	8.2 %	4.9 %	3.0 %	0.3 %	0.0 %	3.8 %	1.2 %	5.6 %	26.4 %	25.3 %	26.7 %	13.7 %	34.7 %
PLASTIC SURGERY	1,800,630	84.2 %	6.4 %	4.6 %	1.4 %	0.4 %	0.0 %	2.0 %	1.6 %	5.4 %	17.9 %	17.0 %	18.0 %	16.2 %	20.0 %
PSYCHIATRY	9,308,283	75.7 %	10.6 %	6.7 %	2.5 %	0.5 %	1.0 %	94.6 %	0.7 %	7.6 %	51.8 %	50.0 %	52.2 %	12.7 %	58.7 %
PULMONARY DISEASE	13,466,574	81.7 %	7.8 %	5.0 %	2.3 %	0.3 %	0.1 %	5.0 %	2.4 %	7.3 %	19.3 %	18.1 %	19.5 %	17.2 %	23.2 %

	All	% Enrollees																
	Total # of Enrollees	White	Black	Hispanic	AAPI[366]	AIAN[367]	SDOH	Behavioral Health	ESRD	ADI	LIS Ever	Dual Ever	LIS/Dual Ever	Non-Metro	Disability
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	12,793,376	83.3 %	6.4 %	4.7 %	2.0 %	0.4 %	0.0 %	0.9 %	0.9 %	7.1 %	11.5 %	10.5 %	11.6 %	20.1 %	13.4 %
RADIOLOGY	181,430,147	81.4 %	6.7 %	5.3 %	2.8 %	0.3 %	0.0 %	0.4 %	1.4 %	5.3 %	15.0 %	14.0 %	15.1 %	14.3 %	17.6 %
RHEUMATOLOGY	166,143,825	85.0 %	5.4 %	4.7 %	1.9 %	0.2 %	0.0 %	0.4 %	0.4 %	5.7 %	6.5 %	5.5 %	6.6 %	12.9 %	21.3 %
THORACIC SURGERY	729,721	80.8 %	8.5 %	5.1 %	2.2 %	0.4 %	0.0 %	2.5 %	4.3 %	8.0 %	18.7 %	17.5 %	19.0 %	19.9 %	19.2 %
UROLOGY	54,057,785	83.2 %	7.4 %	3.9 %	1.5 %	0.2 %	0.0 %	0.4 %	0.7 %	5.4 %	8.3 %	7.6 %	8.4 %	14.0 %	15.9 %
VASCULAR SURGERY	5,409,525	74.5 %	12.9 %	7.0 %	2.3 %	0.3 %	0.0 %	1.2 %	16.2 %	8.0 %	23.2 %	21.6 %	23.4 %	15.1 %	22.1 %
AUDIOLOGIST	2,055,569	85.3 %	4.3 %	3.9 %	2.6 %	0.3 %	0.1 %	0.2 %	0.6 %	4.5 %	12.1 %	11.5 %	12.2 %	15.4 %	12.4 %
CHIROPRACTOR	17,158,259	91.2 %	2.0 %	2.1 %	1.2 %	0.3 %	0.0 %	0.0 %	0.3 %	5.9 %	7.5 %	6.7 %	7.6 %	27.2 %	12.5 %
CLINICAL PSYCHOLOGIST	6,463,428	83.1 %	6.4 %	4.8 %	1.8 %	0.3 %	1.0 %	88.4 %	0.9 %	4.3 %	32.2 %	31.2 %	32.5 %	10.7 %	36.2 %
CLINICAL SOCIAL WORKER	6,599,714	82.9 %	8.3 %	3.9 %	1.0 %	0.4 %	1.6 %	99.6 %	0.8 %	6.7 %	43.9 %	42.5 %	44.3 %	14.7 %	49.2 %

	All	Total # of Enrollees	% Enrollees											
			White	Black	Hispanic	AAPI[366]	AIAN[367]	SDOH	Behavioral Health	ESRD	ADI	LIS Ever	Dual Ever	LIS/Dual Ever	Non-Metro	Disability
DIAGNOSTIC TESTING FACILITY	23,489,346		83.1 %	6.2 %	4.5 %	2.8 %	0.2 %	0.0 %	0.3 %	0.6 %	5.4 %	12.3 %	11.1 %	12.4 %	14.0 %	16.3 %
INDEPENDENT LABORATORY	31,744,057		78.1 %	12.5 %	5.6 %	1.6 %	0.2 %	0.0 %	2.4 %	1.6 %	9.7 %	39.8 %	39.3 %	40.3 %	14.7 %	26.4 %
NURSE ANES / ANES ASST	543,164		86.1 %	4.3 %	4.8 %	1.3 %	0.7 %	0.0 %	14.2 %	1.6 %	8.3 %	16.9 %	15.6 %	17.1 %	31.4 %	23.8 %
NURSE PRACTITIONER	128,768,200		84.8 %	7.2 %	3.7 %	1.4 %	0.4 %	0.1 %	10.6 %	1.9 %	8.5 %	21.1 %	20.2 %	21.5 %	22.1 %	25.7 %
OPTOMETRY	19,912,703		87.0 %	5.1 %	2.8 %	1.6 %	0.5 %	0.0 %	0.1 %	0.6 %	8.8 %	11.7 %	10.8 %	11.8 %	33.8 %	12.1 %
ORAL/MAXILLOFACIAL SURGERY	296,908		79.2 %	4.5 %	6.0 %	6.0 %	0.1 %	0.0 %	1.2 %	0.5 %	3.6 %	20.8 %	19.9 %	20.9 %	10.6 %	20.4 %
PHYSICAL/OCCUPATIONAL THERAPY	159,690,345		85.1 %	4.7 %	3.8 %	2.7 %	0.2 %	0.0 %	2.3 %	0.5 %	3.7 %	10.8 %	10.2 %	10.9 %	13.5 %	13.0 %
PHYSICIAN ASSISTANT	65,080,844		86.5 %	5.1 %	3.5 %	1.4 %	0.5 %	0.1 %	4.3 %	1.1 %	6.0 %	13.7 %	12.8 %	13.9 %	20.2 %	18.6 %
PODIATRY	27,252,983		80.8 %	8.7 %	5.5 %	2.1 %	0.4 %	0.0 %	0.4 %	2.3 %	6.4 %	23.9 %	23.0 %	24.2 %	14.9 %	20.9 %
PORTABLE X-RAY SUPPLIER	3,380,767		79.2 %	10.4 %	6.5 %	2.2 %	0.3 %	0.2 %	0.2 %	2.1 %	9.9 %	59.1 %	59.3 %	60.0 %	17.2 %	28.5 %

		All	White	Black	Hispanic	AAPI[366]	AIAN[367]	SDOH	Behavioral Health	ESRD	ADI	LIS Eyer	Dual Eyer	LIS/Dual Eyer	Non-Metro	Disability
	Total # of Enrollees	% Enrollees														
OTHER	311,487,534		74.2 %	10.1 %	8.6 %	3.2 %	1.0 %	0.0 %	2.1 %	3.8 %	8.2 %	44.9 %	42.9 %	45.2 %	20.7 %	52.9 %
D6	2,597,888		47.5 %	21.5 %	10.2 %	0.1 %	0.0 %	0.0 %	0.0 %	15.5 %	17.0 %	65.5 %	64.6 %	65.5 %	12.1 %	67.8 %

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D. Impact of Proposed Changes Related to Telehealth Services

We are proposing to implement the provisions of the CAA, 2023 that amended section 1834(m) of the Act) to extend the application of certain Medicare telehealth flexibilities through December 31, 2024, including allowing Medicare telehealth services to be furnished to patients located anywhere within the U.S.; continuing the expanded scope of telehealth practitioners to include occupational therapists, physical therapists, speech-language pathologists, and audiologists; extending payment for telehealth services furnished by FQHCs and RHCs; and delaying the requirement that there be an in-person visit with the physician or practitioner within 6 months before an initial mental health telehealth service.

In this proposed rule, we are proposing a refined process for considering requests received for addition of services to the Medicare Telehealth Services List, which would include a decision on whether the services should be proposed for inclusion on the list on either a permanent or provisional basis. Because the underlying criteria for adding services to the Medicare Telehealth Services List are not changing, we do not expect this proposal to have an impact on the utilization of Medicare Telehealth services beginning in CY 2024 but we will continue to monitor utilization of these services. We are proposing that, beginning in CY 2024, claims billed with POS 10 (Telehealth Provided in Patient's Home) would be paid at the non-facility PFS rate. Claims billed with POS 02 (Telehealth Provided Other than in Patient's Home) will continue to be paid at the PFS facility rate. As we are currently paying for the majority of services that will be billed with POS 10 at the PFS non-facility rate under the PHE-specific policy of paying the place of service code had the service been furnished in person, we believe that these services furnished via telehealth will largely be paid as they are currently. Therefore, we believe the impact of this proposal will roughly neutral even if utilization remains at current levels for these services. We anticipate that these provisions will result in continued utilization of Medicare telehealth services during CY 2024 at levels comparable to observed utilization of these services during the PHE for COVID–19.

E. Other Provisions of the Regulation

1. Impact of Proposals for Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Medical Services

In section II.K.2. of this proposed rule, we are: (1) proposing to allow payment for dental examinations, diagnostic, and treatment services prior to and during certain treatments for cancer (chemotherapy and CAR–T cell therapy); (2) proposing to allow payment for dental examinations, diagnostic, and treatment services prior to and during antiresorptive and/or antiangiogenic drug therapy associated with the treatment for cancer; and (3) requesting comments on other types of cardiovascular interventions (analogous to cardiac valve replacements and valvuloplasty procedures) where dental services may be inextricably linked to, and substantially related and integral to the clinical success of, other cardiovascular covered medical services.

If we were to finalize the proposal that Medicare Part A and Part B payment can be made for oral or dental examination, and necessary treatment, performed prior to and during certain cancer treatments or drug therapies associated with managing cancer related care, we do not anticipate any significant increase in utilization or payment impact for additional dental services given the historically low utilization of these therapies. Although, we acknowledge that the observed utilization of these services might have been low because of the size of the population of patients whose treatment would include such dental services and also because the dental services have been viewed as subject to the payment preclusion under section 1862(a)(12).

Based on an analysis of 2018–2022 incurred claims experience, we estimate that there are potentially 155,000 additional beneficiaries who might receive dental services for which Medicare payment could be made, relative to the current number of beneficiaries that received dental services. These are beneficiaries who would receive any of the treatments identified in our proposals for CY 2024 (that is, chemotherapy/CAR T/bone-modifying agent therapies used in the treatment of cancer) who would likely require dental services, and could utilize dental services for which services Medicare could pay in CY 2024, if these proposals are finalized. The estimated average cost for these additional dental services is about $525 per person. This assumption is based on an analysis of 2019 incurred claims, but we believe results using more recent data would not be likely to change, due to the limited claims involving these services. Based on this same analysis, the effective rate of coverage was less than 0.2 percent. We do acknowledge that the actual take-up rate of services could be higher due to the proposed additional examples of medical services to which dental services are inextricably linked, which may raise awareness that payment is available. Therefore, we prepared impact estimates under the utilization assumptions of 0.2 percent and between 1–3 percent. We then applied these utilization ratios to estimate projected payments for dental exams and treatments in connection with cancer therapies. We found that the estimated yearly impact beginning in CY 2024 to be roughly $162,000 per year with a 0.2 percent utilization assumption, and roughly $800,000 to 2 million per year for the utilization assumptions of 1–3 percent. Therefore, we do not anticipate a significant payment impact for these provisions. We note, however, that if we were to finalize, as discussed in section II.K. of this proposed rule, payment in other clinical scenarios for dental services inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services, we may adjust this estimate for the final rule.

We continue to believe that because we are updating existing Medicare payment policies by proposing additional examples of clinical scenarios where dental services are inextricably linked to covered medical services, as stated in the CY 2023 PFS final rule, it is not appropriate to incorporate these budget neutrality adjustments into the conversion factor. Additionally, while the impact of access to these services to some individuals enrolled in Medicare could be very significant, we do not anticipate a significant impact in the context of overall spending and utilization under the PFS nor do we anticipate significant utilization and spending impact of these policies finalized in section II.K.2. of this proposed rule.

We acknowledge that the actual take-up rate of services could be higher than the utilization assumptions included within our current estimates. We continue to be open to updating and conducting further impact analysis once we have additional data and input from interested parties.

2. Impact of Proposal To Implement Separate Payment for the Office/Outpatient (O/O) E/M Visit Inherent Complexity Add-on Code (HCPCS G2211)

In recent years, the AMA's CPT Editorial Committee has restructured the E/M visit code sets largely to acknowledge changes in medical practice. The AMA RUC has reviewed and provided us recommendations for the revised E/M visit code sets in the context of the generally recognized need to better recognize resources involved in furnishing different types of services within the broader PFS. While we adopted the RUC-recommended values for the O/O E/M visit code family in the CY 2021 final rule, recognizing that those values generally reflect the resources involved in furnishing those services, we did not believe those valuations appropriately reflected the resource costs involved in furnishing primary and other similarly longitudinal medical care for a serious or complex condition in office settings. To address this concern, effective beginning in CY 2021, we finalized an add-on code to separately pay for visit complexity inherent to O/O E/M visits for primary care and other medical care services that are part of ongoing care related to a patient's single, serious, or complex condition in the office setting (the O/O E/M visit inherent complexity add-on). After we finalized the CY 2021 payment changes for O/O E/M visits, in the CAA of 2021, Congress imposed a statutory moratorium on Medicare payment for the O/O E/M visit inherent complexity add-on code until January 1, 2024.

We propose to implement payment for the O/O E/M visit inherent complexity add-on, HCPCS code G2211, with significant refinements to target improved payment for primary and other similar longitudinal care for serious or complex conditions. Specifically, we are proposing that the O/O E/M visit complexity add-on code cannot be billed with visits reported using Modifier 25 which is used to indicate that the service is billed on the same day as a minor procedure or another E/M visit. (Previously, in the CY 2021 final rule, we stated we would not expect such billing; but as there was no explicit prohibition, these visits were included in the budget neutrality adjustment (85 FR 84572)). We also propose to set PFS rates with a refined, more specific utilization assumption that better recognizes likely uptake of the code, differential use among specialties, and new and established patient visits, among other changes. These refined assumptions were developed, taking into consideration perspectives and information provided by interested parties. The resulting estimate reflects that the O/O E/M visit inherent complexity add-on code would likely be reported with approximately 38 percent of all O/O E/M visits for CY 2024. As discussed previously and shown below, we estimate the specific portion of the total budget neutrality adjustment attributable to the proposal to make payment for the O/O E/M inherent complexity add-on code to be approximately 2.00 percent compared to an attributable budget neutrality adjustment of 3.20 percent as calculated in CY 2021 rulemaking.

3. Advancing Access to Behavioral Health

a. Impact of Proposed Payment for Marriage and Family Therapist (MFT) Services and Mental Health Counselor (MHC) Services

As discussed in section II.J. of this proposed rule, section 4121 of CAA, 2023 added section 1861(s)(2)(II) to establish a new Medicare benefit category for MFT services and MHC services furnished and billed by MFTs and MHCs, respectively. MFT and MHC services are defined in section 1861(lll)(2) and 1861(lll)(4), respectively, as services for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital). An MFT or MHC is defined as an individual who possesses a master's or doctor's degree, is licensed or certified by the State in which they furnish services, who has performed at least 2 years of clinical supervised experience, and meets other requirements as the Secretary determines appropriate. Section 1833(a)(1)(FF) of the statute requires that MFT and MHC services be paid at 75 percent of the amount determined for payment of a clinical psychologist. MFT and MHC services are excluded from consolidated billing requirements under the skilled nursing facility prospective payment system. Services furnished by an MFT and MHC are covered when furnished in a rural health clinic and federally qualified health center. In addition, the hospice interdisciplinary team is required to include at least one social worker, MFT or MHC. Expenditures associated with payment for services furnished by MFTs and MHCs in CY 2024 will be incorporated into budget neutrality for PFS ratesetting in future years.

4. Drugs and Biological Products Paid Under Medicare Part B

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is either as noted in section 1847A(b)(1)(B) of the Act in the case of a single source drug or biological or as noted in section 1847A(b)(1)(C) of the Act in the case of a biosimilar biological product, multiplied by the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges (subject to certain exclusions) for the drug in a given calendar quarter. In the CY 2023 final rule, we finalized several policies to implement the provision, including: reporting requirements for the JW and JZ modifiers; the date upon which we will begin to edit claims for appropriate use of the JW and JZ modifiers, October 1, 2023; the definition of ''refundable single-dose container or single-use package drug''; the manner in which refund amounts will be calculated; the annual basis we will send reports to manufacturers; the dispute resolution process; and enforcement provisions. In section III.A of this proposed rule, we are proposing the date of the initial report to manufacturers, the date for subsequent reports, method of calculation when there are multiple manufacturers for a refundable drug, increased applicable percentages for drugs with unique circumstances, and a future application process by which manufacturers may apply for an increased applicable percentage for a drug.

For this proposed rule, we reanalyzed JW modifier data from 2021 as if the data represented dates of service on or after the effective date of section 90004 of the Infrastructure Act (that is, January 1, 2023).[368] That is, to assess if there was a change in the status of the billing and payment codes that were identified in the proposed rule as met the definition of refundable single-dose container or single-use package drug and have 10 percent or more discarded units, except for five drugs with higher applicable percentages finalized in the CY 2023 final rule or as proposed under this proposed rule.

Overall in the 2021 calendar year, Medicare paid nearly $1.56 billion for discarded amounts of drugs from a

[368] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

single-dose container or single-use package paid under Part B. In that year, there were 51 billing and payment codes with 10 percent or more discarded units based on JW modifier data. Of these, 11 did not meet the definition of refundable single-dose container or single-use package drug in section 1847A(h)(8) of the Act because they are multiple source drug codes; 5 were excluded from the definition of refundable single-dose container or single-use package drug (as specified in section 1847A(h)(8)(B) of the Act) because they are identified as radiopharmaceuticals or imaging agents in FDA-approved labeling; and 3 are products referred to as skin substitutes, which were removed because we anticipate making changes to coding and payment policies regarding those products in future rulemaking. After these exclusions, there were 31 billing and payment codes that met the definition of refundable single-dose container or single-use package drug and have discarded units above the relevant finalized applicable percentage. Of these, three have discarded units that would fall below increased applicable percentages proposed in this proposed rule.

We estimated refund amounts as described in section 1847A(h)(3) of the Act were calculated based on this data by subtracting the percent units discarded by 10 percent (the applicable percentage), except for drugs with higher applicable percentages finalized in the CY 2023 final rule or as proposed under this proposed rule. Then, we multiplied the appropriate percentage by the CY 2021 total allowed amount to estimate the annual refund for a given billing and payment code. The quarterly refund was estimated by dividing the annual estimate by 4. Based on this data, there would be approximately $83.1 million in refunds due from manufacturers for the calendar year of 2021 ($20.8 million each calendar quarter). See Table 108.

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TABLE 108: Estimated Refund Amounts Based on CY 2021 JW Modifier Data[369]

HCPCS Code	2021 Total Medicare Allowed Amount	Percent Units Discarded	Excluded (Y/N)	Applicable percentage	% Exceeding applicable percentage	Estimated annual refund	Estimated quarterly refund
Q9965	$2,276,001.01	67.41%	Y; Radiopharm or imaging agent	10%			
J7342	$4,559.95	53.26%	N	10%	43.26%	$1,972.63	$493.16
J9281	$26,703,749.86	37.60%	N	35%	2.60%	$694,297.50	$173,574.37
J9262	$220,987.21	30.98%	N	26% (proposed)	4.98%	$11,005.16	$2,751.29
J9043	$146,745,385.39	29.11%	N	10%	19.11%	$28,043,043.15	$7,010,760.79
J9041	$380,429,509.43	27.00%	Y; multiple source	10%			
J9351	$475,677.64	26.37%	Y; multiple source	10%			
Q9961	$19,366.66	26.28%	Y; Radiopharm or imaging agent	10%			
J0894	$17,872,985.28	24.16%	Y; multiple source	10%			
J9044	$4,616,507.83	21.91%	N; see new single source codes J9046, J9048, J9049	10%	11.91%	$549,826.08	$137,456.52
J9025	$37,997,710.06	21.83%	Y; multiple source	10%			
J9017	$1,733,222.58	21.25%	Y; multiple source	10%			
J1448	$1,739,523.98	20.85%	N	10%	10.85%	$188,738.35	$47,184.59
J0775	$68,490,974.85	20.83%	N	45% proposed			
J9065	$451,404.96	20.26%	Y; multiple source	10%			
J9223	$90,785,710.74	20.25%	N	10%	10.25%	$9,305,535.35	$2,326,383.84
J0565	$3,928,811.98	19.53%	N	10%	9.53%	$374,415.78	$93,603.95

[369] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

HCPCS Code	2021 Total Medicare Allowed Amount	Percent Units Discarded	Excluded (Y/N)	Applicable percentage	% Exceeding applicable percentage	Estimated annual refund	Estimated quarterly refund
J9178	$9,922.54	18.95%	Y; multiple source	10%			
J9229	$17,911,595.08	18.21%	N	10%	8.21%	$1,470,541.96	$367,635.49
J0223	$10,731,531.69	17.00%	N	26% (proposed)			
Q9966	$2,230,516.82	16.89%	Y; Radiopharm or imaging agent	10%			
J1640	$8,405,837.59	15.52%	Y; filtered	10%			
J9153	$5,526,153.53	15.00%	N	10%	5.00%	$276,307.68	$69,076.92
J2425	$124,548.01	14.07%	N	10%	4.07%	$5,069.10	$1,267.28
J9027	$62,602.70	13.98%	Y; multiple source	10%			
J9264	$347,464,875.59	13.86%	N	10%	3.86%	$13,412,144.20	$3,353,036.05
J2796	$257,348,654.37	13.60%	N	10%	3.60%	$9,264,551.56	$2,316,137.89
Q9956	$737,908.86	13.03%	Y; Radiopharm or imaging agent	10%			
J0515	$16,911.88	12.88%	Y; multiple source	10%			
J2562	$18,752,340.26	12.81%	N	10%	2.81%	$526,940.76	$131,735.19
J9179	$43,581,966.38	12.71%	N	10%	2.71%	$1,181,071.29	$295,267.82
J9307	$22,805,063.36	12.65%	N	10%	2.65%	$604,334.18	$151,083.54
J9037	$33,082,159.80	12.10%	N	10%	2.10%	$694,725.36	$173,681.34
J3396	$2,537,428.32	11.93%	N	10%	1.93%	$48,972.37	$12,243.09
J9042	$169,482,924.33	11.89%	N	10%	1.89%	$3,203,227.27	$800,806.82
J9319	$6,572,808.69	11.78%	Y; multiple source	10%			
Q9950	$516,142.11	11.77%	Y; Radiopharm or imaging agent	10%			
J0485	$76,861,131.89	11.61%	N	10%	1.61%	$1,237,464.22	$309,366.06
J9205	$59,413,621.44	11.55%	N	10%	1.55%	$920,911.13	$230,227.78

HCPCS Code	2021 Total Medicare Allowed Amount	Percent Units Discarded	Excluded (Y/N)	Applicable percentage	% Exceeding applicable percentage	Estimated annual refund	Estimated quarterly refund
J9228	$417,946,062.94	11.40%	N	10%	1.40%	$5,851,244.88	$1,462,811.22
J3241	$306,975,463.35	11.32%	N	10%	1.32%	$4,052,076.12	$1,013,019.03
J2997	$66,254,826.34	11.31%	N	10%	1.31%	$867,938.23	$216,984.56
J3300	$8,964,090.01	10.97%	N	90% proposed			
J0122	$144,528.76	10.84%	N	10%	0.84%	$1,214.04	$303.51
J3101	$12,921,647.56	10.67%	N	10%	0.67%	$86,575.04	$21,643.76
J9315	$23,154,637.13	10.33%	Y; multiple source	10%			
J9269	$7,755,186.19	10.15%	N	26% proposed			
J9352	$9,225,195.63	10.10%	N	10%	0.10%	$9,225.20	$2,306.30
Q4121	$6,484,123.19	17.85%	Y; skin substitute (proposed)	10%	7.85%		
Q4106	$1,511,046.28	16.64%	Y; skin substitute (proposed)	10%	6.64%		
Q4101	$2,176,035.02	14.58%	Y; skin substitute (proposed)	10%	4.58%		
				TOTAL		$82,883,368.59	$20,720,842.15

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There are several limitations to this analysis that could substantially affect the total quarterly refund. Since new drugs are continually being approved,

this estimate does not consider newer drugs that will meet the definition of refundable single-dose container or single-use package drug on or after the effective date of January 1, 2023. Since section 1847A(h)(8)(B)(iii) of the Act excludes drugs approved by FDA on or after November 15, 2021 and for which payment has been made under Part B for fewer than 18 months from this definition, we expect an impact on refund amounts after the 18-month exclusion has ended if the drug otherwise meets the definition. We also note that this estimate is based on CY 2021 data for discarded drug amounts, which, for reasons discussed in the CY 2023 final rule (87 FR 69716), we believe to be an underestimate due to the frequent omission of the JW modifier. Once we begin to edit claims for both the JW and JZ modifiers, reported discarded drug amounts will likely increase. Other substantial changes to this estimate may occur if a billing and payment code no longer meets this definition. For example, if a generic version of one of these drugs is marketed, the billing and payment code will become a multiple source drug code and will no longer meet the definition of refundable single-dose container or single-use package drug. Subsequently, the manufacturers will not be responsible for refunds under this provision. There may be changes in the percent discarded units for a given refundable single-dose container or single-use package drug if the manufacturer introduces additional vial sizes or modifies the vial size to reduce the amount discarded. Lastly, since data from the CMS website only includes billing and payment codes on the ASP drug pricing file [370] and implementation of section 90004 of the Infrastructure Act is not restricted to billing and payment codes included on the file, there may be other applicable data that was not assessed as part of this estimate.

a. Impacts Related to the Issuance of the Initial Report

In section III.A.3.b. of this proposed rule, we propose to issue the initial refund report to manufacturers, to include all calendar quarters for 2023, no later than December 31, 2024. Accordingly, as discussed in section III.A.3.c., we propose to require that the refund amounts specified in the initial refund report be paid no later than February 28, 2025, except in circumstances where a report is under dispute.

[370] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice.*

Delaying the receipt of the rebate, that is in 2025 instead of 2024, only represents a cost to the extent the SMI trust fund receives less interest revenue. Only a portion of SMI trust fund revenue ends up invested in the bond portfolio. Based on current SMI trust fund operation patterns a delay in rebate collection as described in the rule would represent a cost less than $2 million dollars in any given year and therefore would be negligible to SMI trust fund operations.

b. Impacts Related to the Application for Consideration

As described in section VII.B.1. of this proposed rule, the information collection requirements, we estimate the annual burden per applicant to be 5 hours. If we anticipate no more than 25 applications per year, the total annual drafting and submitting burden would be 125 hours (25 applications per year × 5 hours per applicant). We estimate an annual cost of this burden to be $4,937.50 ($39.50/hour × 125 hours).

5. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In section III.B.2. of this proposed rule, we are proposing to include Remote Patient Monitoring (RPM) and Remote Therapeutic Monitoring (RTM) services, and the proposed Community Health Integration (CHI) and Principal Illness Navigation (PIN) services if finalized, in the general care management HCPCS code G0511 when these services are provided by RHCs and FQHCs. Due to the growing number of services in the code, we are also proposing to revise the calculation for G0511 to include the weighted average of these services based on utilization under the PFS as this may provide a more complete and accurate payment amount.

In terms of estimated impacts to the Medicare program, expanding use of General Care Management HCPCS code G0511 to include RPM, RTM, CHI, and PIN may result in an increase in spending. Prior updates to G0511 have resulted in negligible increases.

6. RHC and FQHC CfC Changes: Permitting MFTs and MHCs To Furnish Services

Section 4121 of the CAA, 2023 amends section 1861(aa)(1)(B) of the Act by adding MFTs and MHCs as eligible practitioners of RHCs and FQHCs beginning January 1, 2024. We are proposing regulation text changes to permit MFT and MHCs to provide services furnished at RHCs and FQHCs. These changes would include MFTs and MHCs as members of the staff who may be the owner or an employee of the clinic or center, or furnish services under contract to the clinic or center. Along with other permitted physicians and nonphysician practitioners, MFT and MHCs may be available to furnish patient care services at all times the clinic or center operates.

At § 491.9(b)(3) RHCs and FQHCs must have patient care policies that include: (1) a description of the services the clinic or center furnishes directly or through agreement or arrangement; (2) guidelines for medical management of health problems; and (3) rules for storage, handling, and administration of drugs and biologicals. Additionally, § 491.9(b)(4) states that the RHC and FQHC patient policies must regularly be reviewed at least once every 2 years by a group of professional personnel that includes one or more physicians, one or more physician assistants (PAs) or nurse practitioners (NPs), and at least one person who is not a member of the clinic or center staff. If an RHC or FQHC provides services furnished by an MHC or MFT they must update their patient care policies with a description of the services they will provide.

The most recently published collection of information for RHCs and FQHCs (OMB control number 0938–0334), estimates that an annual review of the patient care policies may take approximately 2 hours. Therefore, we assume, it would take each medical professional (at least one physician and at least one PA or NP) 1 hour to review all policies and procedures, annually. Based on the prior analysis, we estimate it will take 15 minutes to add the description of MFT and MHC services. We also assume that only half of the RHCs and half of the FQHCs would have this burden applied to them, for a total burden estimate of $361,891.05. We note that there would be variations in how many clinics or centers employ or contract with an MFT and MHC based on their ability to expand their services. We also recognize that some RHCs and FQHCs may already provide these services as some States provide reimbursement under the Medicaid program; however, we do not know the exact number of clinics or centers that already have these practitioners on staff and would not incur the burden.

While this proposed rule does have a 1-time burden, there is evidence to suggest there are long-term financial savings in integrating mental health in medical care. Effectively integrating mental and medical care can save upwards of $52 billion annually due to the existing Medicare mental health

coverage gap.[371] Though this total encompasses all facility types, expanding access to MFT and MHC services in RHCs and FQHCs will have individual and societal cost savings. Older adults with mental health conditions have poorer health outcomes, higher hospitalization rates, and emergency room visits.[372] While there is an increasing need for mental health services, one barrier to effective treatment is access to mental health services.[373] Ensuring access to mental health care in rural communities is challenging as there are fewer mental health providers per capita in nonmetropolitan counties.[374] This coincides with HRSA's second quarter of the fiscal year 2023 designated health professional shortage area (HPSA) quarterly summary, which breaks down the number of HPSAs by primary medical care, dental, and mental health HPSAs based on four categories (rural, non-rural, partial rural, and unknown); and as population HPSAs, geographic HPSAs, or Facility HPSAs. The report does not provide accumulative HPSAs by the four categories.[375] Approximately 65 percent of federally designated health professional shortage areas are located in rural areas, and about 30 percent are located in non-rural areas.[376] The shortage of professionals in rural areas is severe, and the shortage of qualified professionals in combination with geographic limitations only exacerbates the mental health crisis in older adults.[377] While there are disparities in the availability of the behavioral workforce between rural and nonrural areas, counselors are integral to providing care in rural areas.[378]

7. Clinical Laboratory Fee Schedule

In section III.D of this proposed rule, we discuss statutory revisions to the data reporting period and phase-in of payment reductions under the CLFS. In accordance with section 4114 of the CAA, 2023, we are proposing certain conforming changes to the data reporting and payment requirements in our regulations at 42 CFR part 414, subpart G. Specifically, for CDLTs that are not ADLTs, we are proposing to update certain definitions and revise § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning January 2024. The CAA, 2023 delays the next data reporting period under the CLFS for CDLTs that are not ADLTs by 1 year, that is, it requires the next data reporting period for these tests to take place during the period of January 1, 2024 through March 31, 2024. Subsequently, the next private payor rate-based CLFS update for these tests will be effective January 1, 2025, instead of January 1, 2024. In addition, we are proposing to make conforming changes to our requirements for the phase-in of payment reductions to reflect the CAA, 2023 amendments. Specifically, we are proposing to revise § 414.507(d) to indicate that for CY 2023, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2022, and for CYs 2024 through 2026, 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 for the CLFS payment 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.D. of this proposed 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 CAA, 2023 amendments to the data reporting period will delay using updated private payor rate data to set revised CLFS payment rates for CDLTs that are not ADLTs.

Due to unforeseen changes in private payor rates due to shifts in market-based pricing for laboratory tests and the unpredictable nature of test volumes and their impact on calculating updated CLFS payment rates based on the weighted median of private payor rates, it is uncertain whether the delay in data reporting will result in a measurable budgetary impact. In other words, to assess the impact of delayed reporting and subsequent implementation of updated CLFS rates, we will 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, and calculating the updated CLFS rates.

Regarding the conforming changes to our requirements for the phase-in of payment reductions that we are proposing in this rule, we note that for CYs 2024 through 2026, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year. Based on data reported in the 2017 data collection period, we estimate 14.8 percent (191) of tests on the CLFS may be subject to the full 15 percent phase-in reduction in CY 2024.

8. Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Expansion of Supervising Practitioners

As discussed in section III.E. of this proposed rule, we are proposing revisions to §§ 410.47 (PR) and 410.49 (CR/ICR) to codify the statutory changes made in section 51008 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018) (BBA of 2018) which permit other specific types of practitioners to supervise these services effective January 1, 2024. The amendments add to the types of practitioners who may supervise PR, CR and ICR programs to also include a physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist (CNS). Accordingly, we are proposing additions and revisions to the PR and CR/ICR regulations to reflect these statutory amendments.

To assess the potential impact from expanding the types of practitioners that may supervise PR/CR/ICR we searched the literature for articles that evaluated the utilization rates of PR, CR and ICR to determine the historical utilization trends of these services as well as known barriers to utilization. Based on historical utilization trends as well as barriers to utilization discussed in the literature, we do not expect the proposed changes to make a significant impact on the Medicare program.

Nishi et al. (2016) investigated the number of Medicare beneficiaries with COPD who received PR from January 1, 2003, to December 31, 2012. Their results included both individuals who had experienced hospitalizations for COPD and those who were outpatients

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[371] *https://onlinelibrary.wiley.com/doi/full/10.1002/jcad.12409?casa_token=z412GCn3OuYAAAA%3AHO3p-cHeiVrLww0dZjTkIcuCbwMxvYtRUo4aj8AwB-tq2w_ZJV11gGpWW-oxilDK3awU0xIc2XKMnKhtAQ#jcad12409-bib-0003.*

[372] *https://onlinelibrary.wiley.com/doi/full/10.1002/jcad.12409?casa_token=z412GCn3OuYAAAA%3AHO3p-cHeiVrLww0dZjTkIcuCbwMxvYtRUo4aj8AwB-tq2w_ZJV11gGpWW-oxilDK3awU0xIc2XKMnKhtAQ#jcad12409-bib-0005.*

[373] *https://psycnet.apa.org/fulltext/2020-75725-002.html.*

[374] *https://psycnet.apa.org/record/2018-25164-007.*

[375] *https://data.hrsa.gov/topics/health-workforce/shortage-areas.*

[376] *https://data.hrsa.gov/Default/GenerateHPSAQuarterlyReport.*

[377] *https://psycnet.apa.org/fulltext/2020-75725-002.html.*

[378] *chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://depts.washington.edu/fammed/rhrc/wp-content/uploads/sites/4/2016/09/RHRC_DB160_Larson.pdf.*

only. The number of unique patients with COPD who initially participated in PR during the study period was 2.6 percent in 2003 (before conditions of coverage at § 410.47 were established) and 2.88 percent in 2012 (after conditions of coverage at § 410.47 were established).[379] In 2019, *Spitzer, et al.* published an article based on Medicare claims data from 2012, finding that 2.7 percent of eligible Medicare beneficiaries received PR within 12 months of hospitalization with COPD.[380] Using claims data from fee-for-service Medicare beneficiaries hospitalized for COPD in 2014, *Lindenauer et al.* (2020) reported that only 3 percent initiated PR within 1 year of their hospital discharge.[381] Taken together, this data informs us that utilization of PR in the Medicare population is very low.

Million Hearts® 2027, a national initiative co-led by the Centers for Disease Control and Prevention (CDC) and CMS to prevent 1 million preventable cardiovascular disease (CVD) events in the next 5 years,[382] includes a goal of increasing use of CR and states that CR participation rates remain low, ranging from 19 percent to 34 percent.[383] Fleg and colleagues (2020) report that less than 25 percent ''of eligible patients participate in CR'' with a smaller proportion completing 36 sessions as recommended.[384] In their 2022 article, Varghese and colleagues state that less than 30 percent of eligible patients participate in CR in the United States.[385] *Husaini and colleagues* (2022) analyzed a sample of Medicare fee-for-service claims between 2012 and 2016 and reported that within 1 year of a qualifying event, 16 percent of patients completed one or more CR session and 0.1 percent of patients completed one or more ICR sessions. They observed an increase of combined CR and ICR utilization from 14 percent (patients with qualifying events in 2012) to 18 percent (patients with qualifying events in 2015).[386] Taken together, this data informs us that utilization of CR and ICR is low, although not as low as PR.

Underutilization of PR, CR and ICR has been attributed to numerous factors as described by *Fleg et al.* ''including a lack of referral or strong recommendation from a physician and inadequate follow-up or facilitation of enrollment after referral. Financial issues such as limited or absent health insurance coverage and the inability to afford copayments, even when insured, also limit CR/PR participation as do conflicting work and home responsibilities and distance and transportation difficulties. Social and cultural factors, including the lack of gender and racial diversity among CR/PR staff, language and cultural barriers, and lack of program availability and access are additional challenges . . . Many eligible patients are also commonly perceived as too frail . . .'' [387] *Husaini et al.* (2022) reinforce the impact of similar factors in CR underuse. They cite ''lower reimbursements relative to cost and variability in access'', physician ''skepticism over benefit and a primary emphasis on cardiac medications and procedures'', and patient ''reluctance or inability to commit 3–6 hr/wk for 8–12 wk to CR, logistical (transportation, work, etc) or financial impediments, a preference for exercise/rehabilitation at home, fear of failure, and physical limitations.'' [388]

While the expansion of supervision requirements to include nonphysician practitioners could offer greater flexibility for PR and CR programs to operate, the barriers to utilization as described by *Fleg and colleagues* (2020) and *Husiani and colleagues* (2022) are widespread and complex and low participation in PR, CR and ICR has remained steady for many years. We do not believe the expansion of supervising practitioners is likely to address these barriers. Therefore, we do not anticipate any significant increase in utilization of PR, CR and ICR services and subsequent impact to the Medicare program or interested parties.

9. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

As discussed in section III.F. of this proposed rule, we are proposing allowing periodic assessments to be furnished via audio-only communication when two-way audio-video communications technology is not available to the beneficiary through the end of CY 2024, to the extent that it is authorized by SAMHSA and DEA at the time the service is furnished and all other applicable requirements are met.

We believe the Part B cost impact of this flexibility for the use of telecommunications will be minimal because we do not expect that these flexibilities will increase the frequency with which medically necessary assessments are furnished.

10. Medicare Shared Savings Program

a. General Impacts

As of January 1, 2023, 10.9 million Medicare beneficiaries receive care from a health care provider in one of the 456 ACOs participating in the Shared Savings Program, the largest value-based care program in the country. The Shared Savings Program proposed policies advance Medicare's overall value-based care strategy of growth, alignment, and equity, with many proposals overlapping these categories. The proposed policies in this proposed rule are incremental refinements to the broader changes finalized in the CY 2023 PFS final rule (87 FR 69777 through 69968). Those changes were designed to reverse recent trends where

[379] Nishi SP, Zhang W, Kuo YF, Sharma G. Pulmonary Rehabilitation Utilization in Older Adults With Chronic Obstructive Pulmonary Disease, 2003 to 2012. J Cardiopulm Rehabil Prev. 2016;36(5):375–382. doi: 10.1097/HCR.0000000000000194.

[380] Spitzer KA, Stefan MS, Priya A, et al. Participation in pulmonary rehabilitation after hospitalization for chronic obstructive pulmonary disease among Medicare beneficiaries. *Ann Am Thorac Soc.* 2019;16:99–106. DOI: 10.1513/AnnalsATS.201805–332OC. PMID: 30417670; PMCID: PMC6344454.

[381] Lindenauer PK, Stefan MS, Pekow PS, et al. Association Between Initiation of Pulmonary Rehabilitation After Hospitalization for COPD and 1-Year Survival Among Medicare Beneficiaries. *JAMA.* 2020;323(18):1813–1823. doi:10.1001/jama.2020.4437.

[382] *https://millionhearts.hhs.gov/about-million-hearts/index.html.*

[383] *https://millionhearts.hhs.gov/about-million-hearts/optimizing-care/cardiac-rehabilitation.html.*

[384] Fleg JL, Keteyian SJ, Peterson PN, Benzo R, Finkelstein J, Forman DE, Gaalema DE, Cooper LS, Punturieri A, Joseph L, Shero S, Zieman S. Increasing Use of Cardiac and Pulmonary Rehabilitation in Traditional and Community Settings: OPPORTUNITIES TO REDUCE HEALTH CARE DISPARITIES. J Cardiopulm Rehabil. Prev. 2020 Nov;40 (6):350–355. doi: 10.1097/HCR.0000000000000527. PMID: 33074849; PMCID: PMC7644593.

[385] Varghese MS, Beatty AL, Song Y, et al., Cardiac Rehabilitation and the COVID–19 Pandemic: Persistent. Declines in Cardiac Rehabilitation Participation and Access Among US Medicare Beneficiaries. Circ Cardiovasc Qual Outcomes. 2022;15:e009618. DOI: 10.1161/CIRCOUTCOMES.122.009618.

[386] Husaini M, Deych E, Racette SB, et al. Intensive Cardiac Rehabilitation Is Markedly Underutilized by Medicare Beneficiaries: RESULTS FROM A 2012–2016 NATIONAL SAMPLE. J Cardiopulm Rehabil Prev. 2022 May 1;42(3):156–162. doi: 10.1097/HCR.0000000000000632. Epub 2021 Sep 9. PMID: 34508035.

[387] Fleg JL, Keteyian SJ, Peterson PN, Benzo R, Finkelstein J, Forman DE, Gaalema DE, Cooper LS, Punturieri A, Joseph L, Shero S, Zieman S. Increasing Use of Cardiac and Pulmonary Rehabilitation in Traditional and Community Settings: OPPORTUNITIES TO REDUCE HEALTH CARE DISPARITIES. J Cardiopulm Rehabil. Prev. 2020 Nov;40 (6):350–355. doi: 10.1097/HCR.0000000000000527. PMID: 33074849; PMCID: PMC7644593.

[388] Husaini M, Deych E, Racette SB, et al. Intensive Cardiac Rehabilitation Is Markedly Underutilized by Medicare Beneficiaries: RESULTS FROM A 2012–2016 NATIONAL SAMPLE. J Cardiopulm Rehabil Prev. 2022 May 1;42(3):156–162. doi: 10.1097/HCR.0000000000000632. Epub 2021 Sep 9. PMID: 34508035.

program participation had plateaued, higher spending populations were increasingly underrepresented in the program since the change to regionally-adjusted benchmarks, and access to ACOs appeared inequitable as evidenced by data indicating underserved populations are less likely to be assigned to a Shared Savings Program ACO, and to encourage growth of ACOs in underserved communities.

The changes to the Shared Savings Program regulations finalized with the CY 2023 PFS final rule were designed to increase program participation for new ACOs through the AIP option intended to promote health equity, and provide ACOs greater choice in the pace of progression to performance-based risk; sustain program participation by reducing the effect of ACO performance on benchmark updates and benchmark rebasing; mitigate the bias in regional expenditure calculations that benefits ACOs electing prospective assignment; strengthen incentives for ACOs serving high risk and high dual populations; improve the risk adjustment methodology to better account for medically complex, high cost beneficiaries while continuing to guard against coding initiatives; increase opportunities for low revenue ACOs in the BASIC track to share in savings by allowing ACOs that do not meet the minimum savings rate (MSR) requirement to share in savings at a lower rate; encourage ACOs to transition more quickly to all-payer quality measure reporting; update the ACO beneficiary assignment methodology; and reduce administrative burden on ACOs. The proposed changes to Shared Savings Program policies in this proposed rule include modifications designed to further these goals in concert with implementation of certain changes finalized in the CY 2023 PFS final rule, which are applicable for agreement periods beginning on January 1, 2024, and in subsequent years.

On average, updated benchmarks would marginally increase as a result of the proposal to modify the calculation of the regional component of the blended update factor used to update the historical benchmark between benchmark year (BY) 3 and the performance year (PY) by capping an ACO's regional service area risk score growth through use of an adjustment factor to provide more equitable treatment for ACOs and for symmetry with the cap on ACO risk score growth (section III.G.4.b of this proposed rule). This change is expected to increase the regional update factor amount in certain cases where an ACO may operate in a regional service area with rapid change in the average prospective HCC risk score for the FFS assignable beneficiary population. The current methodology for calculating the regional update factor risk adjusts county-level FFS expenditures in an ACO's regional service area by Medicare enrollment type by dividing average county-level FFS expenditures for assignable beneficiaries in the county by the average prospective HCC risk score for both the performance year and BY3. The expenditure growth between BY3 and the performance year calculated using risk-adjusted regional expenditures could therefore be reduced by large increases in average prospective HCC risk scores in the ACO's regional service area that would only be partly offset by the increase in prospective HCC risk score growth for the ACO's assigned beneficiary population due to the cap on ACO assigned beneficiary prospective HCC risk score growth when updating the benchmark between BY3 and the performance year. The proposed adjustment, applicable for agreement periods beginning on January 1, 2024, and in subsequent years, would effectively strengthen the regional portion of the three-way blended update factor and help to limit losses ACOs may face when operating in regional service areas with high risk score growth and a beneficiary population that becomes more medically complex between BY3 and the performance year, increasing incentives for ACOs to form or continue participation in such areas. By utilizing a market share adjusted cap to account for ACO market share in the ACO's regional service area, the proposed adjustment would still retain a disincentive against coding intensity for ACOs that may have a high market share in their region and consequently have greater influence on regional service area risk score changes. For example, this feature of the proposal would help dissuade such ACOs from attempting to artificially increase their benchmark by selectively serving lower risk beneficiaries and increasing the intensity of diagnoses submitted for those beneficiaries.

Analyses described in the section III.G.4.b.(2) of this proposed rule, surrounding tables 33 and 34, provide the basis for estimating the impact for the proposal to cap regional service area risk score growth. Analysis of average prospective HCC risk score changes at the Hospital Referral Region (HRR) level over an extended 2007 to 2021 historical period consistently indicated that risk score changes would be highly unlikely to exceed the proposed cap in the first two years of an ACO's agreement period but would increase somewhat as the 5-year agreement period progresses. The analysis also notably showed that average prospective HCC risk score variation increased markedly in 2020 and 2021 with the COVID–19 PHE.[389] The 11 percent of ACOs simulated to be impacted by the proposed adjustment in PY 2021 (a mix of ACOs with 2-year and 3-year gaps between their respective BY3 and the simulated PY 2021) is therefore anticipated to overstate variation expected in agreement periods that start on January 1, 2024 or later.

Based on the simulation in the context of the longer-run HRR data, we project that starting in 2024 the proposed adjustment would impact less than 1 percent of ACOs in PY1 of an agreement period, between 5 to 7 percent of ACOs by PY3, and up to 10 to 15 percent of ACOs by PY5. The adjustment for ACOs that are simulated to be impacted is relatively small, increasing updated benchmarks by about 0.2 percent up to 0.4 percent on average by PY5, but with the potential for up to a net adjustment of about 1.5 percent in extreme scenarios. The estimated cost from additional shared savings payments resulting from these adjustments totals $370 million over 10 years as shown in Table 109.

[389] Public use data on Medicare Geographic Variation—by Hospital Referral Region, used for this analysis, is available at *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-geographic-comparisons/medicare-geographic-variation-by-hospital-referral-region*.

TABLE 109: Projected Impact of Proposed Adjustment Factor to Apply Risk Score Cap to Regional Portion of Blended Update Factor Calculation ($ Millions)

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	Total
Impact Estimate	10	10	20	40	70	50	20	40	40	70	**370**
Estimate Range:											
Low Estimate	0	0	10	20	40	40	20	20	30	40	**220**
High Estimate	10	20	30	60	90	80	40	50	60	100	**540**

A material, albeit uncertain impact, is also estimated for the proposals to (a) use a rolling 3-year historical period instead of contemporary performance to calculate the 40th percentile of the MIPS Quality performance category scores starting in PY 2024 and (b) the proposal to use the higher of the ACO's health equity adjusted quality performance score or the 40th percentile MIPS Quality performance category score across all MIPS Quality performance scores if measure suppression is required. It is likely that MIPS Quality performance will improve at least marginally over time and therefore the historical performance could produce a target that effectively is lower than the contemporary 40th percentile stipulated at baseline. The effective reduction in the threshold when using the historical MIPS scores, combined with the 'higher of' proposal when suppression is necessary, are assumed to effectively reduce the quality target by 0 to 5 percentage points (mode 1.5 percentage points), which would produce an estimated $110 million in additional shared savings payments over 10 years, as shown in the Table 110.

TABLE 110: Projected Combined Impact of Quality Proposals to (a) Use Rolling 3-Year Historical Period to Calculate the 40th Percentile of the MIPS Quality Performance Category Scores and (b) Use the 'Higher Of Value' When Measures are Suppressed ($ Millions)

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	Total
Impact Estimate	0	10	10	10	10	10	10	10	20	20	**110**
Estimate Range:											
Low Estimate	0	0	0	0	0	0	0	0	0	0	**0**
High Estimate	0	30	30	30	40	40	30	40	40	40	**320**

The impact is also estimated to be material for the proposal to mitigate the impact of the negative regional adjustment on the benchmark. In the CY 2023 PFS final rule, CMS finalized changes applicable for agreement periods beginning on January 1, 2024, and in subsequent years, that would reduce the cap on negative regional adjustments from 5 percent to 1.5 percent and provide an offset factor to gradually decrease the negative regional adjustment amount as an ACO's proportion of dually eligible Medicare and Medicaid beneficiaries increases or its weighted average prospective HCC risk score increases, or both. Removing the regional adjustment entirely, when the ACO's regional adjustment amount (expressed as a single per capita value) is negative, would incrementally increase benchmarks for higher spending ACOs (increasing shared savings payments) but would also improve the incentive for higher spending ACOs to join the Shared Savings Program and drive down unnecessary spending. For a high cost estimate we conservatively assume no new participation is generated in response to this change and estimate the higher benchmarks would generate about $1.8 billion in additional shared savings payments partly offset by about $1.6 billion in reduced spending in response to improved incentives. For a mean estimate we additionally assume 10 percent growth in participation from new high spending ACOs leading to about $490 million net savings over 10 years.[390] For a low cost estimate we instead assume 20 percent growth in participation from high spending ACOs leading to about $1.2 billion in net savings over 10 years. Table 111 shows these estimates over the 2024–2033 window.

[390] Elimination of overall negative regional adjustments, under the proposed approach, would likely generate participation growth from ACOs that will face significant negative adjustments despite the changes from the CY 2023 PFS final rule to reduce the impact of the negative regional adjustment, but also from other prospective high spending ACOs that may have difficulty estimating the relief they will ultimately receive from the offsets applicable to agreement periods beginning on January 1, 2024, and in subsequent years. Eliminating overall negative regional adjustment entirely would materially improve the business case for participation from ACOs in the former category and may at least optically improve the business case for ACOs in the latter category without actually incurring cost to the program by increasing their benchmarks.

TABLE 111: Projected Impact of Proposal to Mitigate the Impact of Negative Regional Adjustment on Benchmarks ($ Millions)

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	Total
Impact Estimate	0	30	10	-20	-70	-110	-100	-70	-90	-70	**-490**
Estimate Range:											
Low Estimate	-10	-10	-40	-80	-130	-200	-200	-180	-200	-170	**-1,220**
High Estimate	10	60	50	30	0	-20	0	30	20	30	**210**

The proposal to specify the use of the CMS–HCC risk adjustment model(s) applicable to the calendar year corresponding to the performance year to calculate a Medicare FFS beneficiary's prospective HCC risk score for the performance year, and for each benchmark year of the ACO's agreement period for agreement periods beginning January 1, 2024, and in subsequent years, is anticipated to remove a potential bias that may otherwise reduce benchmarks particularly for ACOs with beneficiaries exhibiting higher average renormalized risk scores at baseline. An increase in average shared savings payments to ACOs that would have participated regardless of this proposed modification is expected to ultimately be more than offset by additional savings from increased participation from ACOs serving high risk beneficiaries that would have otherwise dropped out or avoided entering the Shared Savings Program under the current approach to calculating prospective HCC risk scores. Net savings are expected to be greater at the end of the 10 year scoring window because residual savings from added participation would grow, whereas benchmarks would not be as impacted in the later part of the scoring window because there is lower likelihood that later agreement periods would have been impacted by changes in the CMS HCC risk adjustment methodology. Table 112 shows these estimates over the 2024–2033 window.

TABLE 112: Projected Impact of Proposal to Use Uniform Approach to Calculate Risk Scores in the Shared Savings Program Benchmark Calculations ($ Millions)

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	Total
Impact Estimate	10	20	60	100	140	-70	-130	-180	-160	-110	**-320**
Estimate Range:											
Low Estimate	10	-10	10	30	50	-120	-200	-270	-280	-260	**-1,040**
High Estimate	20	80	130	190	240	70	10	-50	-40	-20	**630**

An overall net impact is difficult to quantify for the proposed changes in section III.G.3.a of this proposed rule, to incorporate use of a new third step in the step-wise beneficiary assignment methodology and the proposed changes to identification of the assignable beneficiary population. These proposed changes are not currently estimated to have a net impact on program spending in either direction. Impacts on benchmark calculations for individual ACOs would likely be mixed and of relatively limited magnitude. The proposed changes could allow some ACOs to increase efficiency by utilizing more non-physician clinicians in delivering primary care without jeopardizing assignment. On the other hand, they could marginally increase shared savings payments for efficiencies that currently would accrue entirely to the program as spillover effects on beneficiaries unable to be assigned. The overall impact is currently anticipated to be roughly neutral. We will continue to analyze data on the potential impact of these proposed changes on existing ACOs, and will monitor effects if the proposals are finalized and implemented in future agreement periods.

The remaining proposed changes to the Shared Savings Program regulations are not estimated to have an impact on program spending at the aggregate level. These proposed changes include modifying the definition of primary care services for purposes of determining beneficiary assignment, recalculating the prior savings adjustment for changes in the amount of savings earned by an ACO in a benchmark year due to compliance action taken to address avoidance of at-risk beneficiaries or changes in the amount of savings or losses for a benchmark year as a result of the issuance of a revised initial determination of financial performance, expanding quality reporting options to include Medicare CQMs, requiring reporting of MIPS PI performance category for all eligible clinicians participating in ACOs, and using beneficiary counts instead of person years in health equity adjustment calculations, as well as proposals to further refine AIP policies, revise program eligibility requirements, and make technical changes.

b. Compliance With Requirements of Section 1899(i)(3) of the Act

Certain policies, including both existing policies and the proposed new policies described in this proposed rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory

payment model. The following proposals require the use of our authority under section 1899(i) of the Act: the proposed modifications to the calculation of regional component of the three-way blended update factor to cap regional service area risk score growth for symmetry with the ACO risk score growth cap, as described in section III.G.4.b of this proposed rule and the refinements to AIP policies as described in section III.G.5. of this proposed rule. Further, certain existing policies adopted under the authority of section 1899(i)(3) of the Act that depend on use of the assigned population and assignable beneficiary populations, would be affected by the proposed addition of a new third step of the beneficiary assignment methodology and the proposed revisions to the definition of assignable beneficiary, described in section III.G.3. of this proposed rule, including the following: the amount of advance investment payments; factors used in determining shared losses for ACOs under two-sided models (including calculation of the variable MSR/MLR based on the ACO's number of assigned beneficiaries, and the applicability of the extreme and uncontrollable circumstances policy for mitigating shared losses for two-sided model ACOs); and calculation of the ACPT, regional and national components of the three-way blended benchmark update factor. When considered together these changes to the Shared Savings Program's payment methodology are expected to improve the quality and efficiency of items and services furnished under the Medicare program by improving the ability for ACOs to sustain effective participation in regions with changing populations and increasing the overall proportion of Medicare beneficiaries assigned to ACOs, and are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act.

In the CY 2023 PFS final rule we estimated that the projected impact of the payment methodology that incorporates all finalized changes from that final rule would result in $4.9 billion in greater program savings compared to a hypothetical baseline payment methodology that excludes the policies that require section 1899(i)(3) of the Act authority (see 87 FR 70195 and 70196). The marginal impact of the proposed changes discussed in this proposed rule is estimated to be $330 million lower net spending over the ten year window for all new proposals combined, including the proposal to cap an ACO's regional service area risk score growth and the proposals to add a new third step to the beneficiary assignment methodology and to revise the approach to identify the assignable beneficiary population. Therefore, we believe the requirements of section 1899(i)(3)(B) of the Act would not be violated by these relatively minor changes to program spending.

We will continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

11. Medicare Part B Payment for At-Home Preventive Vaccine Administration Services

In section III.H.3.c of this proposed rule, we propose to maintain the additional payment when a COVID–19 vaccine is administered in a beneficiary's home under certain circumstances, and to extend this payment to the administration of a pneumococcal, hepatitis B or influenza vaccines.

We estimated the impact of the proposal to maintain the additional payment for in-home COVID–19 vaccine administrations and to expand the policy to the administration of all Part B preventive vaccines. For this estimate, we analyzed CY 2021–2022 utilization of HCPCS code M0201 for the providers and suppliers that billed it, along with their utilization of the relevant preventive vaccine administration codes. During this period, the in-home additional payment was billed about 200,000 times by roughly 1,500 different providers and suppliers. For those providers or suppliers who administered COVID–19 vaccine in the home in 2021–2022, HCPCS code M0201 was billed about 2 percent of the time they administered any COVID–19 vaccination. Total Medicare payments for this service in 2021 and 2022 were $4 million and $3 million, respectively.

While we expect that in-home administrations of COVID vaccines will continue into CY 2024, we note that the overall utilization of the COVID–19 vaccine was significantly lower in 2022 than in 2021, and future utilization is unknown. Further, if we apply the prevalence of the utilization of HCPCS code M0201 for in-home administration of the COVID–19 vaccine to the utilization of the other three Part B preventive vaccinations, it would result in higher spending of roughly $1–2 million. Therefore, the overall estimated impact of this proposal is increased spending of less than $5 million in 2024. We note that our analysis assumed that there would be no additional providers or suppliers who would decide to begin providing these vaccines at home for CY2024, given that COVID–19 PHE ended on May 11, 2023

12. Effects of Proposals Relating to the Medicare Diabetes Prevention Program Expanded Model

a. Effects on Beneficiaries

We propose to modify certain Medicare Diabetes Prevention Program (MDPP) expanded model policies to: (1) Extend the flexibilities allowed during the PHE for the COVID–191135 waiver event by 4 years (or until December 31, 2027), (2) update the MDPP payment structure to pay for beneficiary attendance on a fee-for-service basis while retaining the diabetes risk reduction performance payments, (3) remove the requirement for MDPP interim preliminary recognition and replace it with CDC preliminary recognition, and (4) remove most references to, and requirements of, the Ongoing Maintenance Sessions given that eligibility for these services will end on December 31, 2023. We anticipate that these proposed changes will have a positive impact on beneficiaries' access to MDPP services by increasing the number of MDPP eligible organizations that enroll in Medicare as MDPP suppliers and, more importantly, increasing beneficiary access to the Set of MDPP services by allowing them continued access to MDPP through a live in-person or virtual classroom (or a combination of both modalities). The proposed changes would also remove barriers specific to attending these classes solely in-person, which may include a lack of MDPP suppliers in certain communities and challenges related to beneficiary logistics concerning course attendance.

These proposed modifications address MDPP supplier and beneficiary needs based upon available monitoring and evaluation data received to date,

feedback from Medicare Advantage plans and existing MDPP suppliers, and feedback from beneficiary focus groups. The proposed changes are also in response to comments from interested parties made through public comments in response to prior rulemaking.

During the initial rulemaking for the MDPP expanded model, we sought to ensure that MDPP would be delivered in-person, in a classroom-based setting, and within an established period of service to maintain consistency with the original DPP model test. At the time, priority was placed on establishing a structured expanded model that, when delivered within the confines of the rule, would create the least risk of fraud, waste, 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 led us to make changes to the MDPP expanded model through implementation of an Emergency Policy for MDPP that allows for temporary flexibilities while prioritizing availability and continuity of services for MDPP suppliers and MDPP beneficiaries impacted by such section 1135 waiver events. For example, in the CY 2021 PFS, we finalized the regulations in the March 31st COVID–19 IFC to amend the MDPP expanded model to revise certain MDPP policies during the COVID–19 PHE as well as any future 1135 waiver events where such 1135 waiver event may cause a disruption to in-person MDPP service delivery. These flexibilities allowed beneficiaries to either continue to have access to MDPP through participation in virtual sessions, pause an in-person MDPP class 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).

When establishing these flexibilities, we could not predict that the COVID–19 PHE would continue for over 3 years. Although beneficiary participation decreased significantly during the initial year of the COVID–19 PHE, MDPP participation has slowly increased since 2021. As this additional modality of delivery has helped improve supplier access to beneficiaries, removing the PHE flexibilities and suppliers' ability to deliver MDPP virtually after 3 years would not only be disruptive to suppliers, it may in-fact be detrimental to the operations of the MDPP expanded model.

During the COVID–19 PHE, we permitted virtual delivery of the Set of MDPP services by MDPP suppliers who were recognized by the CDC with Diabetes Prevention Recognition Program (DPRP) in-person delivery mode, but did not permit suppliers who were only recognized by the CDC with either online or distance learning delivery modes. Although we finalized in the CY 2021 PFS that suppliers had to be prepared to return to in-person delivery when the PHE ended, the PHE lasted for over 39 months. Therefore, returning to a solely in-person, pre-PHE delivery model may not be as simple for some suppliers.

Post-PHE, many beneficiaries and suppliers have reported the desire to continue utilizing virtual delivery of MDPP for a wide range of reasons. Maintaining suppliers' ability to offer both synchronous virtual (distance learning) and in-person MDPP may increase beneficiary uptake of these services. It is important to note that permitting virtual delivery of MDPP throughout the PHE has not resulted in a spike in MDPP utilization. A reason for a lack of beneficiary participation may be tied to the fact that suppliers still had to maintain the ability to deliver in-person services (rent or own physical space), while some suppliers were unfortunately unable to pivot to virtual delivery during the COVID–19 PHE for a variety of reasons.

Current data depict that the most impactful MDPP results correspond to attending MDPP sessions virtually or through utilizing a hybrid approach (attending classes both virtually and in-person). Interim MDPP evaluation data illustrated that average participant weight loss is 5.1 percent since the expanded model launched on April 1, 2018, surpassing the expanded model's weight loss goal of 5 percent. In addition, the interim evaluation data show that, 53 percent of MDPP participants attained the 5 percent weight-loss goal, and 24.6 percent attained the 9 percent weight-loss goal.[391] Aligning with the Diabetes Prevention Program (DPP) model test [392] and studies on the National DPP,[393] [394] MDPP participants who attended more sessions lost more weight. For example, among beneficiaries who attended at least 9 sessions, 64 percent met the 5 percent weight loss goal and 30 percent met the 9 percent weight loss goal. For MDPP participants impacted by the COVID–19 PHE, evaluation data confirm significantly increased weight loss accompanied with a higher number of sessions attended by participants completing the expanded model in 2021, with these participants attending primarily virtual sessions or a mixture of virtual and in-person sessions.

To date, there have been no preliminary indications that the synchronous virtual delivery of MDPP has limited supplier instruction or beneficiary success, as defined by achievement of the 5 percent weight loss goal. However, it is too early to determine the impact of synchronous virtual delivery of MDPP on other outcomes such as cost-savings or incidence of diabetes. MDPP has been fundamentally limited by low beneficiary participation and corresponding small sample sizes. We believe that an increase in supplier uptake, which may be accomplished through our proposal to maintain more options of MDPP delivery modalities, will result in an increase in beneficiary enrollment. This will be critical to conducting robust programmatic evaluations, including a potential future certification of the synchronous virtual delivery of MDPP.

To assist with our ability to improve monitoring and evaluation of the synchronous virtual delivery of MDPP, we have proposed a new HCPCS G-code specific to distance learning. Additionally, extending the flexibilities allowed during the PHE for COVID–19 by 4 years would improve MDPP eligible organizations' MDPP service delivery opportunities due to the use of multiple modalities.

b. Effects on the Market

While we acknowledge that additional changes will likely be necessary to improve beneficiary access to MDPP, we anticipate that the enhancements proposed in this rule are likely to result in an increase of MDPP suppliers and increased beneficiary access to the Set of MDPP services. We anticipate that this will assist in contributing to a reduction of the incidence of diabetes among eligible Medicare beneficiaries, and in particular, those residing in underserved communities. Currently, there are approximately 786 in-person organizations nationally that are eligible to become MDPP suppliers based on

[391] MDPP 2nd Annual Evaluation Report.

[392] RTI International. *Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring: THIRD ANNUAL REPORT.* March 2017. *https://downloads.cms.gov/files/cmmi/hcia-crppm-thirdannrptaddendum.pdf.*

[393] Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med.* 2002;346(6):393–403. doi:10.1056/NEJMoa012512.

[394] Diabetes Prevention Program Research Group. Long-term effects of lifestyle intervention or metformin on diabetes development and microvascular complications over 15-year follow-up: the Diabetes Prevention Program Outcomes Study. *Lancet Diabetes Endocrinol.* 2015;3(11):866–875. doi:10.1016/S2213-8587(15)00291-0.

their preliminary or full CDC Diabetes Prevention Recognition Program (DPRP) status. However, only 25 percent of eligible in-person organizations are participating in MDPP, and only one-third of MDPP suppliers have submitted MDPP-related claims. Through updating the payment structure to one that is similar to those of existing CMS Medicare Preventive Services such as the Intensive Behavioral Counseling for Obesity, the MDPP claims submission process may be more intuitive for existing Medicare suppliers. In addition, we anticipate that simplifying the MDPP payment structure will address some of the complexities related to the process for submitting claims, while encouraging more suppliers to submit claims for MDPP due to a reduced set of codes.

Since MDPP was established through the CY 2017 PFS, we have consistently heard from interested parties that we should include virtual delivery of MDPP as part of the expanded model test, which would increase beneficiary access to the Set of MDPP services while providing flexibility of where both a beneficiary may take the course and from where a supplier may deliver the course. Although we did not allow for a fully virtual delivery of MDPP until the COVID–19 PHE, we did allow a limited number of virtual make-up sessions, which could be delivered either synchronously or asynchronously. The rationale for allowing a limited number of virtual make-up sessions was due to the fact that the data used to certify MDPP were based upon in-person delivery, thereby fully virtual delivery was arguably outside the scope of certification.

The COVID–19 PHE led CMS to establish MDPP flexibilities that allowed fully virtual delivery of the Set of MDPP services by suppliers. We established several emergency flexibilities within the IFC–1 that removed the limit on the number of virtual makeup sessions, and in the CY 2021 PFS, we finalized the MDPP flexibilities from the IFC–1 while establishing the MDPP Emergency Policy that allowed for virtual delivery of MDPP, including virtual weight collection. However, the CY 2021 PFS stated that MDPP suppliers must retain the capacity to deliver the Set of MDPP services in-person, precluding organizations with CDC DPRP recognition solely in the distance learning or online modalities from participating in MDPP during the COVID–19 PHE. Interested parties commented that some beneficiaries may have limited access or ability to use the technology required for participation in virtual MDPP sessions.

In the CY 2022 PFS, although outside the scope of rule, interested parties recommended that we continue the virtual option following the end of the COVID–19 PHE to assist in increasing access to MDPP, especially for those with transportation needs as well as for beneficiaries in rural and low-income communities, who may suffer from a lack of in-person suppliers. As a result of these recommendations, in this rule, we are proposing to extend the PHE flexibilities, specific to allowing synchronous virtual delivery of MDPP, also known as distance learning.

Currently, there are numerous large geographic gaps of MDPP supplier locations, and synchronous virtual delivery may be part of the solution to increasing the accessibility of MDPP to more beneficiaries. It is unclear how the market will respond to the proposed extension of the PHE flexibilities allowed during the COVID–19 PHE, especially since we are still requiring suppliers to have and maintain an in-person DPRP recognition, but we believe organizations will be ready to engage in the delivery of the Set of MDPP services either in-person, through distance learning, or through a combination of in-person and distance learning. We also believe that having more flexibility in how the Set of MDPP services are delivered will make MDPP more accessible to beneficiaries, particularly those who live in rural areas or in communities with gaps in MDPP supplier locations.

c. Payment for MDPP Services

Regulations at § 414.84 specify MDPP suppliers may be eligible to receive payments for furnishing MDPP services and meeting performance targets related to beneficiary weight loss and/or attendance. However, we have consistently heard from suppliers and interested parties that the MDPP performance-based payment structure has been confusing to some suppliers, including those new to Medicare as well as existing suppliers. Approximately 37 percent of MDPP suppliers have submitted FFS claims for MDPP.[395] Confusion with claims submission has been due, in part, to the MDPP payment structure, which pays for performance-based milestones versus paying for traditional fee-for-service. The performance-based payment structure requires 15 HCPCS G-codes if including ongoing maintenance sessions, and 11 G-codes for the 12-month MDPP service period. Therefore, we are proposing to shift this payment structure to pay for attendance on a fee-for-service basis while retaining the diabetes risk reduction performance milestones, for example 5 percent and 9 percent weight loss as well as the maintenance of the 5 percent weight loss in months 7–12. This proposed streamlined payment structure will allow suppliers to receive a more consistent set of payments for their delivery of the Set of MDPP services and reduce the number of G-codes for easier billing.

We anticipate that this updated payment structure will reduce the upfront beneficiary retention costs while motivating eligible suppliers to enroll in Medicare to become MDPP suppliers and provide the Set of MDPP services to eligible Medicare beneficiaries. In the current MDPP payment structure, suppliers submit claims after the 1st, 4th, and 9th sessions attended during the core sessions interval, and following attendance of the two (2) sessions during each of the core maintenance intervals. Although the proposed per session payment of $25 is less than the current per session payment of $38, suppliers will receive up to 22 payments for attendance in the proposed payment structure compared to seven attendance-based payments, for participants who began participation in 2022 or later, or eleven attendance-based payments for participants whose first core session was in 2021 or earlier. The total attendance-based payments will increase by $54 to $550 in the proposed payment structure, compared to $496 in the current one.

This proposed payment schedule would not only eliminate gaps in payment by providing smaller but more frequent per-session payments, it would also reduce or eliminate some of the coding challenges related to the number of existing HCPCS codes. We have proposed to decrease the one-time performance payments for beneficiary achievement of the 5 percent and 9 percent weight loss goals as well as propose a new HCPCS G-code for the maintenance of the 5 percent weight loss during months 7–12. The proposed total maximum payment of $768 consists of the attendance-based payments and the weight loss performance payments. Although the proposed maximum payment of $768 over a one-year service period is the same as the current maximum payment, we believe this simplified payment structure will lead to fewer claims rejections while encouraging more suppliers to submit MDPP claims for the beneficiaries they serve, as well as

[395] Unpublished data from Acumen LLC, Quarter 4 2022 Quarterly Monitoring Report to CMS.

motivate more eligible organizations enroll in Medicare to participate in MDPP.

d. Effects on the Medicare Program

(a) Estimated 10-Year Impact of MDPP

There are two proposed changes to the Medicare Diabetes Prevention Program (MDPP) which are relevant to this impact analysis. Both changes will be implemented in 2024 if finalized: Simplifying the MDPP payment schedule; and allowing specified Public Health Emergency (PHE) flexibilities to continue for 4 years after the PHE ends—namely, allowing for synchronous virtual delivery of the Set of MDPP services.

Table 113 shows the estimated impact (in millions) of these two proposed changes on Medicare spending:

TABLE 113: Estimated Impact (in millions) of the Two Proposed Changes on Medicare Spending

Year	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	Total
Impact on Medicare Spending	$0.3	$0.3	$0.1	$0.0	−$0.2	−$0.8	−$0.7	−$0.6	−$0.5	−$0.3	−$2.4

(b) Assumptions/Notes

- Simplifying the payment schedule will lead to fewer claim denials and more participation from MDPP suppliers . For example, only 55–62% of FFS participants listed in the supplier crosswalks have an associated MDPP claim over the past 2 years, meaning that organizations have submitted data to the CDC as part of their Diabetes Prevention Recognition Program (DPRP) requirements, and also have FFS claims submitted for the same participants for the same sessions recorded in the DPRP data. The proposed payment schedule will reduce the number of HCPCS codes to from 15 to 6 and eliminate some of the coding issues. It will also eliminate the gaps in payment by providing smaller but more frequent per-session payments.
- The average payment per MDPP participant will increase by $150. The new payment schedule will likely lead to more successful claim payment submissions and will motivate MDPP providers to retain participating beneficiaries for longer periods of time.
- In 2022, 551 FFS claims were paid for the initial MDPP session, compared with 514 in 2021. According to counts of new FFS participants, there have been about 700 new entrants per year in recent years. With the implementation of a simpler payment schedule and the extension of PHE flexibilities, we assume that new participation will be more in line with claim payments for HCPCS code G9873 and will increase to 1,000 in 2024 and 1,250 during the following years until the extended flexibilities end. We estimate that there will be 500 new (in-person only) participants each year starting in 2029.
- Since the start of the PHE, synchronous virtual delivery of MDPP services has been more prevalent than in-person delivery. However, given the coding/reporting issues during the PHE, it is difficult to determine how many beneficiaries are still receiving MDPP services in-person. Without the proposed changes, we assume that new participation will be capped at 400 beneficiaries per year.
- For preventing diabetes progression, synchronous virtual delivery of the Set of MDPP services has the same level of effectiveness as in-person delivery. Following 3 years of delivering MDPP almost solely virtually, suppliers and beneficiaries have become adept at utilizing virtual delivery, as many providers in numerous healthcare settings have shifted to utilizing technology. Furthermore, preliminary MDPP data collected during the PHE indicates that beneficiaries have achieved similar weight loss and attendance goals as participants in both the in-person DPP test and MDPP participants who enrolled in MDPP prior to the pandemic. This assumption is revisited in the Sensitivity Analysis section.

(c) Sensitivity Analysis

On March 14, 2016, the Office of the Actuary (OACT) published a certification memorandum setting out the conditions for expansion of the Medicare Diabetes Prevention Program (MDPP), which can be found at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf*. Assumptions about the 10-year cost impacts of virtual delivery of MDPP services takes into account the assumptions of the original certification, and adjusts for diabetes costs in 2023 dollars, and trends those costs over the next 10 years.

Since both the effectiveness and the future participation level of synchronous virtual delivery of MDPP services are largely unknown, Table 114 shows 10-year cost impacts (in millions) of varying levels of effectiveness of the virtual delivery of the Set of MDPP services relative to the in-person delivery of the Set of MDPP services, paired with varying levels of virtual MDPP participation.

TABLE 114: 10-year Cost Impacts (in millions) of Virtual Delivery of MDPP Services

Virtual Beneficiaries Per Year/Effectiveness	25%	50%	75%
1,000	$0.7	−$0.8	−$2.3
2,000	$1.3	−$1.6	−$4.6
3,000	$2.0	−$2.4	−$6.9

As indicated in Table 114, virtual delivery of MDPP services is estimated to produce savings when it is at least 50 percent as effective as in-person delivery.

13. Appropriate Use Criteria for Advanced Diagnostic Imaging

Section 1834(q)(2) of the Act, as added by section 218(b) of the Protecting Access to Medicare Act (Pub. L. 113–93, April 1, 2014) (PAMA), directs CMS to establish a program to promote the use of appropriate use criteria (AUC) for applicable imaging services furnished in an applicable setting.

As discussed in detail in section III.J. of this proposed rule, since 2015, we have taken a thoughtful, stepwise approach that maximized engagement and involvement of interested parties to implement the statutory provisions set forth in section 1834(q), as added by section 218(b) of the PAMA, using notice and comment rulemaking. As codified at § 414.94, we established the first two components of the AUC statutory requirements—establishment of AUC and mechanisms for consultation. We began to build the parameters for the fourth component, outlier identification and prior authorization, leading to prior authorization, by establishing the priority clinical areas (PCAs). We began implementing the third component, the AUC consultation and reporting requirement, using the ongoing educational and operations testing period. However, as discussed previously in this proposed rule, at this time, we have exhausted all reasonable options for fully operationalizing the AUC program consistent with the statutory provisions as prescribed in section 1834(q)(B) of the Act directing CMS to require real-time claims-based reporting to collect information on AUC consultation and imaging patterns for advanced diagnostic imaging services to ultimately inform outlier identification and prior authorization. As a result, we have proposed to pause implementation of the AUC program for reevaluation and to rescind the current AUC program regulations at § 414.94.

In the CY 2019 PFS final rule (83 FR 59452), we performed an RIA for this program and updated that RIA in the CY 2022 PFS final rule (86 FR 64996). The estimated impacts in the CY 2022 PFS final rule are as follows:

- Cost to ordering clinicians of required AUC consultation: $51,039,109 annually.
- Cost to Medicare beneficiaries for additional office visit time: $54,789,518 annually.
- Cost to ordering clinicians of transmitting consultation information: $94,495,192 annually.
- Cost to furnishing clinicians to update processes to report AUC information: $1,851,356,888 (one time).
- Potential savings to Medicare program from decrease in imaging utilization: $700,000,000 annually.

Table 115 also includes the AUC program-related activities and their corresponding impact estimates. By pausing efforts to implement the AUC program for reevaluation and rescinding the AUC program regulation at § 414.94, the Medicare program may not realize the estimated savings, and clinicians and beneficiaries will not experience the estimated costs.

TABLE 115: AUC Program Related Activities with Impact Estimates From CY2022 PFS

AUC Program Related Activity	CY 2022 PFS Rule Impact Estimate
Impact of required AUC consultations by ordering professional	$51,039,109
Impact to Medicare beneficiaries	$54,789,518
Impact on transmitting orders for advanced diagnostic imaging services	$94,495,192
AUC automated solution	$1,851,356,888
Medicare program impacts associated with advanced diagnostic imaging services	$700,000,000

14. Medicare and Medicaid Provider and Supplier Enrollment Changes

In this section, we discuss the impact of our proposed Medicare provider enrollment revocation provisions and our Medicaid termination database proposal. For all provider enrollment proposals not referenced in this section, we have determined that they would not have an economic impact.

a. Medicare Revocation Reasons

As discussed in section III.J of this proposed rule, we are proposing several new or expanded revocation reasons in § 424.535(a).

First, we propose to expand § 424.535(a)(1) to include instances where the provider or supplier is non-compliant with the enrollment requirements in Title 42. Paragraph (a)(1) would no longer be restricted to non-compliance with the provisions of 42 CFR part 424, subpart P.

Second, new § 424.535(a)(15) would give CMS the authority to revoke enrollment if the provider or supplier, an owning or managing employee or organization thereof, or an officer or director thereof has had a civil judgment under the False Claims Act (31 U.S.C. 3729–3733) imposed against them within the previous 10 years.

Third, § 424.535(a)(16) would permit CMS to revoke enrollment if a provider or supplier, or any owner, managing employee or organization, officer, or director thereof, has been convicted of a misdemeanor under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries.

Fourth, we propose in new § 424.535(a)(243) that CMS may revoke an IDTF's, DMEPOS supplier's, OTP's, or HIT supplier's, or MDPP's enrollment based on a violation of any standard or condition in, respectively, §§ 410.33(g), 424.57(c), 424.67(b) or (e), or 424.68(c) or (e), or 424.205(b) or (d).

Based on CMS statistics concerning the average annual amount of Medicare payments a provider or supplier receives, we project a figure of $50,000. We note that we have recently used this figure when estimating the potential savings associated with several new revocation reasons.[396] For purposes of

[396] For example, see the final rule published in the **Federal Register** on November 18, 2022 (87 FR 69404), titled Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings

consistency and accuracy, we propose to use this $50,000 amount in this proposed rule.

Table 116 outlines the estimated annual number of revocations that would ensue with the four aforementioned revocation proposals:

TABLE 116: Estimated Annual Number of Revocations

Proposed Revocation Reason	Number of Revocations
§ 424.535(a)(1)	5
§ 424.535(a)(15)	5
§ 424.535(a)(16)	5
§ 424.535(a)(23)	5
Total	20

These revocations would represent a savings to the Federal Government because Trust Fund dollars would no longer be paid to the revoked providers and suppliers. Accordingly, we project an annual savings to the Federal Government of $1,000,000 ($50,000 × 20 revocations).

b. Medicaid Termination Database

As discussed in section III.J. of this proposed rule, we are proposing certain provisions in 42 CFR part 455 concerning the length of time a provider remains in the Medicaid termination database and how this interacts with the termination periods that States impose upon terminated providers. We do not believe these proposals involve any additional impact or burden on providers or States. In fact, it could result in a reduction of burden because a provider's potential length of time in the termination database would be capped at 10 years, although we have no data available with which to assist us in calculating the possible burden reduction. As a result, since we are uncertain of how much of the burden will be reduced, we are seeking public comments from the public to aid in understanding how to measure said burden reduction.

15. Expand Diabetes Screening and Diabetes Definitions

As discussed in section III.L. in this proposed rule, we propose to: (1) expand coverage of diabetes screening tests to include the Hemoglobin A1C test (HbA1c) test, (2) expand and simplify the frequency limitations for diabetes screening, and (3) simplify the regulatory definition of ''diabetes'' for diabetes screening, Medical Nutrition Therapy (MNT) and Diabetes Outpatient Self-Management Training Services (DSMT).

We anticipate that expanding coverage of diabetes screening to include the HbA1c test and expanding and simplifying the frequency limitations for diabetes screening to result in some additional service utilization, but we also anticipate the additional utilization may be balanced, in part, by potential long term benefits and savings resulting from increased prevention and early detection (allowing for less invasive and more effective treatment). As described earlier in our proposal, Medicare currently covers the Fasting Plasma Glucose (FPG) test and the Glucose Tolerance Test (GTT) for diabetes screening. The HbA1c test does not require fasting and is more convenient than the currently covered FPG and GTT. We also propose to expand and simplify the frequency limitations for diabetes screening by aligning to the statutory limitation of ''not more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual.''

We estimate our proposal to expand diabetes screening to result in approximately $68.5 million in additional annual expenditures for the Medicare Program. Our estimate is based on the following assumptions. Based on calendar year 2022 actual experience, approximately 27.3 percent of beneficiaries had a blood panel test that did not include the HbA1c test. Medicare currently pays approximately $9.50 per HbA1c test for diabetes management. The Medicare statutory and regulatory eligibility factors for an individual at risk for diabetes (section 1861(yy)(2) of the Act, 42 CFR 410.18(e)) cover much of the current Medicare beneficiary population. We assume that approximately 7.6 million potential additional HbA1c tests for diabetes screening to be billed under our proposal in calendar year 2024 and that the HbA1c test would be billed with a blood panel 95 percent of the time. Our estimate does not reflect secondary effects of the proposed policies, such as increased utilization of preventive screening services, additional follow-up services, and potential offsetting savings (including prevention and more effective treatment through early detection) that may result from these coverage expansions. Secondary effects are difficult to predict, may materialize many years after the intervention and may, in part, offset one another.

We do not anticipate that our proposal to simplify and expand the regulatory definition of ''diabetes'' for diabetes screening, MNT and DSMT to result in a significant economic impact on the Medicare program. As described earlier, we propose to remove the regulatorily codified clinical test requirements from the definition of ''diabetes'' for diabetes screening, MNT and DSMT and propose a shortened version of the existing definition that would simply define diabetes as diabetes mellitus, a condition of abnormal glucose metabolism. We believe that our proposal will empower health care professionals to apply clinically accurate and appropriate criteria and that we can ensure certain safeguards through medical coding and claims processing instructions. We do not anticipate our proposal to simplify and expand the regulatory definition of ''diabetes'' for diabetes screening, MNT and DSMT to result in a significant economic impact on the Medicare Program because the regulatory simplification would not otherwise change requirements or conditions of coverage and payment.

Program Requirements; Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs To Provide Refunds With Respect to Discarded Amounts; and COVID–19 Interim Final Rules''.

16. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan (Section 2003 of the SUPPORT Act)

In section III.M. of this proposed rule, we are proposing several updates to the CMS EPCS Program. We are proposing to remove the same entity exception at § 423.160(a)(5)(i) from the CMS EPCS Program and to add ''subject to the exemption in paragraph (a)(3)(iii) of this section'' to § 423.160(a)(5). Under this proposal, prescriptions that are prescribed and dispensed within the same legal entity are included in CMS EPCS Program compliance calculations as part of the 70 percent compliance threshold at § 423.160(a)(5). This proposal provides flexibility to prescribers and dispensing pharmacies that are the same entity to choose either of the electronic standards available at § 423.160(a)(3)(iii) to conduct e-prescribing appropriate for their internal systems without us having to exclude these prescriptions completely from the CMS EPCS Program. This proposal would affect prescriptions where the prescriber and the dispensing pharmacy are part of the same legal entity. Due to the limitations in identifying these prescriptions in the Prescription Drug Event (PDE) data, the ability to quantify the impact of this proposal is unknown. Please see section III.M.3.b. of this proposed rule for our discussion.

We are proposing to specify how we count prescriptions for the compliance calculation by proposing to use the unique identifier given to a prescription by the pharmacy in the measurement year and included in the Part D claims data. We will count renewals as an additional prescription in the CMS EPCS Program compliance threshold calculation, and we will not count refills as an additional prescription in the CMS EPCS Program compliance threshold calculation unless the refill is the first occurrence of the unique prescription in the measurement year. If each refill included on the original prescription were counted as a separate prescription, we believe there would be an incremental impact on small prescribers. Preliminary analysis of 2021 Part D data shows that approximately 23,000 prescribers would no longer qualify for the small prescriber exception and that approximately 6,900 additional prescribers would be noncompliant.

We are proposing updates to the CMS EPCS Program recognized emergency exception and waiver exception presently found at § 423.160(a)(5)(iii) and (iv) and proposed to be codified at § 423.160(a)(5)(ii) and § 423.160(a)(5)(iii) respectively. We are proposing to have discretion to determine which emergencies trigger the recognized emergency exception starting in the 2024 measurement year and proposing that prescribers to whom the exception applies would be excepted from the CMS EPCS Program requirements for the entire measurement year. We are proposing to modify how we have previously defined ''extraordinary circumstance'' for purposes of the waiver exception. We propose that an ''extraordinary circumstance'' means a situation outside of the control of a prescriber that prevents the prescriber from electronically prescribing a Schedule II–V controlled substance that is a Part D drug and does not exclude ''cases of an emergency or disaster.'' In cases of extraordinary circumstances, we are proposing the timeframe that would be covered by a waiver authorized under the CMS EPCS Program to be the entire measurement year. We are proposing that a prescriber has a period of 60 days from the date of the notice of non-compliance to request a waiver. Approved waivers would apply to prescriptions written by a prescriber for the entire measurement year, and the waiver would expire on December 31 of the applicable measurement year. Although we are modifying the situations in which a prescriber can apply for an extraordinary circumstances waiver and limiting the recognized emergencies exception that applies to the CMS EPCS Program, we do not anticipate these proposals to affect many clinicians compared to the current policies. First, we believe that the proposal for CMS to identify which emergencies trigger the recognized emergency exception would still capture the vast majority of emergencies or disasters that affect a prescriber's ability to achieve EPCS compliance and would remove any need for additional prescribers to apply for a waiver. Second, some prescribers who experience an emergency may still meet the 70 percent compliance threshold by the end of the emergency period and would not need to apply for a waiver exception. Finally, we are unable to quantify the additional number of potential disasters or emergencies prescribers might experience due to variability in the number of disasters and emergencies in a given measurement year. Therefore, we are not increasing our assumption that 100 waiver requests would be submitted to the CMS EPCS program, as we discussed in the CY 2022 PFS final rule (86 FR 65562).

We are proposing to continue sending non-compliance notices to prescribers identified as non-compliant with the CMS EPCS Program for any individual measurement year, and we do not believe that causes additional costs or will require additional time. Please see section III.M.6. of this proposed rule for our discussion. We do not anticipate the provisions to have any incremental impact on the cost or time associated with prescriber compliance with the electronic prescribing for controlled substances requirement or the cost to interested parties.

17. Proposed Changes to the Regulations Associated With the Ambulance Fee Schedule and the Medicare Ground Ambulance Data Collection System (GADCS)

As discussed in section III.N.2. of this proposed rule, section 4103 of the CAA amended section 1834(l)(12)(A) and (l)(13) of the Act to extend the payment add-ons set forth in those subsections through December 31, 2024. The ambulance extender provisions are enacted through legislation that is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase and does not require any substantive exercise of discretion on the part of the Secretary. As a result, there are no policy proposals associated with these legislative provisions legislative provisions. The Congressional Budget Office (CBO)'s estimated cost of these provisions was $55 million in 2023, $91 million in 2024, and $29 million in 2025 (*https://www.cbo.gov/system/files/2023-01/PL117-328_1-12-23.pdf*, p. 17). We are proposing only to revise the dates in § 414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to these self-implementing statutory requirements.

In addition, as discussed in section III.N.3. of this proposed rule, we are proposing the following changes to the Medicare Ground Ambulance Data Collection Instrument: Adding the ability to address partial year responses from ground ambulance organizations, introducing a minor edit to improve the reporting consistency of hospital-based ambulance organizations, and four technical corrections to typos. The changes and clarifications aim to reduce burden on respondents, improve data quality, or both.

While we believe that these changes and clarifications will be well received by the ground ambulance interested parties, we do not believe that these changes would have any substantive impact on the cost or time associated

with completing the Medicare Ground Ambulance Data Collection Instrument. We note that the overall length of the Medicare Ground Ambulance Data Collection Instrument will be the same as previously finalized (84 FR 62888) with these changes. Additionally, some of the instructions which we propose to add are intended to improve clarity and may therefore reduce the time the ground ambulance organizations spend addressing the questions.

18. Hospice CoP Changes

a. Permitting MFT and MCH To Serve as Members of the Interdisciplinary Group (IDG)

Under the Medicare Program in accordance with Subtitle C, Section 4121 of the CAA 2023, we are proposing conforming regulations text changes to permit MFT or MHC to serve as members of the IDG. These proposed changes will require hospices to include at least one SW, MFT or MHC to serve as a member of the IDG. Hospices will have the flexibility to determine which discipline(s) are appropriate to serve on the IDG based on the needs of the patients.

b. Modification of the Hospice Personnel Requirements With the Addition of MFT and MHC

Under the Medicare Program in accordance with Subtitle C, Section 4121 of the CAA 2023, we are proposing conforming regulations text changes to permit MFT or MHC to serve as members of the IDG. With the proposed addition of MFT and MHC into the hospice CoPs, it is important to include these new disciplines into the personnel qualifications at § 418.114. However, in section III.C. of this rule, we are proposing to add both MHC and MFT to the provider requirements under 42 CFR subpart B Medical and Other Health Services at §§ 410.53 and 410.54. Therefore, to avoid duplication and confusion between the CoP and the provider requirements under the Medical and Other Health Services provision, we are proposing to add both MHC and MFT to the requirements at § 418.114(c)(3) and (4) and referencing the new requirement at §§ 410.53 and 410.54 respectively. We do not expect any increase in burden for this modification. In addition, we do not expect the changes for this provision to cause any appreciable amount of expense or anticipated saving and we do not believe this standard would impose any additional regulatory burden.

19. RFI: Histopathology, Cytology, and Clinical Cytogenetics Regulations Under the Clinical Laboratory Improvement Amendments (CLIA) of 1988

We are publishing this RFI in this proposed rule to seek comments from interested parties. There is no impact for this RFI.

20. Basic Health Program Provisions

In this proposed rule, we are proposing to update the requirements for a BHP Blueprint revision. We also propose to allow a State with a BHP to suspend its BHP, if necessary, and provide requirements related to a BHP suspension. We also propose updates to the annual report content and timing, if a BHP is suspended. This proposal includes requirements for accessible notices. Finally, we propose changes related to an individual's appeals rights. We do not anticipate that these provisions would impose any additional regulatory burden.

21. A Social Determinants of Health Risk Assessment in the Annual Wellness Visit

We propose in section III.S. to exercise our authority in section 1861(hhh)(2)(I) of the Act to add elements to the Annual Wellness Visit (AWV) by adding a new Social Determinants of Health (SDOH) Risk Assessment as an optional, additional element with an additional payment. We propose that the SDOH Risk Assessment be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV. Our proposal builds upon our separate proposal described earlier to establish a stand-alone G code (GXXX5) for SDOH Risk Assessment furnished in conjunction with an Evaluation and Management (E/M) visit. See section II.E. of this proposed rule for additional information on coding, pricing, and additional conditions of payment for the proposed new SDOH Risk Assessment service. We anticipate our proposal to add a SDOH Risk Assessment as an optional, additional element with additional payment within the AWV to result in some additional service utilization, but we also anticipate the additional utilization may be balanced, in part or in whole, by potential long term benefits and savings resulting from a more effective AWV and increased prevention and early detection (allowing for less invasive and more effective treatment). We do not anticipate that the addition of an optional SDOH Risk Assessment to the AWV would result in a significant impact to the Medicare Program.

22. Updates to the Quality Payment Program

In this section, we estimate the overall and incremental impacts of the Quality Payment Program policies proposed in this rule. We estimate participation, final scores, and payment adjustment for clinicians participating through traditional MIPS, MVPs, and the Advanced APMs. We also present the incremental impacts to the number of expected Qualified Participants (QPs) and associated APM Incentive Payments that result from our policies relative to a baseline model that reflects the status quo in the absence of any modifications to the previously finalized policies.

a. Overall MIPS Modeling Approach and Data Assessment

(1) MIPS Modeling Approach

For this proposed rule we create two MIPS RIA models: a baseline and proposed policy model. Our baseline model includes previously finalized policies that would be in effect for the CY 2024 performance period/2026 MIPS payment year if none of our proposed policies are finalized. Examples of previously finalized policies are an updated methodology for calculating the complex patient bonus, and an increase in the data completeness threshold for quality measures. The proposed policies model builds off the baseline model and incorporates the MIPS policy proposals for the CY 2024 performance period/ 2026 MIPS payment year included in this proposed rule. The aim of the baseline and proposed policy models is to estimate the incremental impacts of the policies in this proposed rule. We used a similar approach in the CY 2023 PFS final rule (87 FR 70199 through 70200).

As discussed in the CY 2023 PFS final rule, our modeling approach utilizes the same scoring engine that is used to determine MIPS payment adjustments. This modeling approach enables our model to align as much as possible with actual MIPS scoring and minimizes differences between our projections and policy implementation. There are still some limitations to our model due to data limitations and assumptions. These limitations are discussed later in this RIA. The aim of the baseline model is to reflect participation, final scores, and payment adjustments for the upcoming performance period and associated MIPS payment year based on previously finalized policies for the performance period and MIPS and MIPS payment year.

(2) Data Used To Estimate Future MIPS Performance

In the 2023 PFS final rule (87 FR 70200), we discussed our decision to use the submissions data for the CY 2021 performance period to estimate eligibility, final scoring, and payment adjustments supplemented by CY 2019 performance period data to estimate participation and payment adjustments for the sake of estimating the size of the budget neutral pool. To mitigate the potential effect of the PHE on our engagement estimates for the CY 2024 performance period/2026 MIPS payment year, for MIPS eligible clinicians who submitted data for the CY 2019 performance period and did not submit data for the CY 2021 performance period, we assigned their participation status and final score data from the CY 2023 PFS proposed rule baseline model (87 FR 46408). This is because the CY 2023 PFS proposed rule baseline model (87 FR 46408) is based on submissions data for the CY 2019 performance period (hereafter called ''2019 data supplement'').

We indicated that we believed this approach would reflect data that is generally more current while mitigating the impacts of changes in reporting behavior during the PHE on our participation estimates. Although we believe that this is the best data source to accurately model the impact of our proposed policies, the use of data from the CY 2021 performance period supplemented by data from the CY 2019 performance period, has the same limitations as discussed in the 2023 PFS final rule (87 FR 70200). We took a similar approach this year.

The submissions for the CY 2022 performance period were not available in time to assess whether the data for that performance period can be used to predict future performance. For the final rule, we will evaluate whether it is appropriate to use the CY 2022 performance period data and whether adjustments to this RIA model based on factors such as clinician behavior or performance category data availability would need to be made if CY 2022 performance category submissions data were used instead.

b. Estimated APM Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

For payment years from 2019 through 2025, through the Medicare Option, eligible clinicians who have a sufficient percentage of their Medicare Part B payments for covered professional services or Medicare patients through Advanced APMs will be QPs for the applicable QP Performance Period for a year and the corresponding payment year. In payment years 2019 through 2024 these QPs will receive a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate paid amounts for covered professional services furnished during the calendar year immediately preceding the payment year. In payment year 2025, QPs will receive a lump-sum APM Incentive Payment equal to 3.5 percent payment of their estimated aggregate paid amounts for covered professional services furnished during CY 2024. 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 or patients through Advanced APMs and services furnished or patients through Other Payer Advanced APMs. 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, will then be scored under MIPS and receive a MIPS payment adjustment. Partial QPs are not eligible to receive the APM Incentive Payment.

If an eligible clinician does not attain either QP or Partial QP status, and is not excluded from MIPS on another basis, the eligible clinician will be subject to the MIPS reporting requirements and will receive the corresponding MIPS payment adjustment.

Beginning in payment year 2026, the update to the PFS CF for services that are furnished by clinicians who achieve QP status for a year is 0.75 percent, while the update to the PFS CF for services that are furnished by clinicians who do not achieve QP status for a year is 0.25 percent. Thus, eligible clinicians who are QPs for the year will receive differentially higher PFS payment rates than those who are not QPs.

We incorporated this change into our baseline eligibility determination. In addition, the thresholds to achieve QP status beginning in the 2024 QP Performance Period will increase to 75 percent for the payment amount method, and 50 percent for the patient count method. Overall, we estimate that for the 2024 QP Performance Period between 187,000 and 241,000 eligible clinicians will become QPs, and therefore be excluded from MIPS reporting requirements and payment adjustments.

In section VII.E.23.b of this proposed 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 2024 QP Performance Period, as well as some Advanced APMs anticipated to be operational during the 2024 QP Performance Period. The projections also reflect an estimated number of eligible clinicians that will attain QP status through the All-Payer Combination Option. The following APMs are expected to be Advanced APMs for the 2024 QP Performance Period:

- Bundled Payments for Care Improvement Advanced Model;
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track);
- ACO REACH Model (formerly Global and Professional Direct Contracting) Model;
- Kidney Care Choices Model (Comprehensive Kidney Care Contracting Options, Professional Option and Global Option);
- Maryland Total Cost of Care Model (Care Redesign Program; Maryland Primary Care Program);
- Medicare Shared Savings Program (Level E of the BASIC Track and the ENHANCED Track);
- Primary Care First (PCF) Model; and,
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).
- Making Care Primary (MCP) tracks 2 and 3.

We used the Participation Lists and Affiliated Practitioner Lists, as applicable, (see 42 CFR 414.1425(a) for information on the APM Participant Lists and QP determinations) for the 2022 QP performance period third snapshot QP determination date 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 2024 QP Performance Period. We examined the extent to which Advanced APM participants will 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.

c. Estimated Number of MIPS Eligible Clinicians for the CY 2024 Performance Period/2026 MIPS Payment Year

(1) Clinicians Included in the RIA Baseline and Final Policies Models Prior to Applying the Low-Volume Threshold Exclusion

For this proposed rule, we applied the same assumptions as in the CY 2023 PFS final rule (87 FR 70201 through 70202), unless otherwise noted. In the CY 2023 PFS final rule (87 FR 70202), we explained that we modified some of our assumptions to estimate engagement in MIPS to mitigate the effects of potential non-engagement due to the extreme and uncontrollable circumstances policies related to the PHE.

In the CY 2023 PFS final rule (87 FR 70201), we explained our use of the final reconciled eligibility determination file. This file reconciles eligibility from two determination periods and aligns with the CY 2021 performance period submissions data on which we based this model. In this proposed rule, we again used the final reconciled 2021 eligibility determination file which aligns with CY 2021 performance period submissions data. We did not propose any modifications to MIPS eligibility requirements, therefore the same eligibility assumptions apply to both the baseline and proposed policies models. Our analysis found that there were 1.7 million clinicians who had PFS claims from October 1, 2020 to September 30, 2021. This initial population of clinicians was used to determine eligibility using the processes described in the following sections.

(2) Estimated Number of MIPS Eligible Clinicians After Applying Assumptions for the Low-Volume Threshold Exclusion and Considering the Extreme and Uncontrollable Circumstances Policies Related to COVID–19 PHE

The low-volume threshold policy may be applied at the individual (TIN/NPI) or group (TIN) levels based on how data are submitted to MIPS. Generally, if a clinician or group does not exceed the low-volume threshold criteria then that clinician or group is excluded from participation in MIPS. The low volume threshold uses three criteria: allowed charges, number of Medicare patients who receive covered professional services, and number of services provided. 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 being measured on performance and receiving a MIPS payment adjustment.

We describe below the estimated MIPS eligibility status and the associated PFS allowed charges of clinicians in the initial population of 1.7 million clinicians for the proposed policies model. We applied the same assumptions as in the CY 2023 PFS final rule (87 FR 70201 through 70202) to apply the low-volume threshold and to determine whether clinicians participate in MIPS as a group, virtual group, APM entity, or as individuals. In the CY 2023 PFS final rule (87 FR 70202), we explained our use of the CY 2019 performance period data to update eligibility assumptions to account for the effects of the extreme and uncontrollable circumstances (EUC) policy that was applied due to the PHE. We noted that the use of CY 2021 performance period data alone might overstate the number of clinicians with ''required eligibility'' who do not participate in MIPS due to the PHE under the EUC policy and therefore may not have submitted data. If we assumed in this RIA model, which estimates of CY 2024 performance period/CY 2026 payment year, participation and non-participation to be similar to the CY 2019 performance period, we would likely overstate the number of clinicians receiving a negative payment adjustment. Since these clinicians actually would have received a neutral score under the CY 2021 performance period EUC reweighting policy but would receive a negative payment adjustment in our simulation.

As we noted in section VII.E.22 of this RIA, in order to mitigate the potential effect of the PHE on our engagement estimates for the CY 2024 performance period, for MIPS eligible clinicians who submitted data for the CY 2019 performance period and did not submit data for the CY 2021 performance period, we followed the same process described in the CY 2023 PFS final rule (87 FR 70202) and assigned their participation status and final score data from the CY 2023 PFS proposed rule baseline model (87 FR 46408). This is because the CY 2023 PFS proposed rule baseline model (87 FR 46408) is based on the 2019 data supplement. We believed these clinicians may participate and perform more similarly to the CY 2019 performance period than the CY 2021 performance period during the CY 2024 performance period.

We do not have ability to assess the performance of clinicians reflected in our 2019 data supplement in our model, so we used the same score for this final rule's baseline and proposed policies models. Because we used the same score for the baseline and proposed policies model, we were not able to assess the incremental impact of policies for this group. However, we believe making this adjustment is valuable because it helps mitigate the potential effect of overestimating the number of clinicians eligible for, and participating in MIPS, versus non-participants, which in turn would affect our estimation of the MIPS redistribution payment and the size of the budget neutral pool.

For our RIA model, we established the ''required eligibility'' category, which means the clinician exceeds the low-volume threshold in all 3 criteria and is subject to a payment adjustment is separated into three buckets this year: (1) ''Clinicians who Report''; (2) ''Did not report in 2021, but did report in 2019''; and (3) ''Did not report in either 2021 or 2019.'' We have done this so that we can isolate both the effects of our proposed policies, which are modeled using 2021 data, the effect of the 2019 data supplement, and model the population of clinicians who did not engage in either year. The year refers to which population of data we used (that is, the 2021 population of clinicians or the 2019 supplement).

(a) MIPS Eligibility Estimates

Table 117 summarizes our eligibility estimates for the proposed policies model after applying our assumptions discussed previously.

We estimate approximately 122,183 MIPS eligible clinicians have the required eligibility criteria and submitted data for at least one performance category in MIPS for the CY 2019 and 2021 performance periods, 9,906 MIPS eligible clinicians who did not engage in MIPS based on 2021 performance period MIPS data but did engage based on 2019 performance period MIPS data, and 14,289 MIPS eligible clinicians counted in our model as ''did not submit in data to MIPS for the CY 2019 or CY 2021 performance period.'' These are clinicians who did not submit data to MIPS for the CY 2019 or CY 2021 performance periods, or did not submit data to MIPS for the CY 2021 performance period and do not have CY 2019 performance period data.

We estimate approximately 664,562 MIPS eligible clinicians as having ''group eligibility'' in Table 117. ''Group eligibility'' means that these clinicians belong to a group that exceeds the low-volume threshold. If they were not associated with the group submission, these clinicians will not be eligible for MIPS.

Finally, we estimate about 9,107 clinicians will be eligible for MIPS and participate through ''opt-in eligibility''

through the ''opt-in'' policy. We updated our opt-in policy to reflect that a clinician can elect to opt-in into MIPS and will be scored, even if they do not submit data to MIPS.

We estimate a total MIPS eligible clinician population of approximately 1,741,607 with $9 billion PFS allowed charges estimated to be included in the CY 2024 performance period/2026 MIPS payment year.

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TABLE 117: Description of MIPS Eligibility Status for CY 2023 Performance Period/2025 MIPS Payment Year Using the CY 2023 PFS Final Rule Assumptions**

		CY 2024 PFS Proposed Rule estimates	
Eligibility Status	**Predicted Participation Status in MIPS Among Clinicians ***	**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)	Reported to MIPS *	122,183	$34,134
	Did not Report in 2021 but Reported in 2019	9,906	$2,963
	Did not Report in 2021 and did not Report 2019 (or did not have data in 2019)*	14,289	$4,261
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria)	Had a group submission	664,562	$17,533
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)	Opted-in To MIPS	9,107	$473
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**820,047**	**$59,363**
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)	Opt-in Eligible; Do not opt-in	185,342	$6,211
	Group Eligible; Did not Report	294,729	$6,701
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	123,231	$834
Excluded for other reasons (Non-eligible clinician type, newly enrolled)	Not applicable	75,836	$4,442
Qualified Participant (QP)***	Not applicable	242,422	$13,502
Total Number of Clinicians Not MIPS Eligible		**921,560**	**$31,690**
Total Number of Clinicians (MIPS and Not MIPS Eligible)		**1,741,607**	**$91,053**

* Participation excludes facility-based clinicians who do not have scores in the 2021 MIPS submission data.
** Allowed charges estimated in 2021 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.
*** Our QP estimate differs from that reported in section VII.E.23.b) of this proposed rule because we 2021 data and a different simulation methodology

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Furthermore, we estimate there will be approximately 185,342 clinicians who are not MIPS eligible, but could be if the clinician or their group elects to

opt-in. We describe this group as ''Potentially MIPS eligible'' in Table 117. These potentially MIPS clinicians would all be included as MIPS eligible in the unlikely scenario in which all group practices elect to submit data as a group, or clinicians in a group that does not submit are eligible to opt-into MIPS individually and choose to do so. We do not expect that every potentially MIPS eligible clinician will elect to submit data to MIPS. We estimate another 294,729 clinicians would be eligible for participation as a group but do not report data. These assumptions are important because they quantify 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 1,300,118 clinicians. Finally, we estimate approximately 123,231 clinicians will not be MIPS eligible because they and their group are below the low-volume threshold on all three criteria and another approximately 318,258 will not be MIPS eligible for other reasons, including 242,422 clinicians with QP status.

Eligibility among many clinicians is contingent on submission to MIPS as a group or election to opt-in, therefore we will not know the number of MIPS eligible clinicians who submit until the submission period for the CY 2023 performance period is closed. For the remaining analysis, we use the estimated population of 820,047 MIPS eligible clinicians described above.

c. Estimated Impacts on Payments to MIPS Eligible Clinicians for the CY 2023 Performance Period/2025 MIPS Payment Year

(1) Summary of Approach for MIPS Value Pathways (MVPs) and Traditional MIPS

In this proposed rule, we present several proposals which impact the measures and activities, the performance category scores, final score calculation, and the MIPS payment adjustment. We discuss these changes in more detail in section VII.E.23.d.(3) of this RIA as we describe our methodology to estimate MIPS payments for the CY 2024 performance period/2026 MIPS payment year. We then present the impact of the overall proposed policies in the CY 2024 performance period/2026 MIPS payment year and then compare select metrics to the baseline model, which only incorporates previously finalized policies for the CY 2024 performance period/2026 MIPS payment year. By comparing the baseline model to the proposed policies model, we are able to estimate the incremental impact of the proposed policies for the CY 2024 performance period/2026 MIPS payment year.

The payment impact for a MIPS eligible clinician is based on the clinician's final score, which is calculated based on the clinician's performance on measures and activities under the four MIPS performance categories: quality, cost, improvement activities, and Promoting Interoperability. MIPS eligible clinicians can participate as an individual, group, virtual group, APM Entity, clinicians participating in MIPS through the APM Performance Pathway (APP) or through an MVP in the four MIPS performance categories. MIPS APM participants can participate in the APP as an individual, group, virtual group, APM Entity and are only scored on three MIPS performance categories: quality, improvement activities, and Promoting Interoperability.

The average percentage change in total revenues that clinicians earn is less than the impact displayed here because MIPS eligible clinicians generally furnish services to both Medicare and non-Medicare patients; MIPS 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 will not be affected by MIPS payment adjustment factors.

(2) Methodology To Assess Impact for MIPS Value Pathways

In the CY 2022 PFS final rule (86 FR 65394 through 65397), we finalized policies at § 414.1365 for implementing MVPs beginning in the CY 2023 performance period/2025 MIPS payment year. In this RIA, we take a similar approach to modeling MVP participation and scoring as described in the CY 2022 PFS final rule (87 FR 70204), incorporating changes to our proposed policies model as described below.

(a) MVP Participant Assumptions

At § 414.1365(b), we require MVP Participants (which can be a group, individual, subgroup, or APM entity) to register prior to submitting an MVP. As we do not yet have information on who will register, we assume for purposes of this model, that MVP Participants are MIPS eligible individual clinicians or groups that currently submit at least four quality measures that are in an MVP. For these MVP Participants, we calculate both an MVP and a traditional MIPS score and take the highest score consistent with the existing scoring hierarchy which was finalized in the CY 2023 PFS final rule (86 FR 65537). For the baseline model, we used the quality measures finalized for MVPs in the CY 2023 PFS final rule Appendix 3: MVP Inventory.

In section IV.A.4.b and Appendix 3 of this proposed rule, we propose modifications to the 12 existing MVPs finalized in the CY 2022 PFS final rule (86 FR 65998 through 66031) and CY 2023 PFS final rule (87 FR 70037) and the consolidation of the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single consolidated primary care MVP titled Value in Primary Care.

In section IV.A.4.a of this proposed rule, we are proposing the inclusion of 5 new MVPs

- Focusing on Women's Health;
- Prevention and Treatment of Infectious Disease Including Hepatitis C and HIV;
- Quality Care in Mental Health and Substance Use Disorder;
- Quality Care for Ear, Nose, and Throat (ENT); and
- Rehabilitative Support for Musculoskeletal Care

For the proposed policies model, we incorporate the quality measure revisions for the existing MVPs and use the quality measures to model scores for the new MVPs in Appendix 3 of this proposed rule.

Our MVP Participant assumptions have limitations: we are not incorporating subgroups due to a lack of data, not all of the assumed participants may elect to register for an MVP, and we may have additional clinicians or groups register for an MVP. However, we believe this is a reasonable approach to simulate the impact of MVPs and we sought comment on this assumption, but did not receive any feedback.

(b) MVP Scoring Methods and Assumptions

We simulate an MVP score using the same data sources as we did for traditional MIPS. We scored according to § 414.1365(d) and § 414.1365(e) using the MVP reporting requirements listed in § 414.1365(c) with one exception. We did not restrict the improvement activities to the activities listed in the MVP inventory. We believed this would lower our estimated MVP score as clinicians and groups were not required to select from a limited inventory in the CY 2021 performance period (upon which our model is based). Therefore, we scored any improvement activities the MVP Participants submitted in 2021

as if those improvement activities are in the MVP inventory.

(3) Methodology To Assess Impact for Traditional MIPS

To estimate the impact of the proposed policies on MIPS eligible clinicians, we generally used the CY 2021 performance period's submissions data, including data submitted or calculated for the quality, cost, improvement activities, and Promoting Interoperability performance categories. As discussed in section VII.E.23.a.(2) of this proposed rule, we supplemented with 2019 data supplement.

We supplemented this information with the most recent data available for CAHPS for MIPS and CAHPS for ACOs, administrative claims data for the new quality performance category measures, and other data sets. We calculated a hypothetical final score for the CY 2024 performance period/2026 MIPS payment year for the baseline and proposed policies scoring models for each MIPS eligible clinician using score estimates for quality, cost, Promoting Interoperability, and improvement activities performance categories, where each are described in detail in the following sections.

(a) Methodology To Estimate the Quality Performance Category Score

We estimated the quality performance category score using a methodology like the one described in the CY 2023 PFS final rule (87 FR 70205) for the baseline and proposed policies RIA models for the CY 2024 performance period/2026 MIPS payment year.

To create the baseline policies RIA model, which does not reflect the policies proposed in this rule, we made the following modifications to the CY 2023 PFS final rule final policies model to reflect the previously finalized quality performance category policies for the CY 2024 performance period/2026 MIPS payment year:

- As discussed in the CY 2023 PFS final rule (87 FR 70049), we increased the data completeness criteria threshold to at least 75 percent for CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years.

For the proposed policies model, we did not implement any changes to the quality performance category relative to the baseline model because we use 2021 data and cannot simulate the addition of new measures.

(b) Methodology To Estimate the Cost Performance Category Score

We estimated the cost performance category score using a methodology similar to the methodology described in the CY 2023 PFS final rule (87 FR 70205) for the baseline and the proposed policies RIA models. For this proposed rule, the baseline policies RIA model included the same method used for the final policies RIA model in the CY 2023 PFS final rule (87 FR 70205). Due to technical limitations, we did not model cost improvement scoring in the baseline policies RIA model.

The proposed policies RIA model incorporated and implemented the following changes:

In section IV.A.4.f.(2).(a) of this proposed rule, we proposed 5 new episode-based cost measures.

- In section IV.A.4.g.(1).(c) of this proposed rule, we proposed to:

++ Determine cost improvement scoring at the category level;

++ Modify how to calculate cost improvement scoring and remove statistical significance requirement; and

++ Set the maximum improvement scoring to 1 percentage point, beginning in CY 2023 performance period/2025 MIPS payment year.

(c) Methodology To Estimate the Facility-Based Measurement Scoring

A limitation of using data from the CY 2021 performance period is that we are not able to estimate facility-based scores because there are no Hospital Value-Based Purchasing total performance scores calculated for the performance period due the COVID–19 PHE. However, for clinicians who did not participate in MIPS during the CY 2021 performance period, we did use the 2019 data supplement to identify final scores based on the CY 2019 performance period submission and these scores include facility-based scores.

(d) Methodology To Estimate the Promoting Interoperability Performance Category Score

We estimated the baseline Promoting Interoperability performance category score by using the same methodology that we used in the CY 2023 PFS final rule (87 FR 70206) final policies. We incorporated the final policies model from that rule into our baseline model. In section IV.A.4.F.(4)(f) of this proposed rule, we proposed to continue reweighting clinical social workers. This is incorporated into our proposed policies model. We did not incorporate changes to the performance period or measure level changes because we are not able to model this using data for the CY 2021 performance period.

(e) Methodology To Estimate the Improvement Activities Performance Category Score

For the baseline and proposed policies model we used the same method to estimate the improvement activities performance category score as described in the CY 2023 PFS final rule (87 FR 70206).

(f) Methodology To Estimate the Complex Patient Bonus Points

For the baseline and proposed policies RIA model, we used the previously established method to calculate the complex patient bonus as described in the CY 2022 PFS final rule (86 FR 64996).

(g) Methodology To Estimate the Final Score

We did not propose any changes for how we calculated the MIPS final score. Our baseline and proposed policies RIA models assigned a final score for each TIN/NPI by multiplying each estimated performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, adding the complex patient bonus, and capping at 100 points.

For the baseline policies RIA model, we applied the performance category weights and redistribution weights finalized in the CY 2022 PFS final rule (86 FR 65519 through 65524).

For both models, after adding any applicable bonus for complex patients, we reset any final scores that exceeded 100 points to equal 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for any performance category, we redistributed the weights according to § 414.1380(c).

(h) Methodology To Estimate the MIPS Payment Adjustment

For the baseline and proposed policies RIA models, we applied the hierarchy as finalized in the CY 2022 PFS final rule (86 FR 65536 through 65537) 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, and minimum and maximum adjustment percentages.

For the baseline model, we applied the performance threshold of 75 points finalized in the CY 2023 PFS final rule (87 FR 70097). In section IV.A.4.h.(2) of this proposed rule, we are proposing a

performance threshold of 82 points for the CY 2024 performance period/2026 MIPS payment year, which we incorporated into our proposed policies model. For both the baseline and proposed policies models, we used these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the allowed charges for covered professional services furnished by the MIPS eligible clinician.

(4) Impact of Payments

We noticed minimal changes to the mean and median final score between our baseline and proposed policies models. In our baseline model, the mean and median final scores are 73.26 and 79.99 points, respectively. In the proposed policies model, the mean final score is 73.52 and the median final score is 80.53. Many clinicians have scores clustered near the proposed performance threshold of 82 points. For instance, 51% of clinicians have a final score between 80 and 100 points and 63.28% of clinicians have final score between 75 and 100 points. Because so many clinicians have final scores near our proposed performance threshold, a small change in actual final scores relative to our model would significantly impact the number of clinicians with a positive, neutral, or negative adjustment.

Our proposed policies are expected to increase the number of clinicians receiving a negative adjustment from 36.75 percent of eligible clinicians to 54.31 percent of eligible clinicians, but decrease the average negative adjustment from −2.89 percent to −2.40 percent. This is because the increased performance threshold will cause many clinicians who previously scored slightly above the performance threshold to now score slightly below the performance threshold, shifting their expected payment from a small positive adjustment to a small negative adjustment.

Among MIPS eligible clinicians who reported data, 35.38 percent receive a negative adjustment in our baseline model compared to 52.24 percent in the proposed policies model. Because many clinicians' scores are close to the performance threshold, the payment adjustments for these clinicians are fairly small and many negative adjustments are much lower in magnitude than the statutory maximum negative adjustment of 9 percent. In our proposed policies model, we project the maximum negative payment adjustment of negative 9 percent for clinicians with a score of 20 points or below compared to a score of 18 in our baseline model.

In our baseline model, 2.13 percent of MIPS eligible clinicians and 1.41 percent of clinicians who report clinicians receive the max negative adjustment. In our proposed rule model, 1.99 percent of MIPS eligible clinicians and 1.19 percent of clinicians who report data receive the max negative adjustment. This is because, while the range of scores subject to the maximum negative adjustment increases slightly (from 18 to 20 points), slightly fewer clinicians in our proposed policies model have a final score below 20 points compared to the baseline model.

The increase in the number of clinicians receiving a negative score will contribute to an increase in the size of the budgetary dollars available, as a result of the budget neutral nature of the program. In the baseline model, we anticipate redistributing $7.4 million and, in the proposed policies model we anticipate, redistributing $8.9 million as a result of budget neutrality.

Because of this increase in the size of the budget neutral pool, the size of our positive payment adjustments increases. In our baseline model, the average positive payment adjustment is 1.99 percent among MIPS eligible clinicians. In the CY 2024 performance period/2026 MIPS payment year proposed policies model, the average positive payment adjustment is 3.35 percent among MIPS eligible clinicians. The maximum positive payment adjustment increased from 4.60 percent in the baseline model to 8.82 percent in the proposed rule model.

We want to highlight that we are primarily using submissions data for the CY 2021 performance period to simulate a final score for the CY 2024 performance period/2026 MIPS payment year, and it is likely that there will be changes that we cannot account for at this time. 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 2023 performance period/2025 MIPS payment year. This is because the PHE may have resulted in fewer clinicians submitting data to MIPS or more clinicians electing to apply for the extreme and uncontrollable circumstances policies due to the PHE for the CY 2019 and CY 2021 performance periods. Therefore, engagement levels in MIPS for the CY 2024 performance period/2026 MIPS payment year may differ from these reported estimates. We also note this participation data is generally based off participation for the CY 2021 performance period/2023 MIPS payment year, which is associated with a performance threshold of 60 points.

TABLE 118: Estimated Proportion of Eligible Clinicians with a Positive or Neutral and a Negative Payment Adjustment CY 2024 Performance Period/2026 MIPS Payment year by Practice Size

Practice Size*	Percent Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
Baseline		
1) Solo	46.94%	53.05%
2) 2-15	53.76%	46.23%
3) 16-99	54.55%	45.44%
4) 100+	68.68%	31.31%
Overall	63.24%	36.75%
Proposed Policies Model		
1) Solo	35.39%	64.60%
2) 2-15	39.81%	60.18%
3) 16-99	37.44%	62.55%
4) 100+	50.15%	49.84%
Overall	45.68%	54.31%

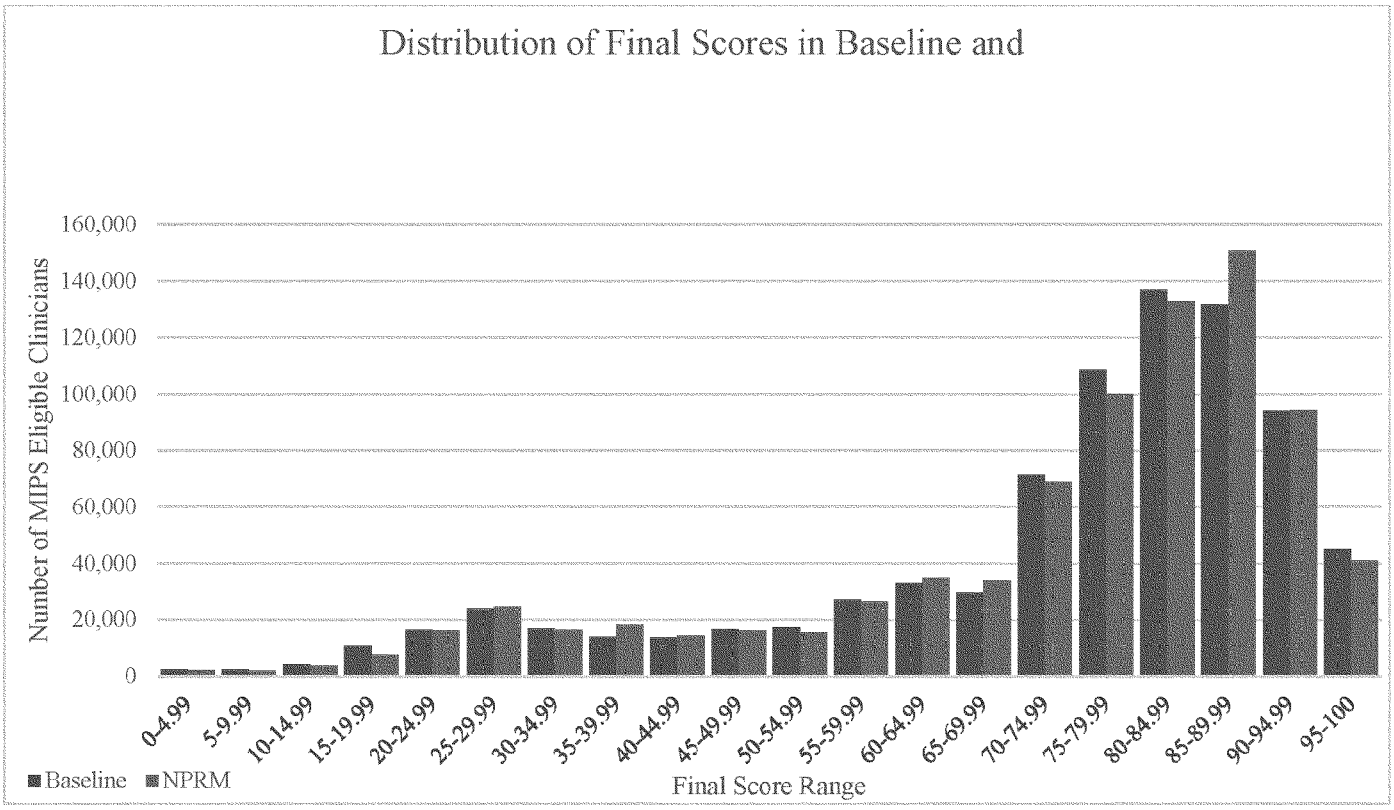
TABLE 119: Average and Maximum Positive Adjustments for Eligible Clinicians in the CY 2024 Performance Period /2026 MIPS Payment Year By Practice Size

Practice Size	Number of MIPS Eligible Clinicians	Average Positive Adjustment	Maximum Positive Payment Adjustment
Baseline			
Solo (1)	7,059	2.49%	4.60%
Small (2-15)	50,559	2.40%	4.60%
Medium (16-99)	104,742	2.01%	4.60%
Large (>99)	353,970	1.92%	4.60%
Overall	516,330	1.99%	4.60%
CY 2024 PFS Proposed Rule			
Solo (1)	5,322	4.62%	8.82%
Small (2-15)	37,503	4.10%	8.82%
Medium (16-99)	72,935	3.38%	8.82%
Large (>99)	258,849	3.21%	8.82%
Overall	374,609	3.35%	8.82%

TABLE 120: Average and Maximum Negative Adjustments for Eligible Clinicians in the CY 2024 Performance Period /2026 MIPS Payment Year By Practice Size

Practice Size	Number of MIPS Eligible Clinicians	Average Negative Adjustment	Maximum Negative Payment Adjustment
Baseline			
Solo (1)	7,977	-4.32%	-9.00%
Small (2-15)	43,476	-4.17%	-9.00%
Medium (16-99)	87,250	-2.95%	-9.00%
Large (>99)	161,379	-2.44%	-9.00%
Overall	300,082	-2.89%	
CY 2024 PFS Proposed Rule			
Solo (1)	9,714	-3.93%	-9.00%
Small (2-15)	56,683	-3.59%	-9.00%
Medium (16-99)	121,819	-2.54%	-9.00%
Large (>99)	257,222	-2.01%	-9.00%
Overall	445,438	-2.40%	-9.00%

FIGURE 4: Distribution of Final Scores in the Baseline and Proposed Policies Model



e. Additional Impacts From Outside Payment Adjustments

(1) Burden Overall

In addition to policies affecting the payment adjustments, we are proposing several policies that have an impact on burden in the CY 2024 performance period/2026 MIPS payment year. In section V.B.11. of this proposed rule, we outline estimates of the costs of data collection that includes both the effect of proposed policy updates and adjustments due to the use of updated data sources. For each proposed provision included in this proposed rule which impacts our estimate of collection burden, the incremental burden for each is summarized in Table 121. We also provide proposed additional burden discussions that we are not able to quantify.

TABLE 121: Incremental Burden from Associated Proposed Policies

Burden Description and associated finalized provisions	Burden Hours	Burden Dollars
Total burden associated with the provision to continue the policies and ICRs set forth in the CY 2023 PFS final rule into the CY 2024 performance period/2026 MIPS payment year (as discussed in section V.B11. of this proposed rule).	630,570	$71,317,983
Burden change for MVP registration ICR due to the provision of additional MVPs (as discussed in section V.B.11e.(7)(a) of this proposed rule). *	+321	+$33,192
Burden change for Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (as discussed in section V.B.11.e.(4) of this proposed rule). *	-4,743	-$530,492
Burden change for Quality Data Submission by Clinicians: CQM/QCDR Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (as discussed in section V.B.11.e.(5) of this proposed rule). *	-3,697	-$423,093
Burden change for Quality Data Submission by Clinicians: eCQM Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (as discussed in section V.B.11.e.(6) of this proposed rule). *	-4,344	-$503,665
Burden change for MVP Quality Submission ICR submissions due to the provision of additional MVPs (as discussed in section V.B.11.e.(7)(a)(iii) of this proposed rule). *	+8,461	+$964,505
Total change in burden due to policy for CY 2024	-4,002	-$459,553
Total burden set forth in the CY 2024 PFS proposed rule	626,568	$70,858,430

* The total change in burden due to this provision includes an increase in burden due to an anticipated increase in the number of respondents that will participate in MVP reporting based on the proposed addition of new MVPs. Therefore, there will be a decrease in burden in the "Quality Data Submission: MIPS CQM and QCDR collection type," "Quality Data Submission: eCQM collection type," and "Quality Data Submission: Claims collection type" ICRS due to respondents who previously submitted MIPS through those collection types submitting data with reduced Quality submission requirements as a MVP participant. Total change in burden also includes the increase in submission burden due to the increase in the number of respondents for "MVP registration." See section V.B.11 of this proposed rule.

(2) Additional Impacts to Clinicians

(a) Impact on Third Party Intermediaries

In section IV.A.4.k of this rule, we are proposing to: (1) add requirements for third party intermediaries to obtain documentation; (2) add requirements for third party intermediaries to submit data in the form and manner specified by CMS; (3) specify the use of a simplified self-nomination process for existing QCDRs and qualified registries; (4) add requirements for QCDRs and qualified registries to provide measure numbers and identifiers for performance categories; (5) Add a requirement for QCDRs and qualified registries to attest that information on the qualified posting is correct; (6) Modify requirements for QCDRs and qualified registries to support MVP reporting; (7) Specify requirements for a transition plan for QCDRs and qualified registries; (8) Specify requirements for data validation execution reports; (9) Add additional criteria for rejecting QCDR measures; (10) Add a requirement for QCDR measure specifications to be displayed throughout the performance period and data submission period; (10) eliminate the Health IT vendor category; (11) Add failure to maintain updated contact information as criteria for remedial action; (12) Revise corrective action plan requirements; (13) Specify the process for publicly posting remedial action; and (14) Specify the criteria for audits. Due to the technical nature of these proposed changes, we are unable to quantify the burden for third party intermediaries during the CY 2024 performance period/2026 MIPS payment year. We refer readers to section V.B.11.c of this rule for additional information on proposed changes to the third party intermediary requirements.

(b) Compare Tools: Public Reporting

In section IV.A.4. of this rule, we are proposing to update our policy for identifying clinicians furnishing telehealth services, such that we remain current with CMS coding changes, without proposing and finalizing such coding changes via rulemaking. Specifically, instead of only using place of service (POS) codes 02, 10, or modifier 95 to identify telehealth services furnished for the telehealth indicator, we would use the most recent codes at the time the data are refreshed. We are proposing that at the time of such a data refresh we would publish the details of which codes are used for the telehealth indicator through education and outreach, such as via a fact sheet, listserv, or information posted on the Care Compare: Doctors and Clinicians Initiative page, available at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/care-compare-dac-*

initiative. We are proposing to revise the policy to publicly report a subset of the Medicare public use file (PUF) on the Provider Data Catalog (PDC) to instead provide a single downloadable dataset reflecting including the procedure utilization data that would appear on clinician profile pages. We are proposing to modify the existing policy such that, in addition to the two previously finalized sources (Restructured BETOS categorization system and code sources used in MIPS), we may use alternate sources to create clinically meaningful and appropriate procedural categories, particularly when no relevant grouping exists. If we develop new procedure categories for publicly reporting utilization data on clinician profile pages, we are proposing to engage subject matter experts and interested parties through periodic requests for feedback using methods outside of rulemaking, such as but not limited to listserv emails, listening sessions, and focus groups, to solicit feedback on bespoke procedure categories planned for future releases of utilization data, as appropriate and technically feasible. We are also proposing to publicly report aggregated counts of procedures performed by providers based on Medicare Advantage (MA) encounter data (also known as MA risk adjustment data) in addition to Medicare fee-for-service (FFS) utilization data counts; as part of this proposal, we are proposing to amend 42 CFR 422.310(f) (the regulation that addresses permissible uses and releases of MA risk adjustment data) to permit use of MA encounter data in developing the data posted on the Care Compare website and release of the MA encounter data as part of the data set that will be downloadable from the Care Compare website more quickly than the regulation would currently permit releases of MA encounter data. While the Compare tool provisions do not increase the burden of collections, we note that the PRA package may require relevant modification to reflect the Compare tool's new uses and public display. We refer readers to section IV.A.I of this rule for additional information on the proposed changes to public reporting on Compare tools.

(c) Data Completeness Criteria for the Quality Measures, Excluding the Medicare CQMs

In section IV.A.5.a.(1) of this proposed rule, we are proposing to maintain the data completeness criteria threshold at 75 percent for the CY 2025 and 2026 performance periods/2027 and 2028 MIPS payment years, and increase the data completeness criteria threshold by 5 percent from 75 percent to 80 percent for the CY 2027 performance period/2029 MIPS payment year. We believe that the proposed policy to maintain the threshold for data completeness at 75 percent for the CY 2025 and 2026 performance periods/ 2027 and 2028 MIPS payment years is consistent with the existing data completeness criteria and therefore, would not result in additional burden to the applicable interested parties. We assume that the proposed increase in data completeness criteria threshold from 75 to 80 percent for the CY 2027 performance period/2029 MIPS payment year would not result in substantive burden to the applicable interested parties We believe that the increase in data completeness criteria threshold would reduce burden for clinicians using EHRs and eCQMs as the collection of eCQM data within the EHR can allow eligible clinicians to report on 100 percent of the eligible population with data in the EHR for a measure. Additionally, we recognize that individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities that continue to utilize other means of data collection for MIPS CQMs, including the collection of MIPS CQM data reported by registries and/or QCDRs, would need have the logic code of their EHRs to be updated to account for the increased data completeness criteria threshold. We believe that increasing the data completeness criteria threshold would not pose a substantial burden to MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities, unless they are manually extracting and reporting quality data. We refer readers to section IV.A.4.f.(1)(d) of this rule for additional information on proposed changes to the data completeness threshold criteria.

(d) Modifications to the Improvement Activities Inventory

As discussed in section IV.A.4.f.(3).(b)(ii) of this proposed rule, we are proposing changes to the improvement activities Inventory for the CY 2024 performance period/2026 MIPS payment year and future years as follows: adding five new improvement activities; modifying one existing improvement activity; and removing three previously adopted improvement activities. We refer readers to Appendix 2: Improvement Activities of this proposed rule for further details. We do not believe these proposed changes to the improvement activities inventory would significantly impact time or financial burden on interested parties 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 proposed changes to the improvement activities 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 most clinicians performing improvement activities, to comply with existing MIPS policies, would continue to perform the same activities under the policies in this proposed 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 CY 2024 performance period/2026 MIPS payment year. We refer readers to section IV.A.4.f.(3)(b) of this rule for additional information on proposed changes to the improvement activities Inventory.

(3) Update to CEHRT Definition for the Medicare Promoting Interoperability Program and the Quality Payment Program

In section III.R of this proposed rule, we propose to update the definitions of CEHRT for the Medicare Promoting Interoperability Program for eligible hospitals and CAHs and for the MIPS Promoting Interoperability performance category. Under this proposal, we would revise the definitions of CEHRT for the Medicare Promoting Interoperability Program at § 495.4, and for the Quality Payment Program at § 414.1305. Specifically, we propose to add a reference to the ''Base EHR Definition'' where the regulatory text refers to the ''2015 Edition Base EHR definition,'' remove ''2015 Edition'' where we reference ''2015 Edition health IT certification criteria,'' and add a cross-reference to health IT certification criteria at § 170.315. We also propose to specify that technology meeting the CEHRT definitions must meet ONC's certification criteria at § 170.315, ''as adopted and updated by ONC.'' We believe that these revisions to the CEHRT definitions, if finalized, would ensure that updates to the definition at § 170.102 and updates to applicable health IT certification criteria in § 170.315 would be incorporated into CEHRT definitions, without requiring additional regulatory action by CMS. Finally, we note that while this proposal is consistent with the approach in ONC's HTI–1 proposed rule (88 FR 23746 through 23917), we do not believe that ONC must finalize their

proposed revisions for us to be able to finalize the changes proposed in this section for our regulatory definitions of CEHRT. These changes would not impact EHR requirements in the CY 2024 EHR reporting period or the CY 2024 performance period, and therefore we predict that it would have no impact on clinicians.

f. Assumptions & Limitations

In section VII.E.23.a.(2) of this rule, we outline several limitations in using 2021 submissions data for estimating performance in the CY 2024 performance period/CY 2026 payment year. In addition, because many scores are clustered between the prior performance threshold of 75 points and the proposed threshold of 82 points, minor variations in actual clinicians final scores relative to our estimations could have significant impacts on the proportion of clinicians receiving a positive or negative payment adjustment.

In our MIPS eligible clinician assumptions, we assumed that clinicians who elected to opt-in for the CY 2021 Quality Payment Program and submitted data will continue to elect to opt-in for the CY 2023 performance period/2025 MIPS payment year. It is difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the proposed policies.

In addition to the limitations described throughout the methodology sections, 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 118.

F. Alternatives Considered

This proposed rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when we proposed to exercise agency discretion, 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 proposed rule, we present above the estimated impact on total allowed charges by specialty.

1. Alternatives Considered Related to the O/O E/M Visit Inherent Complexity Add-On Separate Payment

We considered alternatives to our proposed policy to make separate payment for the O/O E/M visit inherent complexity add-on code, including proposing to maintain our current utilization assumptions. Maintaining our current utilization assumption as finalized in CY 2021 would result in an estimated impact or change to the CF of −3.2 percent (Table 122). However, maintaining the CY 2021 policy utilization assumption would not reflect our proposed limitation on billing of the O/O E/M visit inherent complexity add-on code for services billed with modifier 25 which is used to indicate that the service is billed on the same day as a minor procedure or another E/M visit. It seems likely that visits reported with payment modifiers have resources that are sufficiently distinct from stand-alone office/outpatient E/M visits (85 FR 84571). Interested parties that are unlikely to bill for the O/O E/M visit inherent complexity add-on code have continued to express concerns about potential associated reductions to the CF and redistributive impacts among specialties. Our proposal to better target the add-on code would at least partially allay those concerns. Under our proposed utilization assumption for CY 2024, we estimate the effect of making separate payment for the O/O E/M visit complexity add-on code to be −2.0 percent.

TABLE 122: Estimated Conversion Factor Effect Attributable to the Inherent Complexity Add-on Code

As finalized for CY 2021	-3.2%
As proposed for CY 2024	-2.0%

We also considered proposing not to make separate payment for the O/O E/M visit inherent complexity add-on code for CY 2024, continuing to consider the utilization data, and seeking comment on not making separate payment until CY 2025 instead of CY 2024. While doing so would reduce the change to the CF and the redistributive impacts among specialties our concerns about capturing the work associated with visits that are part of ongoing, comprehensive primary care and/or care management for patients having a single, serious, or complex chronic condition would remain present. We believe separate payment for the O/O E/M visit inherent complexity add-on code will improve accuracy in payment for resource costs inherent to primary care and other medical care services that are part of ongoing care for a patient's single, serious or complex condition in the office setting. This would be particularly important for people without access to such care. We also believe that utilization of high-value preventive services, and promotion of healthy behaviors leveraged by these kinds of longitudinal patient relationships could result in positive patient outcomes and positive health equity impacts. Primary care practitioners and other practitioners who rely heavily on these visit codes and would use the add-on code would likely raise strong objections if CMS did not propose to make separate payment for a code that is intended to address long-standing distortions in PFS payment that CMS has repeatedly acknowledged through notice and comment rulemaking.

2. Alternatives to Provider Enrollment Provisions

We did not consider alternatives to our proposed provider enrollment provisions. We believe these changes are necessary to help ensure that payments are made only to qualified providers and suppliers and/or to increase the efficiency of the Medicare and Medicaid provider enrollment processes.

3. Alternatives Considered Medicare Diabetes Prevention Program

No alternatives were considered. The MDPP flexibilities resulting from the PHE for COVID–19 lasted over 3 years of the initial 5 years of the expanded model. During this time, supplier and beneficiary expectations changed, resulting in the synchronous virtual delivery of healthcare services becoming normalized. Requiring the MDPP expanded model to return to primarily

in-person services following over 3 years of synchronous virtual delivery may have an extremely negative impact for both MDPP suppliers and beneficiaries, which could threaten the success of the entire expanded model.

4. 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 separate proposed policies RIA models based on the actual mean for the CY 2019 performance period/2021 MIPS payment year with a performance threshold of 86. This model has the same mean and median final score as our proposed policies RIA model since the performance threshold does not change the final score. In our analysis of the alternative performance threshold of 86, 67.20 percent of MIPS eligible clinicians who submitted data would receive a negative payment adjustment.

We also report the findings for the baseline RIA model which describes the impact for the CY 2024 performance period/2026 MIPS payment year if this proposal is not finalized including previous polices including a performance threshold of 75. The baseline RIA model has a mean final score of 73.26 and median final score of 79.99. We estimate that $741 million would be redistributed based on the budget neutrality requirement. There would be a maximum payment adjustment of 4.60. In addition, 36.75 percent of MIPS eligible clinicians would receive a negative payment adjustment.

G. Impact on Beneficiaries

1. Medicare Shared Savings Program Provisions

As noted previously in this proposed rule, the proposal to cap an ACO's regional service area risk score growth is expected to increase the incentive for ACOs to participate in regions with high risk score growth, improving the incentive for ACOs to join and/or sustain participation when serving regions with increasingly medically complex beneficiaries. Similarly, the proposal to use a uniform approach to calculating both BY and PY prospective HCC risk scores using the same CMS–HCC risk adjustment model(s) is anticipated to increase participation (and reduce the potential for disenrollment) particularly from ACOs serving greater proportions of complex beneficiaries exhibiting high risk scores. The proposal to mitigate the impact of the negative regional adjustments on benchmarks is expected to increase participation from ACOs serving up to 500,000 new assigned beneficiaries per year. The proposal to revise the definition of an assignable beneficiary is expected to allow more than 760,000 additional beneficiaries to be included in the population of assignable beneficiaries, many of whom would be eligible to be assigned to ACOs. In total these proposals are expected to increase participation in the Shared Savings Program over the 2024–2033 period by roughly 10 to 20 percent.

ACOs have been found to perform better on certain patient-experience and performance measures than physician groups participating in the MIPS. In addition, ACOs continued to have higher mean performance than their MIPS Group counterparts on all 10 of the CMS Web Interface measures for PY 2021. This includes higher performance for quality measures related to diabetes and blood pressure control; depression screening and depression remission rates; breast, colorectal and falls risk screening rates; and flu vaccination, tobacco screening and smoking cessation, and statin therapy for the treatment and prevention of cardiovascular disease.

Increased participation in the Shared Savings Program will extend ACO care coordination and quality improvement to segments of the beneficiary population that potentially have more to benefit from care management.

2. Quality Payment Program

There are several changes in this proposed rule that are expected to have a positive effect on beneficiaries. In general, we believe that many of these changes, including the MVP and subgroup provisions, if finalized, will lead to meaningful feedback to beneficiaries on the type and scope of care provided by clinicians. Additionally, beneficiaries could use the publicly reported information on clinician performance in subgroups to identify and choose clinicians in multispecialty groups relevant to their care needs. Consequently, we anticipate the proposed policies in this proposed rule will improve the quality and value of care provided to Medicare beneficiaries. For example, several of the proposed new quality measures include patient-reported outcome-based measures, which may be used to help patients make more informed decisions about treatment options. Patient-reported outcome-based 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 outcome-based measured are factors frequently of interest to patients when making decisions about treatment.

3. Medicare Diabetes Prevention Program

The proposed changes would have a positive impact on eligible MDPP beneficiaries, as it increases the accessibility of MDPP, particularly among beneficiaries residing in rural and underserved areas of the US, where access to a supplier offering in-person Set of MDPP services may not exist or be geographically feasible.

H. 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 last year's proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters will review this year's proposed rule in detail, and it is also possible that some reviewers will choose not to comment on the proposed rule. For these reasons we believe that the number of commenters will be a fair estimate of the number of reviewers of last year's proposed 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.

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 $123.06, 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 $984.48 (8.0 hours × $123.06). Therefore, we estimated that the total cost of reviewing this regulation is 22,978,748 ($984.48 ×

23,341 reviewers on last year's proposed rule).

As for the Medicare Diabetes Prevention Program, given that we tried to align this rule as much as possible with the CDC DPRP Standards, there should be minimal regulatory familiarization costs. This rule impacts only enrolled MDPP suppliers and eligible beneficiaries who have started the MDPP program or are interested in enrolling in MDPP.

I. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Tables 123 through 125 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2023 to CY 2024 based on the FY 2024 President's Budget baseline.

TABLE 123: Accounting Statement: Classification of Estimated Expenditures

CATEGORY	TRANSFERS
CY 2024 Annualized Monetized Transfers	Estimated decrease in expenditures of $2.4 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 124: Accounting Statement: Classification of Estimated Costs, Transfer, and Savings

CATEGORY	TRANSFER
CY 2024 Annualized Monetized Transfers of beneficiary cost coinsurance.	-$0.6billion
From Whom to Whom?	Beneficiaries to Federal Government.

TABLE 125: Accounting Statement for Proposals for Medicare Shared Savings Program (CYs 2024-2033)

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation
Transfers From the Federal Government to ACOs				
Annualized monetized: Discount rate: 7%	-15 million	-171 million	174 million	Tables 109 through 112
Annualized monetized: Discount rate: 3%	-25 million	-189 million	172 million	

Notes: Negative values reflect reduction in Federal net cost resulting from care management by ACOs. Estimates may be a combination of benefits and transfers. To the extent that the incentives created by Medicare payments change the amount of resources society uses in providing medical care, the more accurate categorization of effects will be as costs (positive values) or benefits/cost savings (negative values), rather than as transfers.

J. 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.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 5, 2023.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, and X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, 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 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, 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

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.

42 CFR Part 455

Fraud, Grant programs—health, Health facilities, Health professions, Investigations,

Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 491

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare Reporting and recordkeeping requirements.

42 CFR Part 600

Administrative practice and procedure, Health care, Health insurance, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

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

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.800 is amended by adding paragraph (d) to read as follows:

§ 405.800 Appeals of CMS or a CMS contractor.

* * * * *

(d) *Scope of supplier.* For purposes of this subpart, the term ''supplier'' includes all of the following:

(1) The individuals and entities that qualify as suppliers under § 400.202 of this chapter.

(2) Physical therapists in private practice.

(3) Occupational therapists in private practice.

(4) Speech-language pathologists.

■ 3. Section 405.2401 is amended by adding the definition of ''Marriage and family therapist (MFT)'' and ''Mental health counselor (MHC)'' to paragraph (b) in alphabetical order to read as follows:

§ 405.2401 Scope and definitions.

* * * * *

(b) * * *

Marriage and family therapist (MFT) means an individual who meets the applicable education, training, and other requirements of § 410.53 of this chapter.

* * * * *

Mental health counselor (MHC) means an individual who meets the applicable education, training, and other requirements of § 410.54 of this chapter.

* * * * *

■ 4. Section 405.2411 is amended by revising paragraphs (a)(4), (a)(6), and (b)(2) to read as follows:

§ 405.2411 Scope of benefits.

(a) * * *

(4) Services and supplies furnished as incident to the services of a nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

* * * * *

(6) Clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services as specified in § 405.2450.

(b) * * *

(2) Covered when furnished during a Part A stay in a skilled nursing facility only when provided by a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor employed or under contract with the RHC or FQHC at the time the services are furnished;

* * * * *

■ 5. Section 405.2413 is amended by revising paragraph (a)(5) to read as follows:

§ 405.2413 Services and supplies incident to a physician's services.

(a) * * *

(5) Furnished under the direct supervision of a physician, except that services and supplies furnished incident to Transitional Care Management, General Care Management, the Psychiatric Collaborative Care Model, and behavioral health services can be furnished under general supervision of a physician when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1) of this chapter.

* * * * *

■ 6. Section 405.2415 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(3), and (a)(5) and

■ b. Adding paragraphs (b)(6) and (7).

The revisions and additions read as follows:

§ 405.2415 Incident to services and direct supervision.

(a) Services and supplies incident to the services of a nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor are payable under this subpart if the service or supply is all of the following:

* * * * *

(3) Furnished as an incidental, although integral part of professional services furnished by a nurse practitioner, physician assistant, certified nurse-midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

* * * * *

(5) Furnished under the direct supervision of a nurse practitioner, physician assistant, or certified nurse-midwife, except that services and supplies furnished incident to Transitional Care Management, General Care Management, the Psychiatric Collaborative Care model, and behavioral health services can be

furnished under general supervision of a nurse practitioner, physician assistant, or certified nurse-midwife, when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1) of this chapter.

(b) * * *

(6) Marriage and family therapist.

(7) Mental health counselor.

* * * * *

■ 7. Section 405.2446 is amended by revising paragraphs (b)(5) and (6) to read as follows:

§ 405.2446 Scope of services.

* * * * *

(b) * * *

(5) Clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services specified in § 405.2450.

(6) Services and supplies furnished as incident to the services of a clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor, as specified in § 405.2452.

* * * * *

■ 8. Section § 405.2448 is amended by revising paragraphs (a)(2) introductory text and (a)(2)(i) to read as follows:

§ 405.2448 Preventive primary services.

(a) * * *

(2) Are furnished by a or under the direct supervision of a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor employed by or under contract with the FQHC.

(i) By a or under the direct supervision of a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor; or

* * * * *

■ 9. Section 405.2450 is amended by revising the section heading and paragraphs (a) introductory text, (a)(2), (a)(3), and (c) to read as follows:

§ 405.2450 Clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services.

(a) For clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor professional services to be payable under this subpart, the services must be—

* * * * *

(2) Of a type that the clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor who furnishes the services is legally permitted to perform by the State in which the service is furnished;

(3) Performed by a clinical social worker, clinical psychologist, marriage and family therapist, or mental health counselor who is legally authorized to perform such services under State law or the State regulatory mechanism provided by the law of the State in which such services are performed; and

* * * * *

(c) The services of clinical psychologists, clinical social workers, marriage and family therapist, or mental health counselors are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

■ 10. Section 405.2452 is amended by revising the section heading, and paragraphs (a) introductory text, (a)(3), (a)(5) and (b) to read as follows:

§ 405.2452 Services and supplies incident to clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services.

(a) Services and supplies incident to a clinical psychologist's, clinical social worker's, marriage and family therapist's, and mental health counselor's services are reimbursable under this subpart if the service or supply is—

* * * * *

(3) Furnished as an incidental, although integral part of professional services furnished by a clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor;

* * * * *

(5) Furnished under the direct supervision of a clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

(b) The direct supervision requirement in paragraph (a)(5) of this section is met only if the clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor is permitted to supervise such services under the written policies governing the FQHC.

■ 11. Section 405.2463 is amended by—

■ a. Adding paragraphs (a)(1)(i)(I) and (a)(1)(i)(J);

■ b. Revising paragraph (b)(3) introductory text;

■ c. Redesignating paragraph (b)(3)(iii) as paragraph (b)(3)(v); and

■ d. Adding paragraphs (b)(3)(iii) and (b)(3)(iv).

§ 405.2463 What constitutes a visit.

(a) * * *

(1) * * *

(i) * * *

(I) Marriage and family therapist.

(J) Mental health counselor.

* * * * *

(b) * * *

(3) A mental health visit is a face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology for the purposes of diagnosis, evaluation or treatment of a mental health disorder, including an in-person mental health service, beginning January 1, 2025, furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record, between an RHC or FQHC patient and one of the following:

* * * * *

(iii) Marriage and family therapist.

(iv) Mental health counselor.

* * * * *

■ 12. Section 405.2464 is amended by revising paragraph (c) to read as follows:

* * * * *

(c) *Payment for care management services.* For chronic care management services furnished between January 1, 2016 and December 31, 2017, payment to RHCs and FQHCs is at the physician fee schedule national non-facility payment rate. For care management services furnished between January 1, 2018 and December 31, 2023, payment to RHCs and FQHCs is at the rate set for each of the RHC and FQHC payment codes for care management services. For general care management services furnished on or after January 1, 2024, the payment amount is based on a weighted average of the services that comprise HCPCS code G0511 using the most recently available PFS utilization data.

* * * * *

■ 13. Section 405.2468 is amended by revising paragraphs (b)(1), (b)(3), and (d)(2)(ii) to read as follows:

§ 405.2468 Allowable costs.

* * * * *

(b) * * *

(1) Compensation for the services of a physician, physician assistant, nurse practitioner, certified nurse-midwife, visiting registered professional or licensed practical nurse, clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor who owns, is employed by, or furnishes services under contract to a FQHC or RHC.

* * * * *

(3) Costs of services and supplies incident to the services of a physician, physician assistant, nurse practitioner, nurse-midwife, qualified clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

* * * * *

(d) * * *

(2) * * *

(ii) Services of physicians, physician assistants, nurse practitioners, nurse-midwives, visiting nurses, qualified clinical psychologists, clinical social workers, marriage and family therapists, and mental health counselors.

* * * * *

■ 14. Section 405.2469 is amended by revising paragraph (d) to read as follows:

§ 405.2469 FQHC supplemental payments.

* * * * *

(d) *Per visit supplemental payment.* A supplemental payment required under this section is made to the FQHC when a covered face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder occurs between a MA enrollee and a practitioner as set forth in § 405.2463. Additionally, beginning January 1, 2025, there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 15. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 16. Section 410.10 is amended by revising paragraph (l) and adding paragraphs (z) and (aa) to read as follows:

§ 410.10 Medical and other health services: Included services.

* * * * *

(l) Pneumococcal, influenza, and COVID–19 vaccines (or monoclonal antibodies used for preexposure prophylaxis of COVID–19) and their administration.

* * * * *

(z) Marriage and Family Therapist services, as provided in § 410.53.

(aa) Mental Health Counselor services, as provided in § 410.54.

■ 17. In § 410.15 amend paragraph (a) by:

■ a. In the definition of ''First annual wellness visit providing personalized prevention plan services'':

■ i. Redesignating paragraph (xiii) as paragraph (xiv); and

■ ii. Adding a new paragraph (xiii).

■ b. In the definition of ''Subsequent annual wellness visit providing personalized prevention plan services'':

■ i. Redesignating paragraph (xi) as paragraph (xii); and

■ ii. Adding a new paragraph (xi).

The additions read as follows:

§ 410.15 Annual wellness visits providing Personalized Prevention Plan Services: Conditions for and limitations on coverage.

(a) * * *

First annual wellness visit providing personalized prevention plan services * * *

(xiii) At the discretion of the health professional and beneficiary, furnish a Social Determinants of Health Risk Assessment that is standardized, evidence-based, and furnished in a manner that all communication with the patient is appropriate for the beneficiary's educational, developmental, and health literacy level, and is culturally and linguistically appropriate.

* * * * *

Subsequent annual wellness visit providing personalized prevention plan services * * *

(xi) At the discretion of the health professional and beneficiary, furnish a Social Determinants of Health Risk Assessment that is standardized, evidence-based, and furnished in a manner that all communication with the patient is appropriate for the beneficiary's educational, developmental, and health literacy level, and is culturally and linguistically appropriate.

* * * * *

■ 18. Amend § § 410.18 by:

■ a. In paragraph (a):

■ i. In the definition of ''Diabetes'' removing the text ''diagnosed using the following criteria: a fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2-hour post-glucose challenge greater than or equal to 200 mg/dL on two different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes''; and

■ ii. Removing the definition of ''Pre-diabetes''.

■ b. Redesignating paragraph (c)(3) as paragraph (c)(4) and adding a new paragraph (c)(3); and

■ c. Revising paragraph (d).

The revisions and addition read as follows:

§ 410.18 Diabetes screening tests.

(a) * * *

Diabetes means diabetes mellitus, a condition of abnormal glucose metabolism.

* * * * *

(c) * * *

(3) Hemoglobin A1C test.

(d) *Amount of testing covered.* Medicare covers two tests within the 12-month period following the date of the most recent diabetes screening test of that individual.

* * * * *

§ 410.32 [Amended]

■ 19. Section 410.32 is amended by revising paragraphs (a)(2) and (b)(3)(ii) to read as follow:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

(a) * * *

(2) *Application to nonphysician practitioners.* Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, marriage and family therapists, mental health

counselors, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.

* * * * *

(b) * * *

(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. Through December 31, 2024, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

■ 20. Section § 410.33 is amended by revising paragraph (g)(2) to read as follows:

§ 410.33 Independent diagnostic testing facility.

* * * * *

(g) * * *

(2) Provides complete and accurate information on its enrollment application. Changes in ownership, changes of location (including additions and deletions of locations), changes in general supervision, and adverse legal actions must be reported to the Medicare fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change. All other changes to the enrollment application must be reported within 90 days.

* * * * *

■ 21. Amend § 410.47 by:

■ a. In paragraph (a):

■ i. Adding the definition of ''Nonphysician practitioner'' in alphabetical order;

■ ii. Revising the definitions of ''Pulmonary rehabilitation'' and ''Supervising physician'';

■ b. Revising paragraphs (b)(3)(ii)(A) and (d) introductory text; and

■ c. Removing paragraph (d)(3).

The addition and revisions read as follows:

§ 410.47 Pulmonary rehabilitation program: Conditions of coverage.

(a) * * *

Nonphysician practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as those terms are defined in section 1861(aa)(5)(A) of the Act.

* * * * *

Pulmonary rehabilitation means a physician or nonphysician practitioner supervised program for COPD and certain other chronic respiratory diseases designed to optimize physical and social performance and autonomy.

Supervising practitioner means a physician or nonphysician practitioner that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished to individuals under pulmonary rehabilitation programs.

* * * * *

(b) * * *

(3) * * *

(ii) * * *

(A) A physician or nonphysician practitioner immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician or nonphysician practitioner meets the requirements for direct supervision for physician office services, at § 410.26 of this subpart; and for hospital outpatient services at § 410.27 of this subpart.

* * * * *

(d) *Supervising practitioner standards.* Physicians or nonphysician practitioners acting as the supervising practitioner must possess all of the following:

* * * * *

■ 22. Amend § 410.49 by:

■ a. In paragraph (a):

■ i. Revising the definitions of ''Cardiac rehabilitation'' and ''Intensive cardiac rehabilitation (ICR) program'';

■ ii. Adding the definition of ''Nonphysician practitioner'' in alphabetical order; and

■ iii. Revising the definition of ''Supervising physician'';

■ b. Revising paragraphs (b)(3)(ii) and (e) introductory text; and

■ c. Removing paragraph (e)(3).

The revisions and addition read as follows:

§ 410.49 Cardiac rehabilitation program and intensive cardiac rehabilitation program: Conditions of coverage.

(a) * * *

Cardiac rehabilitation (CR) means a physician or nonphysician practitioner supervised program that furnishes physician prescribed exercise, cardiac risk factor modification, psychosocial assessment, and outcomes assessment.

* * * * *

Intensive cardiac rehabilitation (ICR) program means a physician or nonphysician practitioner supervised program that furnishes cardiac rehabilitation and has shown, in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in paragraph (c) of this section.

* * * * *

Nonphysician practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as those terms are defined in section 1861(aa)(5)(A) of the Act.

* * * * *

Supervising practitioner means a physician or nonphysician practitioner that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished to individuals under cardiac rehabilitation and intensive cardiac rehabilitation programs.

(b) * * *

(3) * * *

(ii) All settings must have a physician or nonphysician practitioner immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician or nonphysician practitioner meets the requirements for direct supervision for physician office services, at § 410.26 of this subpart; and for hospital outpatient services at § 410.27 of this subpart.

* * * * *

(e) *Supervising practitioner standards.* Physicians or nonphysician practitioners acting as the supervising practitioner must possess all of the following:

* * * * *

■ 23. Add § 410.53 to subpart B to read as follows:

§ 410.53 Marriage and family therapist services.

(a) *Definition: marriage and family therapist.* For purposes of this part, a marriage and family therapist is defined as an individual who—

(1) Possesses a master's or doctor's degree which qualifies for licensure or certification as a marriage and family therapist pursuant to State law of the State in which such individual furnishes the services defined as marriage and family therapist services;

(2) After obtaining such degree, has performed at least 2 years or 3,000 hours

of post master's degree clinical supervised experience in marriage and family therapy in an appropriate setting such as a hospital, SNF, private practice, or clinic; and

(3) Is licensed or certified as a marriage and family therapist by the State in which the services are performed.

(b) *Covered marriage and family therapist services.* Medicare Part B covers marriage and family therapist services.

(1) *Definition: marriage and family therapist services* means services furnished by a marriage and family therapist (as defined in paragraph (a) of this section) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the marriage and family therapist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished. The services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service and must meet the requirements of this section.

(2) *Exception.* The following services are not marriage and family therapist services for purposes of billing Medicare Part B under the MFT and MHC statutory benefit category:

(i) Services furnished by a marriage and family therapist to an inpatient of a Medicare-participating hospital.

(ii) [Reserved]

(c) *Prohibited billing.* (1) A marriage and family therapist may not bill Medicare for the services specified in paragraph (b)(2) of this section.

(2) A marriage and family therapist or an attending or primary care physician may not bill Medicare or the beneficiary for the consultation that is required under paragraph(b)(2) of this section.

■ 24. Add § 410.54 to subpart B to read as follows:

§ 410.54 Mental health counselor services.

(a) *Definition: mental health counselor.* For purposes of this part, a *mental health counselor* is defined as an individual who—

(1) Possesses a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor, clinical professional counselor, or professional counselor under the State law of the State in which such individual furnishes the services defined as mental health counselor services;

(2) After obtaining such a degree, has performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic; and

(3) Is licensed or certified as a mental health counselor, clinical professional counselor, or professional counselor by the State in which the services are performed.

(b) *Covered mental health counselor services.* Medicare Part B covers mental health counselor services.

(1) *Definition: Mental health counselor services* means services furnished by a mental health counselor (as defined in paragraph (a) of this section) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the mental health counselor is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished. The services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service and must meet the requirements of this section.

(2) *Exception.* The following services are not mental health counselor services for purposes of billing Medicare Part B:

(i) Services furnished by a mental health counselor to an inpatient of a Medicare-participating hospital.

(ii) [Reserved]

(c) *Prohibited billing.* (1) A mental health counselor may not bill Medicare for the services specified in paragraph (b)(2) of this section.

(2) A mental health counselor or an attending or primary care physician may not bill Medicare or the beneficiary for the consultation that is required under paragraph(b)(2) of this section.

■ 25. Section 410.57 is amended by revising paragraph (c) to read as follows:

§ 410.57 Preventive vaccines.

* * * * *

(c) Medicare Part B pays for the COVID–19 vaccine (or monoclonal antibodies used for pre-exposure prophylaxis of COVID–19) and its administration.

* * * * *

■ 26. Section 410.59 is amended by revising paragraphs (a)(3)(ii) and (c)(2) to read as follows:

§ 410.59 Outpatient occupational therapy services: Conditions.

* * * * *

(a) * * *

(3) * * *

(ii) By, or under the direct supervision (or as specified otherwise) of, an occupational therapist in private practice as described in paragraph (c) of this section; or

* * * * *

(c) * * *

(2) *Supervision of occupational therapy services.* Except as otherwise provided in this paragraph, occupational therapy services are performed by, or under the direct supervision of, an occupational therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, directly supervised by the therapist, and included in the fee for the therapist's services. Remote therapeutic monitoring services may be performed by an occupational therapy assistant under the general supervision of the occupational therapist in private practice; services performed by an unenrolled occupational therapist must be under the direct supervision of the occupational therapist.

* * * * *

■ 27. Section 410.60 is amended by revising paragraphs (a)(3)(ii) and (c)(2) to read as follows:

§ 410.60 Outpatient physical therapy services: Conditions.

* * * * *

(a) * * *

(3) * * *

(ii) By, or under the direct supervision (or as specified otherwise) of, a physical therapist in private practice as described in paragraph (c) of this section; or

* * * * *

(c) * * *

(2) *Supervision of physical therapy services.* Except as otherwise provided in this paragraph, physical therapy services are performed by, or under the direct supervision of, a physical therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, directly supervised by the therapist, and included in the fee for the therapist's services. Remote therapeutic monitoring services may be performed by a physical therapist assistant under the general supervision of the physical therapist in private practice; services performed by an unenrolled physical therapist must be under the direct supervision of the physical therapist.

* * * * *

§ 410.67 [Amended]

■ 28. In § 410.67 amend paragraph (vii) in the definition of ''Opioid use disorder treatment service'' in paragraph (b) by removing the reference ''through the end of CY 2023'' and adding in its place

the reference ''through the end of CY 2024''.

■ 29. Section 410.72 is amended by revising paragraph (d) to read as follows:

§ 410.72 Registered dietitians' and nutrition professionals' services.

* * * * *

(d) *Professional services.* Except for DSMT services furnished as, or on behalf of, an accredited DSMT entity, registered dietitians and nutrition professionals can be paid for their professional MNT services only when the services have been directly performed by them.

* * * * *

■ 30. Section 410.78 is amended by—

■ a. Adding paragraphs (b)(2)(x) through (xii);

■ b. Revising paragraphs (b)(3)(xiv) introductory text, (b)(4)(iv)(D), and (e)(1); and

■ c. Adding paragraph (e)(3).

The additions and revisions read as follows:

§ 410.78 Telehealth services.

* * * * *

(b) * * *

(2) * * *

(x) Any distant site practitioner who can appropriately report diabetes self-management training services may do so on behalf of others who personally furnish the services as part of the DSMT entity.

(xi) A marriage and family therapist as described in 410.53.

(xii) A mental health counselor as described in 410.54.

(3) * * *

(xiv) The home of a beneficiary for the purposes of diagnosis, evaluation, and/or treatment of a mental health disorder for services that are furnished during the period beginning on the first day after the end of the emergency period as defined in our regulation at § 400.200 and ending on December 31, 2024 except as otherwise provided in this paragraph. Payment will not be made for a telehealth service furnished under this paragraph unless the following conditions are met:

(4) * * *

(iv) * * *

(D) Services furnished on or after January 1, 2025 for the purposes of diagnosis, evaluation, and/or treatment of a mental health disorder. Payment will not be made for a telehealth service furnished under this paragraph unless the physician or practitioner has furnished an item or service in person, without the use of telehealth, for which Medicare payment was made (or would have been made if the patient were entitled to, or enrolled for, Medicare benefits at the time the item or service is furnished) within 6 months prior to the initial telehealth service and within 6 months of any subsequent telehealth service.

* * * * *

(e) * * *

(1) A clinical psychologist and a clinical social worker, a marriage and family therapist (MFT), and a mental health counselor (MHC) may bill and receive payment for individual psychotherapy via a telecommunications system, but may not seek payment for medical evaluation and management services.

* * * * *

(3) The distant site practitioner who reports the DSMT services may bill and receive payment when a professional furnishes injection training for an insulin-dependent patient using interactive telecommunications technology when such training is included as part of the DSMT plan of care referenced at § 410.141(b)(2).

* * * * *

■ 31. Amend § 410.79 by:

■ a. In paragraph (b):

■ i. Adding the definition of ''Combination delivery'' in alphabetical order;

■ ii. Removing the definition of ''Core maintenance session interval'';

■ iii. Adding the definitions of ''Distance learning'', ''Extended flexibilities'', ''Extended flexibilities period'', and ''Full-Plus CDC DPRP recognition'' in alphabetical order;

■ iv. Revising the definitions of ''Make-up session'', ''MDPP services period'', and ''MDPP session''

■ v. Adding the definition ''Online delivery'' in alphabetical order;

■ vi. Removing the definition of ''Ongoing maintenance sessions'';

■ vii. Adding the definition of ''Virtual session'' in alphabetical order.

■ b. By removing paragraphs (c)(1)(ii) and (iii);

■ c. By redesignating paragraph (c)(1)(iv) as paragraph (c)(1)(ii);

■ d. By revising paragraphs (c)(2)(i)(A) and (B);

■ e. By removing and reserving paragraph (c)(2)(ii);

■ f. By revising paragraph (c)(3)(i);

■ g. By removing and reserving paragraph (c)(3)(ii); removing paragraph (c)(3)(iii), removing and reserving paragraphs (d)(2)(iii)(B) and (d)(3)(ii);

■ h. Revising paragraphs (e)(3)(iv) introductory text, (e)(3)(iv)(D), (e)(3)(iv)(F)(*1*) and (*2*).

The additions and revisions read as follows:

§ 410.79 Medicare Diabetes Prevention Program expanded model: Conditions of coverage.

* * * * *

(b) * * *

Combination delivery. MDPP sessions that are delivered by trained Coaches and are furnished in a manner consistent with the DPRP Standards for distance learning and in-person sessions for each individual participant.

* * * * *

Distance learning refers to an MDPP session that is delivered by trained Coaches via remote classroom and is furnished in a manner consistent with the DPRP Standards for distance learning sessions. The Coach provides live (synchronous) delivery of session content in one location and participants call-in or video-conference from another location.

Extended flexibilities refer to the flexibilities as described in paragraphs (e)(3)(iii) and (iv) of this section.

Extended flexibilities period refers to the 4-year period (January 1, 2024 to December 31, 2027) for the Extended flexibilities to apply.

* * * * *

Full-Plus CDC DPRP recognition refers to organizations that have met the Full CDC DPRP recognition, and at the time full recognition is achieved, has met the following retention criterion: Eligible participants in the evaluation cohort must have been retained at the following percentages: A minimum of 50 percent at the beginning of the fourth month since the cohorts held their first sessions; A minimum of 40 percent at the beginning of the seventh month since the cohorts held their first sessions; and A minimum of 30 percent at the beginning of the tenth month since the cohorts held their first sessions.

* * * * *

Make-up session means a core session or a core maintenance session furnished to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session or core maintenance session.

MDPP services period means the time period, beginning on the date an MDPP beneficiary attends his or her first core session, over which the Set of MDPP services is furnished to the MDPP beneficiary, to include the core services period described in paragraph (c)(2)(i) and, subject to paragraph (c)(3) of this section.

MDPP session means a core session or a core maintenance session.

* * * * *

Online delivery refers to an MDPP session that is delivered online for all

participants and is furnished in a manner consistent with the DPRP Standards for online sessions. The program is experienced through the internet via phone, tablet, laptop, in an asynchronous classroom where participants are experiencing the content on their own time without a live Coach teaching the content. However, live Coach interaction should be provided to each participant no less than once per week during the first 6 months and once per month during the second 6 months. Emails and text messages can count toward the requirement for live coach interaction as long as there is bi-directional communication between coach and participant.

* * * * *

Virtual session refers to an MDPP session that is not furnished in person and that is furnished in a manner consistent with the DPRP standards for distance learning sessions.

(c) * * *

(2) * * *

(i) * * *

(A) Up to 16 core sessions offered at least 1 week apart during months 1 through 6 of the MDPP services period; and

(B) Up to 6 core maintenance sessions offered at least 1 month apart during months 7 through 12 of the MDPP services period

(ii) [Reserved]

(3) * * *

(i) The MDPP services period ends upon completion of the core services period described in paragraph (c)(2)(i) of this section.

* * * * *

(e) * * *

(3) * * *

(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, through distance learning or a combination of in-person or distance learning, 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 Extended flexibilities period, a PHE as defined in § 400.200 of this chapter or applicable 1135 waiver event, he/she may continue to receive the Set of MDPP 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:

* * * * *

(D) Virtual sessions are furnished in a manner consistent with the DPRP standards for distance learning sessions.

* * * * *

(F) * * *

(*1*) Up to 16 virtual sessions offered weekly during the core session period, months 1 through 6 of the MDPP services period;

(*2*) Up to 6 virtual sessions offered monthly during the core maintenance session interval periods, months 7 through 12 of the MDPP services period.

* * * * *

§ 410.130 [Amended]

■ 32. Amend § 410.130 in the definition of ''Diabetes'' by removing the text ''diagnosed using the following criteria: A fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2 hour post-glucose challenge greater than or equal to 200 mg/dL on 2 different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes''.

§ 410.140 [Amended]

■ 33. Amend § 410.140 in the definition of ''Diabetes'' by removing the text ''diagnosed using the following criteria: A fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2 hour post-glucose challenge greater than or equal to 200 mg/dL on 2 different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes''.

■ 34. Amend § 410.150 by adding paragraphs (b)(21) and (22) to read follows:

§ 410.150 To whom payment is made.

* * * * *

(b) * * *

(21) To a marriage and family therapist on the individual's behalf for marriage and family therapist services.

(22) To a mental health counselor on the individual's behalf for mental health counseling services.

■ 35. Section 410.152 is amended by:

■ a. Revising paragraphs (b) introductory text, (h)(2) and (h)(3), (h)(4) introductory text, (h)(5); and

■ b. Adding paragraphs (m) and (n).

The revisions and additions read as follows:

§ 410.152 Amounts of payment.

* * * * *

(b) *Basic rules for payment.* Except as specified in paragraphs (c) through (h) and (m) and (n) of this section, Medicare Part B pays the following amounts:

* * * * *

(h) * * *

(2) For the administration of a COVID–19 vaccine:

(i) Effective January 1, 2022, for administration of a COVID–19 vaccine, $40 per dose.

(ii) For services furnished on or after January 1 of the year following the year in which the Secretary ends the March 27, 2020 Emergency Use Authorization declaration for drugs and biologicals (issued at 85 FR 18250) pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), for administration of a COVID–19 vaccine, an amount equal to the amount that would be paid for the administration of a preventive vaccine described in paragraph (h)(1) of this section.

(3) Subject to conditions specified in this paragraph, in addition to the payment described in paragraph (h)(1) or (2) of this section, an additional payment for preventive vaccine administration in the patient's home:

(i) Effective January 1, 2022 for administration of a COVID–19 vaccine in the home, an additional payment of $35.50.

(ii) Effective January 1, 2024, for the administration of one or more of the preventive vaccines described in paragraphs (h)(1) and (2) of this section in the home, a payment equal to that of the payment in paragraph (h)(3)(i) of this section.

(iii) An additional payment for preventive vaccine administration in the home can be made if:

(A) The patient has difficulty leaving the home, or faces barriers to getting a vaccine in settings other than their home.

(B) The sole purpose of the visit is to administer one or more preventive vaccines.

(C) The home is not an institution that meets the requirements of sections 1861(e)(1), 1819(a)(1), or 1919(a)(1) of the Act, or §§ 409.42(a) of this subchapter.

(4) The payment amount for the administration of a preventive vaccine described in paragraphs (h)(1) and (2) of this section, and the additional payment for the administration of a preventive vaccine in the home as described in paragraph (h)(3) of this section, is adjusted to reflect geographic cost variations:

* * * * *

(5) For services furnished on or after January 1, 2023, the payment amount for administration of a preventive vaccine described in paragraphs (h)(1) and (2) of this section, and the additional payment for the administration of a preventive vaccine

in the home as described in paragraph (h)(3) of this section, is updated annually using the percentage change in the Medicare Economic Index (MEI), as described in section 1842(i)(3) of the Act and § 405.504(d) of this subchapter.

* * * * *

(m) *Amount of payment: Rebatable drugs.* In the case of a rebatable drug (as defined in section 1847A(i)(2)(A) of the Act), including a selected drug (as defined in section 1192(c) of the Act), furnished by providers on or after April 1, 2023, in a calendar quarter during which the payment amount for such drug as specified in section 1847A(i)(3)(A)(ii)(I)(aa) or (bb), as applicable, exceeds the inflation-adjusted amount (as defined in section 1847A(i)(3)(C) of the Act) for such drug, Medicare Part B pays, subject to the deductible, the difference between the allowed payment amount determined under section 1847A of the Act and 20 percent of the inflation-adjusted amount, which is applied as a percent to the payment amount for such calendar quarter.

(n) *Amount of payment: Insulin furnished through an item of durable medical equipment.* For insulin furnished on or after July 1, 2023 through an item of durable medical equipment (as defined in § 414.202), Medicare Part B pays the difference between the applicable payment amount for such insulin and the coinsurance amount, with the coinsurance amount not to exceed $35 for a month's supply.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 36. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 37. Section 411.15 is amended by revising paragraph (i)(3)(i)(A) to read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(i) * * *

(3) * * *

(i) * * *

(A) Dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the following Medicare-covered services: organ transplant, hematopoietic stem cell transplant, bone marrow transplant, cardiac valve replacement, valvuloplasty procedures, chemotherapy when used in the treatment of cancer, chimeric antigen receptor (CAR) T-cell therapy when used in the treatment of cancer, administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer, and radiation, chemotherapy, and surgery when used in the treatment of head and neck cancer.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 38. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 39. Section 414.53 is added to read as follows:

§ 414.53 Fee schedule for clinical social worker, marriage and family therapist, and mental health counselor services.

The fee schedule for clinical social worker, marriage and family therapist, and mental health counselor services is set at 75 percent of the amount determined for clinical psychologist services under the physician fee schedule.

■ 40. Amend § 414.84 by:

■ a. In paragraph (a):

■ i. Adding the definition of ''Attendance payment'' in alphabetical order;

■ ii. Revising the definition of ''Performance goal'';

■ b. Revising paragraph (b) introductory text;

■ c. Removing paragraphs (b)(1) through (5);

■ d. Redesignating paragraphs (b)(6) and (7) as paragraphs (b)(1) and (2), respectively;

■ e. Revising newly redesignated paragraphs (b)(1) paragraph heading and (b)(1)(i);

■ f. Adding paragraph (b)(1)(iii);

■ g. Revising newly redesignated paragraphs (b)(2) paragraph heading and (b)(2)(i);

■ h. Redesignating paragraphs (c) and (d) as paragraphs (d) and (e), respectively;

■ i. Adding new paragraph (c); and

■ j. Revising newly redesignated paragraphs (d)(1) and (e).

The additions and revisions read as follows:

§ 414.84 Payment for MDPP Services.

(a) * * *

Attendance payment means a payment that is made to an MDPP supplier for furnishing services to an MDPP beneficiary when the MDPP beneficiary attends an MDPP core or core maintenance session. CMS will allow up to 22 sessions (alone or in combination with other codes, not to exceed 22 sessions in a 12- month timeframe).

* * * * *

Performance goal means a weight loss goal that an MDPP beneficiary must achieve during the MDPP services period for an MDPP supplier to be paid a performance payment.

* * * * *

(b) *Performance payment.* CMS makes one or more types of performance payments to an MDPP supplier as specified in this paragraph (b). Each type of performance payment is made only if the beneficiary achieves the applicable performance goal and only once per MDPP beneficiary. A performance payment is made only on an assignment-related basis in accordance with § 424.55 of this chapter, and MDPP suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount. CMS will make a performance payment only to an MDPP supplier that complies with all applicable enrollment and program requirements and only for MDPP services that are furnished by an eligible coach, on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date. As a condition of payment, the MDPP supplier must report the NPI of the coach who furnished the session on the claim for the MDPP session. The two types of performance payments are as follows:

(1) *Performance Goal 1: Achieves the required minimum 5-percent weight loss.* * * *

(i) For a core session or core maintenance session, as applicable, furnished January 1, 2024 through December 31, 2024 the amount is $145.

* * * * *

(iii) If the beneficiary maintains the required minimum weight loss during a core maintenance session, as measured in-person or described in § 410.79(e)(3)(iii) the amount is $8.

(2) *Performance Goal 2: Achieves 9-percent weight loss.* * * *

(i) For a core session or core maintenance session, as applicable, furnished January 1, 2024 through December 31, 2024. $25.

* * * * *

(c) *Attendance payment: Attends a core session or core maintenance session.* CMS makes a payment to an MDPP supplier if an MDPP beneficiary attends a core session or core maintenance session. An attendance

payment is made only on an assignment-related basis in accordance with § 424.55 of this chapter, and MDPP suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount. CMS will make an attendance payment only to an MDPP supplier that complies with all applicable enrollment and program requirements and only for MDPP services that are furnished by an eligible coach, on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date. As a condition of payment, the MDPP supplier must report the NPI of the coach who furnished the session on the claim for the MDPP session.

(1) The first core session attended, which initiates the MDPP services period, and that first core session was furnished by that supplier.

(2) For the Extended flexibilities period described in § 410.79(e)(2)(iii), the distance learning HCPCS G-code applies for any Set of MDPP services that are delivered by distance learning, as described in § 410.79(b).

(3) Medicare pays for up to 22 sessions in a 12-month period. The amount of this payment is determined as follows:

(i) For a core session or core maintenance session furnished January 1, 2024 through December 31, 2024. $25.

(ii) [Reserved]

(d) * * *

(1) For core session or core maintenance session, as applicable, furnished January 1, 2024 through December 31, 2024 the amount is $25.

* * * * *

(e) *Updating performance payments, attendance payments, and the bridge payment.* The performance payments, attendance payments, and bridge payment will be adjusted each calendar year by the percent change in the Consumer Price Index for All Urban Consumers (CPI–U) (U.S. city average) for the 12-month period ending June 30th of the year preceding the update year. The percent change update will be calculated based on the level of precision of the index as published by the Bureau of Labor Statistics and applied based on one decimal place of precision. The annual MDPP services payment update will be published by CMS transmittal.

§ 414.94 [Removed]

■ 41. Remove § 414.94.

■ 42. 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, 2024 through March 31, 2024, 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, 2024 through March 31, 2024.

* * * * *

§ 414.504 [Amended]

■ 43. Amend § 414.504 in paragraph (a)(1) by removing the reference ''January 1, 2023'' and adding in its place the reference ''January 1, 2024''.

■ 44. Section 414.507 is amended by—

■ a. Revising paragraph (d) introductory text and paragraph (d)(6); and

■ b. Adding paragraph (d)(9).

The revisions and addition read as follows:

§ 414.507 Payment for clinical diagnostic laboratory tests.

* * * * *

(d) *Phase-in of payment reductions.* For years 2018 through 2026, 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—

* * * * *

(6) 2023—0.0 percent of the payment rate established in 2022.

* * * * *

(9) 2026—15 percent of the payment rate established in 2025.

* * * * *

§ 414.610 [Amended]

■ 45. Amend § 414.610 in paragraphs (c)(1)(ii) introductory text and (c)(5)(ii) by removing the date ''December 31, 2022'' and adding in its place the date ''December 31, 2024''

■ 46. Section 414.902 is amended by adding the definitions of ''Applicable five-year period'', ''Low volume dose'', ''New refund quarter'', ''Qualifying biosimilar biological product'', and ''Updated refund quarter'' in alphabetical order to read as follows:

§ 414.902 Definitions.

* * * * *

Applicable five-year period means:

(1) For a qualifying biosimilar biological product for which payment has been made under section 1847A(b)(8) of the Act as of September 30, 2022, the 5-year period beginning on October 1, 2022; and

(2) For a qualifying biosimilar biological product for which payment is first made under section 1847A(b)(8) of the Act during a calendar quarter during the period beginning October 1, 2022 and ending December 31, 2027, the 5-year period beginning on the first day of such calendar quarter during which such payment is first made.

* * * * *

Low volume dose means, with respect to determination of whether an increased applicable percentage is warranted, an FDA-labeled dose of a drug for which the volume removed from the vial or container containing the labeled dose does not exceed 0.4 mL.

* * * * *

New refund quarter means a calendar quarter that is included in a report described in § 414.940(a) that is sent in the first year following the year in which the calendar quarter occurs.

* * * * *

Qualifying biosimilar biological product means a biosimilar biological product (as described in section 1847A(b)(1)(C) of the Act) with an average sales price (as described in section 1847A(b)(8)(A)(i) of the Act) less than the average sales price of the reference biological for a calendar quarter during the applicable 5-year period.

* * * * *

Updated refund quarter means a calendar quarter that is included in a report described in § 414.940(a) that is sent in the second year following the year in which the calendar quarter occurs.

* * * * *

■ 47. Section 414.904 is amended by revising paragraphs (e)(4) and (j) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(e) * * *

(4) *Payment amount in a case where the average sales price during the first quarter of sales is unavailable.* During an initial period (not to exceed a full calendar quarter) in which data on the prices for sales of the drug are not sufficiently available from the manufacturer to compute an average sales price:

(i) *In general.* Except as provided in paragraph (e)(4)(ii) of this section,

(A) For dates of service before January 1, 2019, the payment amount for the drug is based on the wholesale acquisition cost or the Medicare Part B drug payment methodology in effect on November 1, 2003.

(B) For dates of service on or after January 1, 2019, the payment amount for the drug is an amount not to exceed 103 percent of the wholesale acquisition cost or based on the Medicare Part B drug payment methodologies in effect on November 1, 2003.

(ii) *Limitation on payment amount for biosimilar biological products during initial period.* For dates of service on or after July 1, 2024, the payment amount for a biosimilar biological product (as defined in § 414.902) during the initial period is the lesser of the following:

(A) The payment amount for the biosimilar biological product as determined under clause (e)(4)(i)(B) of this section or

(B) 106 percent of the amount determined under section 1847A(b)(1)(B) of the Act for the reference biological product (as defined in § 414.902).

* * * * *

(j) *Biosimilar biological products*—(1) *In general.* Except as provided in paragraph (j)(2), effective January 1, 2016, the payment amount for a biosimilar biological product (as defined in § 414.902), for all NDCs assigned to such product, is the sum of the average sales price of all NDCs assigned to the biosimilar biological products included within the same billing and payment code as determined under section 1847A(b)(6) of the Act, and 6 percent of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902).

(2) *Temporary increase in Medicare Part B payment for qualifying biosimilar biological products.* In the case of a qualifying biosimilar biological product (as defined in § 414.902) that is furnished during the applicable five-year period (as defined in § 414.902) for such product, the payment amount for such product with respect to such period is the sum determined under as determined under section 1847A(b)(6) of the Act and 8 percent of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902).

■ 48. Section 414.940 is amended by—

■ a. Redesignating paragraph (a)(1)(iii) as paragraph (a)(1)(iv).

■ b. Adding new paragraph (a)(1)(iii).

■ c. Revising paragraphs (a)(3), (b)(1) and (2), (c), and (d);

■ d. Redesignating paragraphs (e) and (f) as paragraphs (f) and (g), respectively; and

■ e. Adding new paragraph (e).

The revisions and additions read as follows:

§ 414.940 Refund for certain discarded single-dose container or single-use package drugs.

(a) * * *

(1) * * *

(iii) Reports will include information in paragraphs (a)(1)(i) and (ii) of this section for new refund quarters and updated refund quarters (as defined at § 414.902).

* * * * *

(3) *Report Timing.* Reports are sent once annually.

(b) * * *

(1) Refund amounts for which the manufacturer is liable, pursuant to this paragraph, must be paid by December 31 of the year in which the report described in paragraph (a) of this section is sent, except that refund amounts for which the manufacturer is liable, pursuant to this paragraph, for amounts in the initial report for calendar quarters in 2023 must be paid no later than February 28, 2025.

(2) In the case that a disputed report results in a refund amount due, refund amounts that the manufacturer is liable for pursuant to this paragraph shall be paid no later than the dates specified in paragraph (b)(1) of this section or 30 days following the resolution of the dispute, whichever is later.

* * * * *

(c) *Refund amount.* The amount of the refund specified in this paragraph is with respect to a refundable single-dose container or single-use package drug of a manufacturer assigned to a billing and payment code (except as provided in paragraph (c)(4) of this section) for:

(1) A new refund quarter (as defined at § 414.902) beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which:

(i) The product of the total number of units of the billing and payment code for such drug that were discarded during such new refund quarter; and the amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such new refund quarter;

(ii) Exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such drug for the new refund quarter.

(2) The refund amount owed by a manufacturer for an updated refund quarter (as defined at § 414.902) beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which:

(i) The product of the total number of units of the billing and payment code for such drug that were discarded during such updated refund quarter; and the amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such quarter.

(ii) Exceeds the difference of:

(A) An amount equal to the applicable percentage of the estimated total allowed charges for such a drug during the updated refund quarter; and

(B) The refund amount already paid for such refundable drug for such quarter.

(3) Negative refund amount for an updated refund quarter. If the refund amount described in paragraph (c)(2) of this section is negative, the amount will be netted from refunds owed for other updated and new refund quarters included in the same report as such updated refund quarter.

(4) Exception when there are multiple manufacturers. If there is more than one manufacturer of a refundable single-dose container or single-use package drug for a quarter, the refund amount for which a manufacturer is liable is an amount equal to the estimated amount (if any) by which—

(i) The product of the amount calculated in paragraph (c)(1) of this section and the percentage of billing unit sales (of the applicable billing and payment code attributed to the National Drug Code; exceeds:

(ii) The product of the amount in paragraph (c)(2) of this section and percentage of billing unit sales of the applicable billing and payment code attributed to the National Drug Code.

(iii) The number of billing unit sales for each NDC is the reported number of NDCs sold (as submitted in the ASP report to CMS each quarter) multiplied by the billing units per package for such NDC.

(d) *Applicable percentage.* For purposes of paragraph (c) of this section, and except as provided in paragraph (e) of this section, the applicable percentage is:

(1) 10 percent, unless specified otherwise in this section.

(2) 35 percent for a drug that is reconstituted with a hydrogel and has variable dosing based on patient-specific characteristics.

(3) 90 percent for a drug with a low volume dose (as defined at § 414.902 of this part) contained within 0.1 mL or less.

(4) 45 percent for a drug with a low volume dose (as defined in § 414.902 of

this part) contained within 0.11 mL up to 0.4 mL.

(5) 26 percent for a drug designated an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition (or diseases or conditions) and approved by the FDA only for one or more indications within such designated rare disease or condition (or diseases or conditions) and is furnished to fewer than 100 unique beneficiaries per calendar year.

(e) *Application process for increased applicable percentage.* Manufacturers may submit an application to CMS requesting consideration of an increased applicable percentage for purposes of paragraph (c) of this section because of the drug's unique circumstances. The process for submitting such an application is as follows:

(1) *Application.* An application must include:

(i) A written request that a drug be considered for an increased applicable percentage based on its unique circumstances;

(ii) FDA-approved labeling;

(iii) Justification for the consideration of an increased applicable percentage based on such unique circumstances; and

(iv) Justification for the requested applicable percentage.

(2) *Application timeline.* An application must be submitted in a form and manner specified by CMS by February 1 of the calendar year prior to the year the increased applicable percentage would apply.

(3) *Application processing.* Following a review of timely applications, CMS will summarize its analyses of applications and propose appropriate increases in rulemaking. If adopted, the increased applicable percentage will be the applicable percentage for purposes of paragraph (c) beginning as of the following January 1.

* * * * *

■ 49. Section 414.1305 is amended by—

■ a. In the definition of ''Attestation'', by removing the term ''MIPS eligible clinician or group'' and adding in its in place the term ''MIPS eligible clinician, subgroup, or group''.

■ b. In the definition of ''Attribution-eligible beneficiary'', by revising paragraph (6);

■ c. In the definition of ''Certified Electronic Health Record Technology (CEHRT)'', by revising paragraphs (2) introductory text and (2)(ii), and adding paragraph (3);

■ d. By revising the definition of ''Collection type'';

■ e. By adding the definition of ''Qualified posting''.

■ f. In the definition of ''Submitter type'', by removing the term ''MIPS eligible clinician, group, Virtual Group, APM Entity, or third party intermediary'' and adding in its place the term the ''MIPS eligible clinician, group, Virtual Group, subgroup, APM Entity, or third party intermediary.''

The revisions and addition read as follows:

§ 414.1305 Definitions.

* * * * *

Attribution-eligible beneficiary * * *

* * * * *

(6) Has a minimum of one claim for covered professional services furnished by an eligible clinician who is on the Participation List for an Advanced APM Entity at any determination date during the QP Performance Period.

* * * * *

Certified Electronic Health Record Technology (CEHRT) * * *

* * * * *

(2) For 2019 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition, or subsequent Base EHR definition (as defined in 45 CFR 170.102), and has been certified to the ONC health IT certification criteria as adopted and updated in 45 CFR 170.315—

* * * * *

(ii) Necessary to report on applicable objectives and measures specified for MIPS including the following:

* * * * *

(3) For purposes of determinations under §§ 414.1415 and 414.1420, beginning for CY 2024, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets—

(i) The 2015 Edition Base EHR definition, or subsequent Base EHR definition (as defined in 45 CFR 170.102); and

(ii) Any such ONC health IT certification criteria adopted or updated in 45 CFR 170.315 that are determined applicable for the APM, for the year, considering factors such as clinical practice area, promotion of interoperability, relevance to reporting on applicable quality measures, clinical care delivery objectives of the APM, or any other factor relevant to documenting and communicating clinical care to patients or their health care providers in the APM.

* * * * *

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; CMS Web Interface measures (except as provided in paragraph (1) of this definition, for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years); the CAHPS for MIPS survey measure; administrative claims measures; and Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs).

* * * * *

Qualified Posting means the document made available that lists qualified registries or QCDRs available by CMS for use by MIPS eligible clinicians, groups, subgroups, virtual groups, and APM Entities.

* * * * *

■ 50. Section 414.1320 is amended by—

■ a. Revising paragraph (h) introductory text; and

■ b. Adding paragraph (i).

The addition and revision read as follow:

§ 414.1320 MIPS performance period.

* * * * *

(h) For purposes of the 2024 MIPS payment year and the 2025 MIPS payment year, the performance period for:

* * * * *

(i) For purposes of the 2026 MIPS payment year and each subsequent payment year, the performance period for:

(1) The Promoting Interoperability performance category is a minimum of a continuous 180-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]

■ 51. Section 414.1325 is amended by revising paragraphs (a)(1), (c) introductory text, and (d) to read as follows.

§ 414.1325 Data submission requirements.

(a) * * *

(1) Except as provided in paragraph (a)(2) of this section, or under § 414.1370 or § 414.1365(c), as applicable, individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities must submit data on measures and activities for the quality, improvement activities, and Promoting Interoperability performance categories in accordance

with this section. Except for the Medicare Part B claims submission type, the data may also be submitted on behalf of the individual MIPS eligible clinician, group, virtual group, subgroup, or APM Entity by a third party intermediary described at § 414.1400.

* * * * *

(c) *Data submission types for groups, virtual groups, subgroups, and APM Entities.* Groups, virtual groups, subgroups, and APM Entities may submit their MIPS data using:

* * * * *

(d) *Use of multiple data submission types.* Beginning with the 2021 MIPS payment year as applicable to MIPS eligible clinicians, groups, and virtual groups, beginning with the 2023 MIPS payment year as applicable to APM Entities, and beginning with the 2025 MIPS payment year as applicable to subgroups, MIPS eligible clinicians, groups, virtual groups, APM Entities, and subgroups may submit their MIPS data using multiple data submission types for any performance category described in paragraph (a)(1) of this section, as applicable; provided, however, that the MIPS eligible clinician, group, virtual group, APM Entity, or subgroup uses the same identifier for all performance categories and all data submissions.

■ 52. Section 414.1335 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(1)(i), (a)(1)(ii), (a)(3) paragraph heading, and (a)(3)(i); and

■ b. Adding paragraph (a)(4).

The revisions and additions read as follows:

§ 414.1335 Data submission criteria for the quality performance category.

(a) *Criteria.* A MIPS eligible clinician, group, virtual group, subgroup, or APM Entity must submit data on MIPS quality measures in one of the following manners, as applicable:

(1) * * *

(i) Except as provided in paragraph (a)(1)(ii) of this section, submits data on at least six measures, including at least one outcome measure. If an applicable outcome measure is not available, reports one other high priority measure. If fewer than six measures apply to the MIPS eligible clinician, group, virtual group, or APM Entity, reports on each measure that is applicable.

(A) For eCQMs, the submission of data requires the utilization of CEHRT, as defined at § 414.1305.

(B) [Reserved]

(ii) A MIPS eligible clinician, group, virtual group, and APM Entity that report on a specialty or subspecialty measure set, as designated in the MIPS final list of quality measures established by CMS through rulemaking, must submit data on at least six measures within that set, including at least one outcome measure. If an applicable outcome measure is not available, report one other high priority measure. If the set contains fewer than six measures or if fewer than six measures within the set apply to the MIPS eligible clinician, group, virtual group, or APM Entity, report on each measure that is applicable.

(A) For eCQMs, the submission of data requires the utilization of CEHRT, as defined at § 414.1305.

(B) [Reserved]

* * * * *

(3) *For the CAHPS for MIPS survey measure.* (i) For the 12-month performance period, a group, virtual group, subgroup, or APM Entity that participates in the CAHPS for MIPS survey must use a survey vendor that is approved by CMS for the applicable performance period to transmit survey measures data to CMS.

* * * * *

(4) *For Medicare CQMs.* (i) A MIPS eligible clinician, group, and APM Entity reporting on the Medicare CQMs (reporting quality data on beneficiaries eligible for Medicare CQMs as defined at § 425.20) within the APP measure set and administering the CAHPS for MIPS Survey as required under the APP.

(ii) [Reserved]

* * * * *

■ 53. Section 414.1340 is amended by—

■ a. Revising paragraph (a) introductory text;

■ b. Adding paragraphs (a)(2)(i) and (a)(3)(i) and (ii);

■ c. Revising paragraph (a)(4);

■ d. Adding paragraph (a)(5);

■ e. Revising paragraph (b) introductory text;

■ f. Adding paragraphs (b)(2)(i) and (ii) and (b)(3)(i) and (ii);

■ g. Revising paragraph (b)(4);

■ h. Adding paragraph (b)(5);

■ i. Revising paragraph (d); and

■ j. Adding paragraph (e).

The revisions and additions read as follows:

§ 414.1340 Data completeness criteria for the quality performance category.

(a) MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs must submit data on:

* * * * *

(2) At least 60 percent of the MIPS eligible clinician, group, and virtual group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2020 and 2021.

(3) At least 70 percent of the MIPS eligible clinician, group, and virtual group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2022, 2023, 2024, and 2025.

(i) Applicable to an APM Entity for MIPS payment years 2023, 2024, and 2025.

(ii) Applicable to a subgroup for MIPS payment year 2025.

(4) At least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, and APM Entity's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2026, 2027, and 2028.

(5) At least 80 percent of the MIPS eligible clinician, group, virtual group, subgroup, or and APM Entity's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment year 2029.

(b) MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities submitting quality measure data on Medicare Part B claims measures must submit data on:

* * * * *

(2) * * *

(i) Applicable to virtual groups starting with MIPS payment year 2020.

(ii) [Reserved]

(3) * * *

(i) Applicable to APM Entities starting with MIPS payment year 2023 and subgroups starting with MIPS payment year 2025.

(ii) [Reserved].

* * * * *

(4) At least 75 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment years 2026, 2027, and 2028.

(5) At least 80 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment year 2029.

* * * * *

(d) APM Entities, specifically Medicare Shared Savings Program Accountable Care Organizations meeting reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on:

(1) At least 75 percent of the applicable beneficiaries eligible for the Medicare CQM, as defined at § 425.20, who meet the measure's denominator criteria for MIPS payment years 2026, 2027, and 2028.

(2) At least 80 percent of the applicable beneficiaries eligible for the

Medicare CQM, as defined at § 425.20, who meet the measure's denominator criteria for MIPS payment year 2029.

(e) If quality data are submitted selectively such that the submitted data are unrepresentative of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's performance, any such data would not be true, accurate, or complete for purposes of § 414.1390(b) or § 414.1400(a)(5).

■ 54. Section 414.1350 is amended by revising paragraphs (c)(4) through (6) and adding paragraph (c)(7) to read as follows:

§ 414.1350 Cost performance category.

* * * * *

(c) * * *

(4) For the procedural episode-based measures specified beginning with and after the CY 2019 performance period/2021 MIPS payment year, the case minimum is 10, unless otherwise specified for individual measures. Beginning with the CY 2022 performance period/2024 MIPS payment year, the case minimum for Colon and Rectal Resection procedural episode-based measure is 20 episodes.

(5) For the acute inpatient medical condition episode-based measures specified beginning with and after CY 2019 performance period/2021 MIPS payment year, the case minimum is 20, unless otherwise specified for individual measures.

(6) For the chronic condition episode-based measures specified beginning with and after the CY 2022 performance period/2024 MIPS payment year, the case minimum is 20, unless otherwise specified for individual measures.

(7) For the care setting episode-based measures specified beginning with and after the CY 2024 performance period/2026 MIPS payment year, the case minimum is 20, unless otherwise specified for individual measures.

* * * * *

■ 55. Section 414.1360 is amended by revising paragraph (a) introductory text to read as follows:

§ 414.1360 Data submission criteria for the improvement activities performance category.

(a) For purposes of the transition year of MIPS and future years, MIPS eligible clinicians, subgroups, or groups must submit data on MIPS improvement activities in one of the following manners:

* * * * *

■ 56. Section 414.1365 is amended by—

■ a. Revising paragraphs (e)(2)(ii) introductory text and (e)(3); and

■ b. Adding paragraphs (e)(4)(i) and (ii).

The revisions and addition read as follow:

§ 414.1365 MIPS Value Pathways.

* * * * *

(e) * * *

(2) * * *

(ii) *Subgroups.* For an MVP Participant that is a subgroup, any reweighting applied to its affiliated group will also be applied to the subgroup. In addition, for the CY 2023 performance period/2025 MIPS payment year, if reweighting is not applied to the affiliated group, the subgroup may receive reweighting in the following circumstances independent of the affiliated group:

* * * * *

(3) *Facility-based scoring.* If an MVP Participant, that is not an APM Entity or a subgroup, is eligible for facility-based scoring, a facility-based score also will be calculated in accordance with § 414.1380(e).

(4) * * *

(i) For subgroups, the affiliated group's complex patient bonus will be added to the final score.

(ii) [Reserved]

■ 57. Section 414.1375 is amended by revising paragraph (b)(2)(ii)(C), and adding paragraph (b)(2)(ii)(D) to read as follows:

§ 414.1375 Promoting Interoperability (PI) performance category.

* * * * *

(A) * * *

(B) * * *

(C) Beginning with the 2024 MIPS payment year through the 2025 MIPS payment year, submit an attestation, with either an affirmative or negative response, with respect to whether the MIPS eligible clinician completed the annual self-assessment under the SAFER Guides measure during the year in which the performance period occurs.

(D) Beginning with the 2026 MIPS payment year, submit an affirmative attestation regarding the MIPS eligible clinician's completion of the annual self-assessment under the SAFER Guides measure during the year in which the performance period occurs.

* * * * *

■ 58. Section 414.1380 is amended by—

■ a. Revising paragraphs (a)(1)(i) and (ii), (b)(1)(v)(A), (b)(2)(iv)(A), (B), (C) and (E), (b)(3)(i), and (c)(2)(i)(A)(*4*)(*iii*);

■ b. Adding paragraphs (c)(2)(iv);

■ c. In paragraph (c)(3)(v) removing the term ''MIPS eligible clinicians, groups, subgroups, APM Entities and virtual groups'' and adding in its place the term ''MIPS eligible clinicians, groups, APM Entities and virtual groups;'' and

■ d. In paragraph (c)(3)(vi) removing the term ''MIPS eligible clinicians, groups, and subgroups'' and adding in its place the term ''MIPS eligible clinicians and groups''.

The revisions and additions read as follow:

§ 414.1380 Scoring.

(a) * * *

(1) * * *

(i) For the quality performance category, measures are scored between zero and 10 measure achievement points. Performance is measured against benchmarks. Prior to the CY 2023 performance period/2025 MIPS payment year, measure bonus points are available for submitting high-priority measures and submitting measures using end-to-end electronic reporting. Measure bonus points are available for small practices that submit data on at least 1 quality measure. Beginning with the 2020 MIPS payment year, improvement scoring is available in the quality performance category.

(ii) For the cost performance category, measures are scored between 1 and 10 points. Performance is measured against a benchmark. Beginning with the 2025 MIPS payment year, improvement scoring is available in the cost performance category.

* * * * *

(b) * * *

(1) * * *

(v) * * *

(A) *High priority measures.* Subject to paragraph (b)(1)(v)(A)(*1*) of this section, for the CY 2017 through 2021 MIPS performance periods/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive 2 measure bonus points for each outcome and patient experience measure and 1 measure bonus point for each other high priority measure. Beginning in the 2021 MIPS payment year, MIPS eligible clinicians do not receive such measure bonus points for CMS Web Interface measures. Beginning in the 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians will no longer receive these measure bonus points.

* * * * *

(2) * * *

(iv) * * *

(A) The cost improvement score is determined at the category level for the cost performance category.

(B) The cost improvement score is calculated only when data sufficient to measure improvement are available. Sufficient data are available when a MIPS eligible clinician or group participates in MIPS using the same identifier in 2 consecutive performance periods and is scored on the cost performance category for 2 consecutive

performance periods. If the cost improvement score cannot be calculated because sufficient data are not available, then the cost improvement score is zero.

(C) The cost improvement score is determined at the category-level by subtracting the cost performance category score from the previous performance period from the cost performance category percent score from the current performance period, and then by dividing the difference by the cost performance category score from the previous performance period, and by dividing by 100.

* * * * *

(E) The maximum cost improvement score for the 2020, 2021, 2022, 2023, and 2024 MIPS payment year is zero percentage points. The maximum cost improvement score beginning with the 2025 MIPS payment year is 1 percentage point.

* * * * *

(3) * * *

(i) For MIPS eligible clinicians participating in APMs, the improvement activities performance category score is at least 50 percent. MIPS eligible clinicians participating in APMs must attest to having completed an improvement activity or submit data for the quality and Promoting Interoperability performance categories in order to receive such credit.

* * * * *

(c) * * *

(2) * * *

(i) * * *

(A) * * *

(*4*) * * *

(*iii*) For the 2024 through 2026 MIPS payment years, the MIPS eligible clinician is a clinical social worker. 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 distributed.

* * * * *

(iv) If CMS has granted an application for a hardship exception or any other type of exception to a MIPS eligible clinician under paragraph (c)(2)(i)(A)(*6*) or (c)(2)(i)(C)(*2*) of this section, or has identified a MIPS eligible clinician in a CMS-designated region as being affected by an automatic extreme and uncontrollable circumstances event under paragraph (c)(2)(i)(A)(*8*) or (c)(2)(i)(C)(*3*) of this section, CMS will not apply the improvement activities score described in paragraph (b)(3)(i) of this section to the MIPS eligible clinician's score.

* * * * *

■ 59. Section 414.1385 is amended—

■ a. In paragraph (a) by removing the term ''MIPS eligible clinician or group'' and adding in its in place the term ''MIPS eligible clinician, virtual group, subgroup or group;''

■ b. In paragraph (a)(1) by removing the term ''MIPS eligible clinician or group'' and adding in its place the term ''MIPS eligible clinician, virtual group, subgroup, or group;''

■ c. By revising paragraph (a)(2);

■ d. In paragraph (a)(3) by removing the term ''MIPS eligible clinician or group'' and adding in its place the term ''MIPS eligible clinician, virtual group, subgroup, group;''

■ e. By revising paragraph (a)(5); and

■ f. In paragraph (a)(6) by removing the term ''MIPS eligible clinician or group'' and adding in its place the term ''MIPS eligible clinician, virtual group, subgroup, or group''.

The revisions read as follows:

§ 414.1385 Targeted review and review limitations.

(a) * * *

(2) All requests for targeted review must be submitted during the targeted review request submission period, which begins on the day CMS makes available the MIPS final score, and ends 30 days after publication of the MIPS payment adjustment factors for the MIPS payment year. The targeted review request submission period may be extended as specified by CMS.

* * * * *

(5) A request for a targeted review may include additional information in support of the request at the time it is submitted. If CMS requests additional information from the MIPS eligible clinician, subgroup, virtual group, or group that is the subject of a request for a targeted review, the information must be provided and received by CMS within 15 days of CMS' request. Non-responsiveness to CMS' request for additional information may result in a final decision based on the information available, although another non-duplicative request for targeted review may be submitted before the end of the targeted review request submission period.

* * * * *

■ 60. Section 414.1400 is amended by—

■ a. Revising paragraphs (a)(1)(iii), (a)(2)(i), (a)(2)(ii)(A), (a)(3), and (b)(1)(ii);

■ b. Adding paragraphs (b)(1)(iii);

■ c Revising paragraphs (b)(2), (b)(3)(v)(E)(*1*) and (*2*);

■ d. Adding paragraphs (b)(3)(ix) through (xvii);

■ e. Revising paragraph (b)(4)(i)(B);

■ f. Adding paragraphs (b)(4)(i)(C) and (b)(4)(iv)(O) and (P);

■ g. Revising paragraph (e)(1) introductory text;

■ h. Adding paragraph (e)(1)(i)(F);

■ i. Revising paragraph (e)(1)(ii);

■ j. Adding paragraphs (e)(2)(iv) and (v);

■ k. Revising paragraphs (e)(3) and (4) and (f).

The additions and revisions read as follows:

§ 414.1400 Third party intermediaries.

(a)* * *

(1)* * *

(iii) Before the CY 2025 performance period/2027 payment year, Health IT vendor;

* * * * *

(2) * * *

(i) To be approved as a third party intermediary, an organization must meet the following requirements:

(A) The organization's principal place of business and the location in which it stores data must be in the U.S.

(B) The organization must have the ability to indicate the source of any data it will submit to CMS if the data will be derived from CEHRT, a QCDR, qualified registry, or health IT vendor.

(C) The organization must certify that it intends to provide services throughout the entire performance period and applicable data submission period.

(ii) * * *

(A) Whether the organization failed to comply with the requirements of this section for any prior MIPS payment year for which it was approved as third party intermediary, including past compliance; and

* * * * *

(3) For third-party intermediary program requirements:

(i) All data submitted to CMS by a third party intermediary on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge. Such certification must be made in a form and manner and at such time as specified by CMS.

(ii) All data submitted to CMS by a third party intermediary must be submitted in the form and manner specified by CMS.

(A) The submission of data on measures by a third party intermediary to CMS must include data on all of the MIPS eligible clinician's patients, regardless of payer, unless otherwise specified by the collection type.

(B) [Reserved]

(iii) If the clinician chooses to opt-in to participate in MIPS in accordance with § 414.130, the third party intermediary must be able to transmit that decision to CMS.

(iv) Prior to discontinuing services to any MIPS eligible clinician, group, virtual group, subgroup, or APM Entity during a performance period, a third party intermediary must support the transition of such MIPS eligible clinician, group, virtual group, subgroup, or APM Entity 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 transition plan by a date specified by CMS. The transition plan must address the following issues, unless different or additional information is specified by CMS:

(A) The issues that contributed to the withdrawal mid-performance period or discontinuation of services mid-performance period.

(B) Impacted entities:

(*1*) The number of clinicians, groups, virtual groups, subgroups or APM entities (inclusive of MIPS eligible, opt-in and voluntary participants) that would need to find another way to report.

(*2*) As applicable, identify any QCDRs that were granted licenses to QCDR measures which would no longer be available for reporting due to the transition.

(C) The steps the third party intermediary will take to ensure that the clinicians, groups, virtual groups, subgroups, or APM Entities identified in paragraph (a)(3)(iv)(B)(1) of this section are notified of the transition in a timely manner, and successfully transitioned to an alternate third party intermediary, submitter type, or, for any measure or activity on which data has been collected, collection type, as applicable.

(D) A detailed timeline that outlines timing for communications, the start of the transition, and completion of the transition of these clinicians, groups, virtual groups, subgroups, or APM Entities.

(E) The third party intermediary must communicate to CMS that the transition was completed by the date included in the detailed timeline.

(v) As a condition of its qualification and approval to participate in MIPS as a third party intermediary, a third party intermediary must:

(A) Make available to CMS the contact information of each MIPS eligible clinician, group, virtual group, subgroup, or APM Entity on behalf of whom it submits data. The contact information must include, at a minimum, the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity phone number, address, and, if available, email.

(B) Retain all data submitted to CMS for purposes of MIPS for 6 years from the end of the MIPS performance period.

(C) Upon request, provide CMS with any records or data retained in connection with its operation as a third party intermediary for up to 6 years from the end of the MIPS performance period.

(vi) 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) * * *

(1) * * *

(ii) Beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data. QCDRs and qualified registries may also support the APP. A QCDR or qualified registry must support all measures and activities included in the MVP with the following exceptions:

(A) If an MVP is intended for reporting by multiple specialties, a QCDR or a qualified registry are required to report those measures pertinent to the specialty of its MIPS eligible clinicians.

(B) If an MVP includes a QCDR measure, it is not required to be reported by a QCDR other than the measure owner.

(iii) Beginning with the CY 2023 performance period/2025 MIPS payment year, A QCDR or qualified registry must support subgroup reporting.

(2) *Self-nomination.* For the CY 2019 performance period/2021 MIPS payment year and future years, an existing QCDR or qualified registry that is in good standing may use the Simplified Self-Nomination process form during the self-nomination period, from July 1 and September 1 of the CY preceding the applicable performance period.

(3) * * *

(v) * * *

(E) * * *

(*1*) Uses a sample size of at least 3 percent of a combination of the individual MIPS eligible clinicians, groups, virtual groups, subgroups and APM entities for which the QCDR or qualified registry will submit data to CMS, except that the sample size may be no fewer than a combination of 10 individual clinicians, groups, virtual groups, subgroups and APM entities, no more than a combination of 50 individual clinicians, groups, virtual groups, subgroups and APM entities.

(*2*) Uses a sample that includes at least 25 percent of the patients of each individual clinician, group, virtual group, subgroup or APM entity in the sample, except that the sample for each individual clinician, group, virtual group, subgroup or APM entity must include a minimum of 5 patients and need not include more than 50 patients.

* * * * *

(ix) During the self-nomination period, a QCDR or a qualified registry must submit to CMS quality measure numbers, Promoting Interoperability identifiers, improvement activity identifiers and MVP titles.

(x) A QCDR or a qualified registry must be able to submit to CMS data for at least six quality measures including at least one outcome measure.

(A) If no outcome measure is available, a QCDR or qualified registry must be able to submit to CMS results for at least one other high priority measure.

(B) [Reserved]

(xi) A QCDR or a qualified registry must submit to CMS risk-adjusted measure results when submitting data for measures that include risk adjustment in the measure specification.

(xii) A QCDRs or qualified registry must enter into appropriate Business Associate Agreements with MIPS eligible clinicians to collect and process their data.

(xiii) A QCDR or a qualified registry must maintain records of their authorization to submit data to CMS for the purpose of MIPS participation for each NPI whom the QCDR or qualified registry will submit data to CMS for. The records must:

(A) Be annually obtained by the QCDR or qualified registry at the time the clinician or group enters into an agreement with the QCDR or qualified registry for the submission of MIPS data to the QCDR or qualified registry.

(B) Be signed by an eligible clinician, if reporting individually, or by an authorized representative of the reporting group, subgroup, Virtual Group, or APM Entity.

(C) Records of the authorization must be maintained for 6 years after the performance period ends.

(xiv) A QCDR or a qualified registry must attest that the information listed on the qualified posting is accurate.

(xv) A QCDR or a qualified registry must provide to CMS, upon request, the data submitted by the QCDR or qualified registry *for purposes of MIPS.*

(xvi) A QCDR or qualified registry must attest to the following:

(A) A QCDR or a qualified registry must attest that it has required each MIPS eligible clinician on whose behalf it reports to provide the QCDR or qualified registry with all documentation necessary to verify the accuracy of the data on quality measures that the eligible clinician submitted to the QCDR or qualified registry.

(B) A QCDR or qualified registry must also attest that it has required each MIPS eligible clinician to permit the QCDR or qualified registry to provide the information described in paragraph (b)(3)(xviii)(A) of this section to CMS upon request.

(xvii) A QCDR or a qualified registry must accept and maintain clinician data by January 1 of the applicable performance period.

(4) * * *

(i) * * *

(B) For a QCDR measure, the entity must submit for CMS approval measure specifications including: Name/title of measure, descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms. In addition, no later than 15 calendar days following CMS posting of all approved specifications for a QCDR measure, the entity must publicly post the CMS-approved measure specifications for the QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted. The approved QCDR measure specifications must remain published through the performance period and data submission period.

(C) For a QCDR measure, the QCDR must provide, if available, data from years prior before the start of the performance period.

* * * * *

(iv) * * *

(O) QCDR measures submitted after self-nomination.

(P) More than 30 QCDR measures are submitted by a single QCDR.

* * * * *

(e) * * *

(1) If CMS determines that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, failed to comply with the program requirements of this section, has submitted a false certification under paragraph (a)(3) of this section, or has submitted data that are inaccurate, unusable, or otherwise compromised, CMS may take one or more of the following remedial actions after providing written notice to the third party intermediary:

(i) * * *

(F) Once the issue has been resolved, the detailed final resolution and an update, if any, to the monitoring plan provided pursuant to § 414.1400(e)(1)(i)(C).

(ii) Publicly disclose as follows:

(A) For the purposes of the CY 2025 performance period/2027 MIPS payment year and prior reporting periods and payment years, publicly disclose the entity's data error rate on the CMS website until the data error rate falls below 3 percent.

(B) Beginning with the CY 2025 performance period/2027 MIPS payment year, publicly disclose on the CMS website that CMS took remedial action against or terminated the third party intermediary.

(2) * * *

(iv) The third party intermediary has not maintained current contact information for correspondence.

(v) The third party intermediary is on remedial action for two consecutive years.

(3) A data submission that contains data inaccuracies affecting the third party intermediary's clinicians may lead to remedial action/termination of the third party intermediary for future program year(s) based on CMS discretion.

(4) For purposes of this paragraph (e), CMS may determine that submitted data are inaccurate, unusable, or otherwise compromised, if the submitted data includes, without limitation, TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies.

* * * * *

(f) *Auditing of entities submitting MIPS data.* Third party intermediaries may be randomly selected for compliance evaluation or may be selected at the suggestion of CMS if there is an area of concern regarding the third party intermediary. For example, areas of concern could include, but are not limited to: high data errors, support call absences, delinquent deliverables, remedial action status, clinician concerns regarding the third party intermediary, a continuing pattern of Quality Payment Program Service Center inquiries or support call questions, and/or CMS concerns regarding the third party intermediary.

■ 61. Section 414.1405 is amended by—

■ a. Adding paragraphs (b)(9)(iii); and

■ b. Revising paragraph (g).

The addition and revision read as follows:

§ 414.1405 Payment.

* * * * *

(b) * * *

(9) * * *

(iii) The performance threshold for 2026 MIPS payment year is 82 points. The prior period to determine the performance threshold is the 2019 through 2021 MIPS payment years.

* * * * *

(g) *Performance threshold methodology.* (1) For each of the 2024, 2025, and 2026 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under paragraph (b) of this section.

(2) For purposes of establishing a performance threshold as identified in § 414.1405(b), beginning with the 2026 MIPS payment year, a prior period is a time span of three performance periods.

■ 62. Section 414.1415 is amended by revising paragraph (a) to read as follows:

§ 414.1415 Advanced APM criteria.

(a) *Use of certified electronic health record technology (CEHRT)*—(1) *Required use of CEHRT.* To be an Advanced APM, an APM must:

(i) For QP Performance Periods ending with 2018, require at least 50 percent, or for QP Performance Periods beginning with 2019 and ending with 2023, 75 percent, of eligible clinicians in each participating APM Entity group, or for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or health care providers;

(ii) For QP Performance Periods prior to 2019, for the Shared Savings Program, apply a penalty or reward to an APM Entity based on the degree of the use of CEHRT of the eligible clinicians in the APM Entity; and

(iii) For QP Performance Periods beginning with 2024, require use of CEHRT as defined at paragraph (3) under CEHRT at § 414.1305.

(2) [Reserved].

* * * * *

■ 63. Section 414.1420 is amended by revising paragraph (b) to read as follows:

§ 414.1420 Other payer advanced APM criteria.

* * * * *

(b) *Use of CEHRT.* To be an Other Payer Advanced APM:

(1) CEHRT must be used, for QP Performance Periods ending with 2019, by at least 50 percent; and for QP Performance Periods for 2020 through 2023, by at least 75 percent, of participants in each participating APM Entity group, or each hospital if hospitals are the APM Entities, in the other payer arrangement to document and communicate clinical care; and

(2) For QP Performance Periods beginning on or after January 1, 2024, use of CEHRT (as defined in § 414.1305, paragraph (3) in the definition of ''Certified Electronic Health Record Technology (CEHRT)''), must be a requirement of participation in the APM.

* * * * *

■ 64. Section 414.1425 is amended by adding paragraph (b)(3) to read as follows:

§ 414.1425 Qualifying APM participant determination: In general.

* * * * *

(b) * * *

(3) *Individual QP determinations.* For QP Performance Periods beginning for calendar year 2024, except as provided in paragraph (b)(2) of this section and in § 414.1440, QP determinations are made individually at the eligible clinician level. To be assessed as a QP, an eligible clinician's APM participant identifier must be included on the Participation List of an APM Entity participating in an Advanced APM on one of the following dates during the QP Performance Period: March 31, June 30, or August 31. An eligible clinician included on such a Participation List on any one of these dates is assessed as a QP even if the eligible clinician is not included on the Participation List at one of the prior or later listed dates. CMS performs QP determinations for the identified eligible clinicians during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination dates for which the eligible clinician is included on the Participation List: March 31, June 30, and August 31.

* * * * *

■ 65. Section 414.1430 is amended by—
■ a. Revising paragraph (a)(1)(iv);
■ b. Adding paragraph (a)(1)(v);
■ c. Revising paragraph (a)(2)(iv);
■ d. Adding paragraph (a)(2)(v);
■ e. Revising paragraph (a)(3)(iv);
■ f. Adding paragraph (a)(3)(v);
■ g. Revising paragraph (a)(4)(iv);
■ h. Adding paragraph (a)(4)(v); and
■ i. Revising paragraph (b)(1)(i)(A) and (B), (b)(2)(i)(A) and (B), (b)(3)(i)(A) and (B), (b)(4)(i)(A) and (B).

The revisions and additions read as follows:

§ 414.1430 Qualifying APM participant determination: QP and partial QP thresholds.

(a) * * *
(1) * * *
(iv) 2025: 50 percent.
(v) 2026 and later: 75 percent.
(2) * * *
(iv) 2025: 40 percent.
(v) 2026 and later: 50 percent.
(3) * * *
(iv) 2025: 35 percent.
(v) 2026 and later: 50 percent.
(4) * * *
(iv) 2025: 25 percent.
(v) 2026 and later: 35 percent.
(b) * * *
(1) * * *
(i) * * *
(A) 2021 through 2025: 50 percent.
(B) 2026 and later: 75 percent.

* * * * *

(2) * * *
(i) * * *
(A) 2021 through 2025:40 percent.
(B) 2026 and later: 50 percent.

* * * * *

(3) * * *
(i) * * *
(A) 2021 through 2025: 35 percent.
(B) 2026 and later: 50 percent.

* * * * *

(4) * * *
(i) * * *
(A) 2021 through 2025: 25 percent.
(B) 2026 and later: 35 percent.

* * * * *

■ 66. Section 414.1450 is amended by—
■ a. Adding paragraphs (a)(1)(i) and (ii); and
■ b. Revising paragraph (b)(1).

The addition and revision read as follows:

§ 414.1450 APM incentive payment.

(a) * * *

(i) For payment years 2019 through 2025, CMS makes a lump sum payment to QPs in the amount described in paragraph (b) of this section in the manner described in paragraphs (d) and (e) of this section.

(ii) [Reserved]

* * * * *

(b) * * *

(1) For payment years 2019 through 2024, the amount of the APM Incentive Payment is equal to 5 percent or, with respect to payment year 2025, 3.5 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.

* * * * *

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 67. The authority for part 415 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 415.140 [Amended]

■ 68. In § 415.140 in paragraph (a) amend the definition of ''Substantive portion'' by removing the reference ''year 2022 and 2023'' and adding in its place the reference ''years 2022 through 2024''.

PART 418—HOSPICE CARE

■ 69. The authority citation for part 418 continues to read as follow:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 70. Section 418.56 is amended by revising paragraph (a)(1)(iii) to read as follows:

§ 418.56 Condition of participation: Interdisciplinary group, care planning, and coordination of services.

* * * * *

(a) * * *
(1) * * *

(iii) A social worker, marriage and family therapist, or a mental health counselor, depending on the preferences and needs of the patient.

* * * * *

■ 71. Section 418.114 is amended by adding paragraphs (c)(3) and (4) to read as follows:

§ 418.114 Condition of participation: Personnel qualifications.

* * * * *

(c) * * *

(3) Marriage and family counselor as defined at § 410.53.

(4) Mental health counselor as defined at § 410.54.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 72. The authority citation for part 422 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–22 through 1395w–28, and 1395hh.

■ 73. Section 422.310 is amended by adding paragraph (f)(3)(iv) to read as follows:

§ 422.310 Risk adjustment data.

* * * * *

(f) * * *
(3) * * *

(iv) CMS determines that releasing aggregated data before reconciliation is

necessary and appropriate to support activities or authorized uses under paragraph (f)(1)(vii) of this section.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 74. 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.

■ 75. Section 423.160 is amended by—

■ a. Revising paragraph (a)(5) introductory text;

■ b. Removing paragraph (a)(5)(i);

■ c. Redesignating paragraphs (a)(5)(ii) through (iv) as paragraphs (a)(5)(i) through (iii), respectively and revising newly redesignated paragraph (a)(5)(ii).

The revisions read as follows:

§ 423.160 Standards for electronic prescribing.

(a) * * *

(5) Beginning on January 1, 2021, prescribers must, except in the circumstances described in paragraphs (a)(5)(i) through (iii) of this section, conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically using the applicable standards in paragraph (b) of this section, subject to the exemption in paragraph (a)(3)(iii) of this section. Prescriptions written for a beneficiary in a long-term care facility will not be included in determining compliance until January 1, 2025. Compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a long-term care facility will commence on or after January 1, 2025. Compliance actions against prescribers who do not meet the compliance threshold based on other prescriptions will commence on or after January 1, 2023. Prescribers will be exempt from this requirement in the following situations:

* * * * *

(ii) Prescriber has an address in PECOS in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. If a prescriber does not have an address in PECOS, prescriber has an address in NPPES in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. Starting in the 2024 measurement year, CMS will identify which emergencies or disasters qualify for this exception.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 76. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 77. Section 424.205 is amended by—

■ a. In paragraph (a), by removing the definition of ''MDPP interim preliminary recognition'';

■ b. Revising paragraph (b)(1);

■ c. Removing paragraph (c);

■ d. Redesignating paragraphs (d) through (i) as paragraphs (c) through (h), respectively; and

■ e. Revising newly designated paragraph (c)(1);

■ f. Removing newly redesignated paragraph (c)(10)(iii);

■ g. Revising newly redesignated paragraph (c)(14);

■ h. Revising newly redesignated paragraphs (f)(2)(i);

■ i. Removing newly redesignated paragraph (f)(5)(iii);

■ j. Redesignating newly redesignated paragraphs (f)(5)(iv) and (v) as paragraphs (f)(5)(iii) and (iv), respectively;

■ k. Revising newly redesignated paragraph (f)(5)(iii) and paragraph (g)(1)(i)(C).

The revisions read as follows:

§ 424.205 Requirements for Medicare Diabetes Prevention Program suppliers.

* * * * *

(b) * * *

(1) Has either preliminary, full, full plus CDC DPRP recognition.

* * * * *

(c) * * *

(1) The MDPP supplier must have and maintain preliminary, full, or full plus CDC DPRP recognition.

* * * * *

(14) The MDPP supplier must submit performance data for MDPP beneficiaries who ever attended ongoing maintenance sessions with data elements consistent with the CDC's DPRP standards for data elements required for the core services period.

* * * * *

(f) * * *

(2) * * *

(i) Documentation of the type of session, whether a core session, a core maintenance session, an in-person make-up session, or a virtual make-up session.

* * * * *

(5) * * *

(iii) Has achieved at least a 9-percent weight loss percentage as measured in accordance with § 410.79(e)(3)(iii) of this chapter during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(7) of this chapter.

* * * * *

(g) * * *

(1) * * *

(i) * * *

(C) An MDPP supplier that does not satisfy the requirements in paragraph (b)(1) of this section may become eligible to bill for MDPP services again if it successfully achieves preliminary, full, or full plus CDC DPRP recognition, and successfully enrolls again in Medicare as an MDPP supplier after any applicable reenrollment bar has expired.

* * * * *

■ 78. Section 424.210 is amended by revising paragraphs (b)(2) and (d)(1) to read as follows:

§ 424.210 Beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model.

* * * * *

(b) * * *

(2) The item or service must be reasonably connected to the CDC-approved National Diabetes Prevention Program curriculum furnished to the MDPP beneficiary during a core session or core maintenance session furnished by the MDPP supplier.

* * * * *

(d) * * *

(1) Attendance at core sessions or core maintenance sessions.

* * * * *

■ 79. Section 424.502 is amended by—

■ a. Revising the definition of ''Authorized official''; and

■ b. Adding the definitions of ''Indirect ownership interest,'' ''Pattern or practice,'' and ''Supplier'' in alphabetical order.

The revision and additions read as follows:

§ 424.502 Definitions.

* * * * *

Authorized official means an appointed official (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program. For purposes of this definition only, the term ''organization'' means the enrolling entity as identified by its legal business name and tax identification number.

* * * * *

Indirect ownership interest means as follows:

(1)(i) Any ownership interest in an entity that has an ownership interest in the enrolling or enrolled provider or supplier.

(ii) Any ownership interest in an indirect owner of the enrolling or enrolled provider or supplier.

(2) The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation that owns 80 percent of the provider or supplier, A's interest equates to an 8 percent indirect ownership interest in the provider or supplier and must be reported on the enrollment application. Conversely, if B owns 80 percent of the stock of a corporation that owns 5 percent of the stock of the provider or supplier, B's interest equates to a 4 percent indirect ownership interest in the provider or supplier and need not be reported.

* * * * *

Pattern or practice means:

(1) For purposes of § 424.535(a)(8)(ii), at least three submitted non-compliant claims.

(2) For purposes of § 424.535(a)(14), at least three prescriptions of Part B or Part D drugs that are abusive, represent a threat to the health and safety of Medicare beneficiaries, or otherwise fail to meet Medicare requirements.

(3) For purposes of § 424.535(a)(21), at least three orders, certifications, referrals, or prescriptions of Medicare Part A or B services, items, or drugs that are abusive, represent a threat to the health and safety of Medicare beneficiaries, or otherwise fail to meet Medicare requirements.

* * * * *

Supplier means, for purposes of this subpart, all of the following:

(1) The individuals and entities that qualify as suppliers under § 400.202.

(2) Physical therapists in private practice.

(3) Occupational therapists in private practice.

(4) Speech-language pathologists.

* * * * *

■ 80. Section 424.516 is amended by revising paragraphs (d)(1)(iii) and (e)(1) to read as follows:

§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

* * * * *

(d) * * *

(1) * * *

(iii) A change, addition, or deletion of a practice location.

* * * * *

(e) * * *

(1) Within 30 days for a change of ownership or control (including changes in authorized official(s) or delegated official(s)) or a change, addition, or deletion of a practice location;

* * * * *

■ 81. Section 424.530 is amended by—

■ a. Revising paragraph (a)(1); and

■ b. Adding paragraphs (a)(16), (17), and (18).

The revision and additions read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

(a) * * *

(1) *Noncompliance.* The provider or supplier is determined to not be in compliance with the enrollment requirements described in this title 42, or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter.

* * * * *

(16) *Certain misdemeanors.* (i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has been convicted (as that term is defined in 42 CFR 1001.2) of a misdemeanor under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries.

(ii) Offenses under paragraph (a)(16)(i) of this section include, but are not limited in scope or severity to, the following:

(A) Fraud or other criminal misconduct involving the provider's or supplier's participation in a Federal or State health care program or the delivery of services or items thereunder.

(B) Assault, battery, neglect, or abuse of a patient (including sexual offenses).

(C) Any other misdemeanor that places the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

(17) *False Claims Act (FCA).* (i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has had a civil judgment under the FCA (31 U.S.C. 3729 through 3733) imposed against them within the previous 10 years.

(ii) In determining whether a denial under this paragraph is appropriate, CMS considers the following factors:

(A) The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted).

(B) The types of provider or supplier actions involved.

(C) The monetary amount of the judgment.

(D) When the judgment occurred.

(E) Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502 of this chapter).

(F) Any other information that CMS deems relevant to its determination.

(18) *Supplier standard or condition violation.* (i) The independent diagnostic testing facility is non-compliant with any provision in § 410.33(g).

(ii) The DMEPOS supplier is non-compliant with any provision in § 424.57(c).

(iii) The opioid treatment program is non-compliant with any provision in § 424.67(b).

(iv) The home infusion therapy supplier is non-compliant with any provision in § 424.68(c).

(v) The Medicare diabetes prevention program is non-compliant with any provision in § 424.205(b) or (d).

* * * * *

■ 82. Section 424.535 is amended by—

■ a. Revising paragraphs (a)(1) introductory text, (a)(8)(ii) introductory text, and (a)(14)(i) introductory text and (ii) introductory text;

■ b. Adding paragraphs (a)(15) and (16);

■ c. Revising paragraph (a)(17) introductory text;

■ d. Redesignating paragraphs (a)(17)(i) through (vi) as paragraphs (a)(17)(i)(A) through (F);

■ e. Adding paragraph (a)(17)(ii);

■ f. Revising paragraph (a)(21) introductory text;

■ g. Adding paragraph (a)(23); and

■ h. Revising paragraphs (e) and (g).

The additions and revisions read as follows:

§ 424.535 Revocation of enrollment in the Medicare program.

(a) * * *

(1) *Noncompliance.* The provider or supplier is determined to not be in compliance with the enrollment requirements described in this title 42, or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter. The provider or supplier may also be determined not to be in compliance if it has failed to pay any user fees as assessed under part 488 of this chapter.

* * * * *

(8) * * *

(ii) CMS determines that the provider or supplier has a pattern or practice of submitting claims that fails to meet Medicare requirements and that a revocation on this basis is warranted. In determining whether a revocation is warranted, CMS considers, as appropriate or applicable, the following:

* * * * *

(14) * * *

(i) The pattern or practice is abusive or represents a threat to the health and safety of Medicare beneficiaries, or both, and CMS determines that a revocation on this basis is warranted. In determining whether a revocation is warranted, CMS considers the following factors:

* * * * *

(ii) The pattern or practice of prescribing fails to meet Medicare requirements and CMS determines that a revocation on this basis is warranted. In determining whether a revocation is warranted, CMS considers the following factors:

* * * * *

(15) *False Claims Act (FCA).* (i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has had a civil judgment under the FCA (31 U.S.C. 3729 through 3733) imposed against them within the previous 10 years.

(ii) In determining whether a revocation under this paragraph is appropriate, CMS considers the following factors:

(A) The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted).

(B) The types of provider or supplier actions involved.

(C) The monetary amount of the judgment.

(D) When the judgment occurred.

(E) Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502).

(F) Any other information that CMS deems relevant to its determination.

(16) *Certain misdemeanors.* (i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has been convicted (as that term is defined in 42 CFR 1001.2) of a misdemeanor under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries.

(ii) Offenses under paragraph (i) include, but are not limited in scope or severity to, the following:

(A) Fraud or other criminal misconduct involving the provider's or supplier's participation in a Federal or State health care program or the delivery of services or items thereunder.

(B) Assault, battery, neglect, or abuse of a patient (including sexual offenses).

(C) Any other misdemeanor that places the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

(17) *Debt referred to the United States Department of Treasury.* (i) The provider or supplier failed to repay a debt that CMS appropriately referred to the United States Department of Treasury. In determining whether a revocation under this paragraph (a)(17) is appropriate, CMS considers the following factors:

* * * * *

(ii) Paragraph (17)(i) of this paragraph does not apply to the following situations:

(A) The provider's or supplier's Medicare debt has been discharged by a bankruptcy court; or

(B) The administrative appeals process concerning the debt has not been exhausted or the timeframe for filing such an appeal (at the appropriate level of appeal) has not expired.

* * * * *

(21) *Abusive ordering, certifying, referring, or prescribing of Part A or B services, items or drugs.* The physician or eligible professional has a pattern or practice of ordering, certifying, referring, or prescribing Medicare Part A or B services, items, or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements, and CMS determines that a revocation on this basis is warranted. In determining whether a revocation is warranted, CMS considers the following factors:

* * * * *

(23) *Supplier standard or condition violation.* (i) The independent diagnostic testing facility is non-compliant with any provision in 42 CFR 410.33(g).

(ii) The DMEPOS supplier is non-compliant with any provision in § 424.57(c).

(iii) The opioid treatment program is non-compliant with any provision in § 424.67(b) or (e).

(iv) The home infusion therapy supplier is non-compliant with any provision in § 424.68(c) or (e).

(v) The Medicare diabetes prevention program is non-compliant with any provision in § 424.205(b) or (d).

* * * * *

(e) *Reversal of revocation.* If the revocation was due to adverse activity (sanction, exclusion, or felony) against the provider's or supplier's owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, the revocation may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that party within 15 days of the revocation notification.

* * * * *

(g) *Effective date of revocation.* (1) Except as described in paragraphs (g)(2) and (g)(3) of this section, a revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier.

(2) Except as described in paragraph (g)(3) of this section, the revocation effective dates in the situations identified in this paragraph (g)(2) are as follows:

(i) For revocations based on a Federal exclusion or debarment, the date of the exclusion or debarment.

(ii) For revocations based on a felony conviction, the date of the felony conviction.

(iii) For revocations based on a State license suspension or revocation, the date of the license suspension or revocation.

(iv) For revocations based on a CMS determination that the provider's or supplier's practice location is non-operational, the date on which the provider's or supplier's practice location was no longer operational (per CMS' or the CMS contractor's determination).

(v) For revocations based on a misdemeanor conviction, the date of the misdemeanor conviction.

(vi) For revocations based on a State license surrender in lieu of further disciplinary action, the date of the license surrender.

(vii) For revocations based on termination from a Federal health care program other than Medicare (for example, Medicaid), the date of the termination.

(viii) For revocations based on termination of a provider agreement under part 489 of this chapter, and as applicable to the type of provider involved, the later of the following:

(A) The date of the provider agreement termination; or

(B) The date that CMS establishes under § 489.55.

(ix) For revocations based on § 424.535(a)(23), the effective dates are as follows:

(A) If the standard or condition violation involves the suspension, revocation, or termination (or surrender in lieu of further disciplinary action) of the provider's or supplier's Federal or State license, certification, accreditation, or MDPP recognition, the effective date is the date of the license, certification, accreditation, or MDPP recognition suspension, revocation, termination, or surrender.

(B) If the standard or condition violation involves a non-operational practice location, the effective date is the date the non-operational status began.

(C) If the standard violation involves a felony conviction of an individual or entity described in § 424.67(b)(6)(i), the effective date is the date of the felony conviction.

(D) For all standard violations not addressed in paragraphs (A) through (C), the effective date in paragraph (g)(1) applies if the effective date in paragraph (g)(3) does not.

(3) If the action that resulted in the revocation occurred prior to the effective date of the provider's or supplier's enrollment, the effective date of the revocation is the same as the effective date of enrollment.

* * * * *

■ 83. Section 424.541 is added to read as follows:

§ 424.541 Stay of enrollment.

(a)(1) CMS may stay an enrolled provider's or supplier's enrollment if the provider or supplier:

(i) Is non-compliant with at least one enrollment requirement in Title 42; and.

(ii) Can remedy the non-compliance via the submission of, as applicable to the situation, a Form CMS–855, Form CMS–20134, or Form CMS–588 change of information or revalidation application.

(2) During the period of any stay imposed under this section, the following apply:

(i) The provider or supplier remains enrolled in Medicare;

(ii) Claims submitted by the provider or supplier with dates of service within the stay period will be denied.

(3) A stay of enrollment lasts no longer than 60 days from the postmark date of the notification letter.

(4) CMS notifies the affected provider or supplier in writing of the imposition of the stay.

(b)(1) If a provider or supplier receives written notice from CMS or its contractor that the provider or supplier is subject to a stay under this section, the provider or supplier has 15 calendar days from the date of the written notice to submit a rebuttal to the stay as described in paragraph (b) of this section.

(2) CMS may, at its discretion, extend the 15-day time-period referenced in paragraph (b)(1) of this section.

(3) Any rebuttal submitted pursuant to paragraph (b) of this section must:

(i) Be in writing.

(ii) Specify the facts or issues about which the provider or supplier disagrees with the stay's imposition and/or the effective date, and the reasons for disagreement.

(iii) Submit all documentation the provider or supplier wants CMS to consider in its review of the stay.

(iv) Be submitted in the form of a letter that is signed and dated by the individual supplier (if enrolled as an individual physician or nonphysician practitioner), the authorized official or delegated official (as those terms are defined in 42 CFR 424.502), or a legal representative (as defined in 42 CFR 498.10). If the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the provider or supplier; this statement is sufficient to constitute notice of such authority. If the legal representative is not an attorney, the provider or supplier must file with CMS written notice of the appointment of a representative; this notice of appointment must be signed and dated by, as applicable, the individual supplier, the authorized official or delegated official, or a legal representative.

(4) The provider's or supplier's failure to submit a rebuttal that is both timely under paragraph (b)(1) of this section and fully compliant with all of the requirements of paragraph (b)(3) of this section constitutes a waiver of all rebuttal rights under this section.

(5) Upon receipt of a timely and compliant stay rebuttal, CMS reviews the rebuttal to determine whether the imposition of the stay and/or the effective date thereof are correct.

(6) A determination made under paragraph (b) of this section is not an initial determination under § 498.3(b) and therefore not appealable.

(7) Nothing in paragraph (b) of this section requires CMS to delay the imposition of a stay pending the completion of the review described in paragraph (b)(5) of this section.

(8)(i) Nothing in paragraph (b) of this section requires CMS to delay the imposition of a deactivation or revocation, pending the completion of the review described in paragraph (b)(5) of this section.

(ii)(A) If CMS deactivates the provider or supplier during the stay, any rebuttal to the stay that the provider or supplier submits that meets the requirements of paragraph (b) of this section is combined and considered with the provider's or supplier's rebuttal to the deactivation under § 424.546 if CMS has not yet made a determination on the stay rebuttal pursuant to this section.

(B) In all cases other than that described in paragraph (b)(8)(ii)(A) of this section, a stay rebuttal that was submitted in compliance with the requirements of paragraph (b) of this section is considered separately and independently of any review of any other rebuttal or, for revocations, appeal under 42 CFR part 498.

■ 84. Section 424.555 is amended by revising paragraph (b) to read as follows:

§ 424.555 Payment liability.

* * * * *

(b) No payment may be made for otherwise Medicare covered items or services furnished to a Medicare beneficiary by a provider or supplier if the billing privileges of the provider or supplier are deactivated, denied, or revoked, or if the provider or supplier is currently under a stay of enrollment. The Medicare beneficiary has no financial responsibility for expenses, and the provider or supplier must refund on a timely basis to the Medicare beneficiary any amounts collected from the Medicare beneficiary for these otherwise Medicare covered items or services.

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 85. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 86. Section 425.20 is amended—

■ a. By revising the definitions of ''Assignable beneficiary'' and ''Assignment window'';

■ b. In the definition of ''At-risk beneficiary'' by—

■ i. Removing the periods at the end of paragraphs (5) and (6), and adding in their place semicolons; and

■ ii. Revising paragraph (7);

■ c. By adding the definitions of ''Beneficiary eligible for Medicare CQMs'' and ''Expanded window for assignment'' in alphabetical order;

■ d. In the definition of ''Experienced with performance-based risk Medicare

ACO initiatives'' by revising paragraph (2);

■ e. In the definition of ''Inexperienced with performance-based risk Medicare ACO initiatives'' by revising paragraph (2);

■ f. In the definition of ''Rural health center'' by—

■ i. Removing the word ''center'' and adding in its place the word ''clinic''; and

■ ii. Removing the phrase ''under § 405.2401(b)'' and adding in its place the phrase ''under § 405.2401(b) of this chapter''.

The revisions and additions read as follows:

§ 425.20 Definitions.

* * * * *

Assignable beneficiary means a Medicare fee-for-service beneficiary who receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c). For performance year 2025 and subsequent performance years, a Medicare fee-for-service beneficiary who does not meet this requirement but who meets both of the following criteria will also be considered an assignable beneficiary—

(1) Receives at least one primary care service with a date of service during a specified 24-month expanded window for assignment from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c).

(2) Receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled practitioner who is one of the following:

(i) A physician assistant (as defined at § 410.74(a)(2) of this chapter).

(ii) A nurse practitioner (as defined at § 410.75(b) of this chapter).

(iii) A clinical nurse specialist (as defined at § 410.76(b) of this chapter).

* * * * *

Assignment window means the 12-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both.

At-risk beneficiary * * *

(7) Is entitled to Medicare because of disability; or

* * * * *

Beneficiary eligible for Medicare CQMs means a beneficiary identified for purposes of reporting Medicare CQMs for ACOs participating in the Medicare Shared Savings Program (Medicare CQMs), who is either of the following:

(1) A Medicare fee-for-service beneficiary (as defined at § 425.20) who—

(i) Meets the criteria for a beneficiary to be assigned to an ACO described at § 425.401(a); and

(ii) Had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or certified nurse specialist.

(2) A Medicare fee-for-service beneficiary who is assigned to an ACO in accordance with § 425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

* * * * *

Expanded window for assignment means the 24-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both that includes the applicable 12-month assignment window and the preceding 12 months.

Experienced with performance-based risk Medicare ACO initiatives * * *

(2) Forty percent or more of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in any of the 5 most recent performance years. An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years.

* * * * *

Inexperienced with performance-based risk Medicare ACO initiatives * * *

(2) Less than 40 percent of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in each of the 5 most recent performance years. An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years.

* * * * *

■ 87. Section 425.106 is amended by revising paragraph (c)(5) to read as follows:

§ 425.106 Shared governance.

* * * * *

(c) * * *

(5) In cases in which the composition of the ACO's governing body does not meet the requirements of paragraph (c)(2) of this section, the ACO must describe why it seeks to differ from these requirements and how the ACO will provide meaningful representation in ACO governance by Medicare beneficiaries.

* * * * *

■ 88. Section 425.204 is amended by revising paragraph (c)(3) to read as follows:

§ 425.204 Content of the application.

* * * * *

(c) * * *

(3) If an ACO requests an exception to the governing body requirement in § 425.106(c)(2), the ACO must describe—

(i) Why it seeks to differ from the requirement; and

(ii) How the ACO will provide meaningful representation in ACO governance by Medicare beneficiaries.

* * * * *

■ 89. Section 425.302 is amended by revising paragraph (a)(3)(iii) to read as follows:

§ 425.302 Program requirements for data submission and certifications.

(a) * * *

(3) * * *

(iii) For performance years starting on January 1, 2019 through 2023, the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage specified by CMS at § 425.506(f).

* * * * *

■ 90. Section 425.308 is amended by adding paragraph (b)(9) to read as follows:

§ 425.308 Public reporting and transparency.

* * * * *

(b) * * *

(9) The number of MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305 of this chapter) participating in the ACO that earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual,

group, virtual group, or APM entity level as set forth in § 425.507.

* * * * *

■ 91. Section 425.316 is amended by revising paragraphs (e)(2) introductory text and (e)(2)(i) to read as follows:

§ 425.316 Monitoring of ACOs.

* * * * *

(e) * * *

(2) If CMS determines that an ACO participating in advance investment payments became experienced with performance-based risk Medicare ACO initiatives during its first or second performance year of its agreement period or that the ACO became a high revenue ACO during any performance year of its agreement period, CMS—

(i) Will cease payment of advance investment payments no later than the quarter after the ACO became experienced with performance-based risk Medicare ACO initiatives or became a high revenue ACO.

* * * * *

■ 92. Section 425.400 is amended—

■ a. By revising paragraph (a)(2)(ii);

■ b. In paragraph (a)(3)(i), by removing the phrase ''most recent 12 months'' and adding in its place the phrase ''most recent 12 or 24 months, as applicable,'';

■ c. By revising paragraph (c)(1)(vii) introductory text;

■ d. By adding paragraph (c)(1)(viii); and

■ e. By revising paragraphs (c)(2)(i) introductory text and (c)(2)(ii).

The revisions and addition read as follows:

§ 425.400 General.

(a) * * *

(2) * * *

(ii) Assignment will be updated quarterly based on the most recent 12 or 24 months of data, as applicable, under the methodology described in §§ 425.402 and 425.404.

* * * * *

(c) * * *

(1) * * *

(vii) For the performance year starting on January 1, 2023 as follows:

* * * * *

(viii) For the performance year starting on January 1, 2024, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 96202 and 96203 (codes for caregiver behavior management training).

(*3*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*4*) 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).

(*5*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*6*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home).

(*7*) 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)(viii)).

(*8*) 99406 and 99407 (codes for smoking and tobacco-use cessation counseling services).

(*9*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*10*) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(*11*) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*12*) 99439 (code for non-complex chronic care management).

(*13*) 99457 and 99458 (codes for remote physiologic monitoring).

(*14*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*15*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*16*) 99495 and 99496 (codes for transitional care management services).

(*17*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(*18*) 9X015, 9X016, and 9X017 (codes for caregiver training services).

(B) HCPCS codes:

(*1*) G0101 (code for cervical or vaginal cancer screening).

(*2*) G0317, G0318, and G2212 (codes for prolonged office or other outpatient visit for the evaluation and management of a patient).

(*3*) G0402 (code for the Welcome to Medicare visit).

(*4*) G0438 and G0439 (codes for the annual wellness visits).

(*5*) G0442 (code for alcohol misuse screening service).

(*6*) G0443 (code for alcohol misuse counseling service).

(*7*) G0444 (code for annual depression screening service).

(*8*) G0463 (code for services furnished in ETA hospitals).

(*9*) G0506 (code for chronic care management).

(*10*) G2010 (code for the remote evaluation of patient video/images).

(*11*) G2012 and G2252 (codes for virtual check-in).

(*12*) G2058 (code for non-complex chronic care management).

(*13*) G2064 and G2065 (codes for principal care management services).

(*14*) G2086, G2087, and G2088 (codes for office-based opioid use disorder services).

(*15*) G2211 (code for complex evaluation and management services add-on).

(*16*) G2214 (code for psychiatric collaborative care model).

(*17*) G3002 and G3003 (codes for chronic pain management).

(*18*) GXXX1 and GXXX2 (codes for community health integration services).

(*19*) GXXX3 and GXXX4 (codes for principal illness navigation services).

(*20*) GXXX5 (code for social determinants of health risk assessment services).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(viii)(A) of this section or a HCPCS code specified in paragraph (c)(1)(viii)(B) of this section, when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

(2) * * *

(i) Except as otherwise specified in paragraph (c)(2)(i)(A)(*2*) of this section, when the assignment window or applicable expanded window for assignment (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:

* * * * *

(ii) Except as otherwise specified in paragraph (c)(2)(i)(A)(*2*) of this section, the additional primary care service codes specified in paragraph (c)(2)(i) of this section are applicable to all months of the assignment window or applicable expanded window for assignment (as defined in § 425.20), when the assignment window or applicable expanded window for assignment includes any month(s) during the COVID–19 Public Health Emergency defined in § 400.200 of this chapter.

■ 93. Section 425.402 is amended—
■ a. By revising paragraph (b)(1);
■ b. By adding paragraph (b)(5);
■ c. By revising paragraph (c) introductory text; and
■ d. In paragraph (e)(2)(ii)(A), by removing the reference ''§ 425.400(a)(4)(ii)'' and adding in its place the reference ''§ 425.226(a)(1)''.

The revisions and addition read as follows:

§ 425.402 Basic assignment methodology.

* * * * *

(b) * * *

(1) Identify all beneficiaries that had at least one primary care service during the applicable assignment window with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in paragraph (c) of this section.

* * * * *

(5) For performance year 2025 and subsequent performance years, CMS employs the following third step to assign Medicare fee-for-service beneficiaries who were not identified by the criterion specified in paragraph (b)(1) of this section:

(i) Identify all beneficiaries who had at least one primary care service with a non-physician ACO professional in the ACO during the applicable assignment window.

(ii) For the beneficiaries identified in paragraph (b)(5)(i) of this section, identify those beneficiaries that had at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in paragraph (c) of this section during the applicable expanded window for assignment.

(iii) Identify all primary care services furnished to beneficiaries identified in paragraph (b)(5)(ii) of this section by ACO professionals in the ACO who are primary care physicians as defined under § 425.20, non-physician ACO professionals, and physicians with specialty designations included in paragraph (c) of this section during the applicable expanded window for assignment.

(iv) A beneficiary identified in paragraph (b)(5)(ii) of this section is assigned to the ACO if the allowed charges for primary care services furnished to the beneficiary by ACO professionals in the ACO who are primary care physicians, physicians with specialty designations included in paragraph (c) of this section, or non-physician ACO professionals during the applicable expanded window for assignment are greater than the allowed charges for primary care services furnished by primary care physicians, physicians with specialty designations as specified in paragraph (c) of this section, nurse practitioners, physician assistants, and clinical nurse specialists who are—

(A) ACO professionals in any other ACO; or

(B) Not affiliated with any ACO and identified by a Medicare-enrolled billing TIN.

(c) ACO professionals considered in the second and third step of the assignment methodology in paragraphs (b)(4) and (5) of this section include physicians who have one of the following primary specialty designations:

* * * * *

■ 94. Section 425.506 is amended by revising paragraph (f) introductory text to read as follows:

§ 425.506 Incorporating reporting requirements related to adoption of certified electronic health record technology.

* * * * *

(f) For performance years starting on January 1, 2019 through 2023, ACOs in a track that—

* * * * *

■ 95. Section 425.507 is added to subpart F to read as follows:

§ 425.507 Incorporating promoting interoperability requirements related to the Quality Payment Program for performance years beginning on or after January 1, 2024.

(a) For performance years beginning on or after January 1, 2024, unless otherwise excluded under paragraph (b) of this section, all MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305 of this chapter) participating in the ACO must satisfy all of the following:

(1) Report the MIPS Promoting Interoperability performance category measures and requirements to MIPS according to 42 CFR part 414 subpart O as either of the following—

(i) All MIPS eligible clinicians, QPs, and Partial QPs participating in the ACO as an individual, group, or virtual group; or

(ii) The ACO as an APM entity.

(2) Earn a performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level.

(b) A MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity may be excluded from the requirements set forth in paragraph (a) of this section if the MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity—

(1) Does not exceed the low volume threshold set forth at § 414.1310(b)(1)(iii) of this chapter;

(2) Is an eligible clinician as defined at § 414.1305 of this chapter who is not a MIPS eligible clinician and has opted to voluntarily report measures and activities for MIPS as set forth in § 414.1310(b)(2) of this chapter; or

(3) Has not earned a performance category score for the MIPS Promoting Interoperability performance category because the MIPS Promoting Interoperability performance category has been reweighted in accordance with applicable policies set forth at § 414.1380(c)(2) of this chapter.

■ 96. Section 425.512 is amended—
■ a. By revising paragraph (a)(2);
■ b. In paragraph (a)(5)(i) introductory text, by removing the phrase ''paragraph (a)(2) of this section'' and adding in its place the phrase ''paragraphs (a)(2) and (a)(7) of this section'';
■ c. By revising paragraph (a)(5)(i)(A)(*2*), (a)(5)(iii)(A) and (B);
■ d. By adding paragraph (a)(7);
■ e. In paragraph (b)(1)—
■ i. By adding a new first sentence;
■ ii. By removing the reference ''paragraph (b)(2)'' and adding in its place the reference ''paragraph (b)(3)'';
■ f. By redesignating paragraphs (b)(2) and (3) as paragraphs (b)(3) and (4), respectively;
■ g. By adding new paragraph (b)(2);
■ h. By revising the newly redesignated paragraph (b)(3)(ii)(B);
■ i. In newly redesignated paragraph (b)(3)(iii), by removing the phrase ''paragraph (b)(2)(ii) of this section'' and adding in its place the phrase ''paragraph (b)(3)(ii) of this section'';
■ j. By revising newly redesignated paragraph (b)(3)(iv)(A);
■ k. In newly redesignated paragraph (b)(3)(iv)(B), by removing the phrase ''paragraph (b)(2)(iv)(A) of this section'' and adding in its place the phrase ''paragraph (b)(3)(iv)(A) of this section'';
■ l. In newly redesignated paragraph (b)(3)(v)—
■ i. By removing the phrase ''paragraph (b)(2)(iv)(B) of this section'' and adding in its place the phrase ''paragraph (b)(3)(iv)(B) of this section'';
■ ii. By removing the phrase ''paragraph (b)(2)(iii) of this section'' and adding in its place the phrase ''paragraph (b)(3)(iii) of this section'';
■ iii. By removing the phrase ''paragraph (b)(2)(iv) of this section'' and adding in its place the phrase ''paragraph (b)(3)(iv) of this section'';
■ m. In newly redesignated paragraph (b)(4) introductory text, by removing the

phrase ''paragraphs (b)(1) and (b)(2) of this section'' and adding in its place the phrase ''paragraphs (b)(1) through (b)(3) of this section''; and

■ n. By revising paragraph (c)(3).

The revisions and additions read as follows:

§ 425.512 Determining the ACO quality performance standard for performance years beginning on or after January 1, 2021.

(a) * * *

(2) For the first performance year of an ACO's first agreement period under the Shared Savings Program, the ACO will meet the quality performance standard if it meets the requirements under this paragraph (a)(2).

(i) For performance years 2022 and 2023. If the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter and the case minimum requirement at § 414.1380 of this subchapter on the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs, and the CAHPS for MIPS survey, for the applicable performance year.

(ii) For performance year 2024. If the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter on the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, for the applicable performance year.

(iii) For performance year 2025 and subsequent performance years. If the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter on the three eCQMs/MIPS CQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, for the applicable performance year.

* * * * *

(5) * * *

(i) * * *

(A) * * *

(*2*) If the ACO reports the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all three eCQMs/MIPS CQMs, and achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set.

* * * * *

(iii) * * *

(A) For performance year 2024, the ACO does not report any of the ten CMS Web Interface measures, any of the three eCQMs/MIPS CQMs/Medicare CQMs and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this chapter) under the APP.

(B) For performance year 2025 and subsequent years, the ACO does not report any of the three eCQMs/MIPS CQMs/Medicare CQMs and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this chapter) under the APP.

* * * * *

(7) For performance years 2024 and subsequent performance years, if an ACO reports all of the required measures, meeting the data completeness requirement at § 414.1340 of this chapter for each measure in the APP measure set and receiving a MIPS quality performance category score as described at § 414.1380(b)(1) of this chapter, and the ACO's total available measure achievement points used to calculate the ACO's MIPS quality performance category score is reduced under § 414.1380(b)(1)(vii)(A) of this chapter, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(b) * * *

(1) For performance year 2023. * * *

(2) For performance year 2024 and subsequent performance years. For an ACO that reports the three eCQMs/MIPS CQMs/Medicare CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 of this chapter for all three eCQMs/MIPS CQMs/Medicare CQMs, and administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this chapter), CMS calculates the ACO's health equity adjusted quality performance score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP measure set and the ACO's health equity adjustment bonus points calculated in accordance with paragraph (b)(3) of this section. The sum of these values may not exceed 100 percent.

(3) * * *

(ii) * * *

(B) Values of zero for each measure that CMS does not evaluate because the measure is unscored or the ACO does not meet the case minimum or the minimum sample size for the measure.

* * * * *

(iv) * * *

(A) (*1*) CMS determines the proportion ranging from zero to one of the ACO's assigned beneficiary population for the performance year that is considered underserved based on the highest of either of the following:

(*i*) The proportion of the ACO's assigned beneficiaries residing in a census block group with an Area Deprivation Index (ADI) national percentile rank of at least 85. An ACO's assigned beneficiaries without an available numeric ADI national percentile rank are excluded from the calculation of the proportion of the ACO's assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85.

(*ii*) The proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D low-income subsidy (LIS); or are dually eligible for Medicare and Medicaid.

(*2*) CMS calculates the proportions specified in paragraph (b)(3)(iv)(A)(*1*)(*ii*) of this section as follows:

(*i*) For performance year 2023, the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or are dually eligible for Medicare and Medicaid divided by the total number of the ACO's assigned beneficiaries' person years.

(*ii*) For performance year 2024 and subsequent performance years, the proportion of the ACO's assigned beneficiaries with any months enrolled in LIS or dually eligible for Medicare and Medicaid divided by the total number of the ACO's assigned beneficiaries.

* * * * *

(c) * * *

(3) If CMS determines the ACO meets the requirements of paragraph (c)(1) of this section and the ACO reports quality data via the APP, CMS calculates the ACO's quality score as follows:

(i) For performance years 2021 and 2022, if the ACO reports quality data via the APP and meets data completeness and case minimum requirements, CMS will use the higher of the ACO's quality

performance score or the equivalent of the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(ii) For performance year 2023, if the ACO reports quality data via the APP and meets data completeness and case minimum requirements, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(iii) For performance year 2024 and subsequent performance years, if the ACO reports quality data via the APP and meets the data completeness requirement at § 414.1340 of this chapter and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this chapter, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

* * * * *

§ 425.600 [Amended]

■ 97. Amend § 425.600 in paragraph (f)(4)(ii) by removing the reference ''425.656(d)'' and adding in its place the reference ''425.656(e)''.

§ 425.601 [Amended]

■ 98. Amend § 425.601 in paragraph (a) introductory text by removing the reference ''§ 425.226(a)(1)'' and adding in its place the reference ''§ 425.400(a)(4)(ii)''.

§ 425.611 [Amended]

■ 99. Amend § 425.611 in paragraph (c)(2)(iii) by removing the reference ''§ 425.652(a)(8)(iv)'' and adding in its place the reference ''§ 425.658(c)(1)(ii)''.

■ 100. Section 425.630 is amended—

■ a. By revising paragraphs (b)(2) and (3), (e)(3), (f) introductory text, and (g)(4);

■ b. In paragraph (h)(1)(i), by removing ''or'' at the end of the paragraph;

■ c. In paragraph (h)(1)(ii), by removing ''.'' at the end of the paragraph, and adding in its place ''; or''; and

■ d. By adding paragraphs (h)(1)(iii) and (i).

The revisions and additions read as follows:

§ 425.630 Option to receive advance investment payments.

* * * * *

(b) * * *

(2) CMS has determined that the ACO is eligible to participate in the Shared Savings Program.

(3) The ACO is inexperienced with performance-based risk Medicare ACO initiatives during its first two performance years and participates in the BASIC track's glide path as follows:

(i) For performance year 1, the ACO must participate in Level A of the BASIC track's glide path.

(ii) For performance year 2, the ACO may participate in Level A of the BASIC track's glide path (in accordance with § 425.600(a)(4)(i)(C)(*3*)) or Level B.

(iii) For performance years 3 through 5, the ACO may participate in Level A of the BASIC track's glide path (in accordance with § 425.600(a)(4)(i)(C)(*3*)), or Levels B through E.

* * * * *

(e) * * *

(3) *Duration for spending payments.* An ACO may spend an advance investment payment over its entire agreement period. An ACO must repay to CMS any unspent funds remaining at the end of the ACO's agreement period, except if the ACO terminated its current participation agreement under § 425.220 beginning with the third or fourth performance year and immediately enters a new agreement period to continue its participation in the Shared Savings Program, the ACO must spend its advance investment payments within 5 performance years of when it first received advance investment payments and repay to CMS any unspent funds remaining at the end of that fifth performance year.

* * * * *

(f) *Payment methodology.* An ACO receives two types of advance investment payments: a one-time payment of $250,000 and quarterly payments calculated pursuant to the methodology defined in paragraph (f)(2) of this section. CMS notifies in writing each ACO of its determination of the amount of advance investment payment and the notice will inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part. If CMS does not make any advance investment payment, the notice will specify the reason(s) why and inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part.

* * * * *

(g) * * *

(4) If an ACO terminates its participation agreement during the agreement period in which it received an advance investment payment, the ACO must repay all advance investment payments it received, unless the ACO terminated its current participation agreement under § 425.220 at the end of performance year 2 or later during the agreement period in which it received advance investment payments and immediately enters a new agreement period to continue its participation in the program. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

* * * * *

(h) * * *

(1) * * *

(iii) Voluntarily terminates its participation agreement in accordance with § 425.220(a).

* * * * *

(i) *Reporting information on advance investment payments.* The ACO must report information on its receipt of and use of advance investment payments, as follows:

(1) The ACO must publicly report information about the ACO's use of advance investment payments for each performance year, in accordance with § 425.308(b)(8).

(2) In a form and manner and by a deadline specified by CMS, the ACO must report to CMS the same information it is required to publicly report under § 425.308(b)(8).

§ 425.650 [Amended]

■ 101. Amend § 425.650 in paragraph (a) by removing the references ''§§ 425.601, 425.602, and 425.603'' and adding in their place the references ''§§ 425.601, 425.602, 425.603, and 425.659''.

■ 102. Section 425.652 is amended—

■ a. In paragraph (a) introductory text, by removing the reference ''§ 425.226(a)(1)'' and adding in its place the reference ''§ 425.400(a)(4)(ii)'';

■ b. By revising paragraphs (a)(5)(v)(A), (a)(8), (a)(9) introductory text, and (a)(9)(ii);

■ c. In paragraph (a)(9)(iv), by removing the reference ''§ 425.400(a)(4)(ii)'' and adding in its place the reference ''§ 425.226(a)(1)'';

■ d. In paragraph (a)(9)(v), by removing the phrase '', or a combination of these two adjustments'';

■ e. By adding paragraphs (a)(9)(vi) and (b)(2)(ii)(C); and

■ f. By revising paragraph (b)(2)(iv)(A).

The revisions and additions read as follows:

§ 425.652 Establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.

(a) * * *

(5) * * *

(v) * * *

(A) Calculating the county-level share of assignable beneficiaries that are assigned to the ACO for each county in the ACO's regional service area. The assignable population of beneficiaries is identified for BY3 using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

* * * * *

(8) Except as provided in paragraph (a)(8)(iii) of this section, adjusts the historical benchmark based on the ACO's regional service area expenditures (as specified under § 425.656), or for savings generated by the ACO, if any, in the 3 most recent years prior to the start of the agreement period (as specified under § 425.658). CMS does all of the following to determine the adjustment, if any, applied to the historical benchmark:

(i) Computes the regional adjustment in accordance with § 425.656 and the prior savings adjustment in accordance with § 425.658.

(ii) If an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i), and the regional adjustment, expressed as a single per capita value as described in § 425.656(d), is positive, the ACO will receive an adjustment to its benchmark equal to the positive regional adjustment amount. The adjustment will be calculated as described in § 425.656(c) and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(iii) If an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i), and the regional adjustment, expressed as a single per capita value as described in § 425.656(d), is negative or zero, the ACO will not receive an adjustment to its benchmark.

(iv) If an ACO is eligible to receive a prior savings adjustment and the regional adjustment, expressed as a single value as described in § 425.656(d), is positive, the ACO will receive an adjustment to its benchmark equal to the higher of the following:

(A) The positive regional adjustment amount. The adjustment will be calculated as described in § 425.656(c) and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(B) A prior savings adjustment. The adjustment will be calculated as described in § 425.658(c) and applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(v) If an ACO is eligible to receive a prior savings adjustment and the regional adjustment, expressed as a single value as described in § 425.656(d), is negative or zero, the ACO will receive an adjustment to its benchmark equal to the prior savings adjustment. The adjustment will be calculated as described in § 425.658(c) and applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(9) For the first performance year during the term of the agreement period, the ACO's benchmark is adjusted for the following, as applicable: For changes in values used in benchmark calculations in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315. 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), for a change to the beneficiary assignment methodology specified in subpart E of this part, for a change in the CMS–HCC risk adjustment methodology used to calculate prospective HCC risk scores under § 425.659, and for changes in values used in benchmark calculations in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315. To adjust the benchmark, CMS does the following:

* * * * *

(ii) Redetermines the regional adjustment amount under § 425.656 according to the ACO's assigned beneficiaries for BY3, and based on the assignable population of beneficiaries identified for BY3 using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

* * * * *

(vi) Redetermines factors based on prospective HCC risk scores calculated for benchmark years by calculating the prospective HCC risk scores using the CMS–HCC risk adjustment methodology that applies for the calendar year corresponding to the applicable performance year in accordance with § 425.659(b)(1).

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(C) Multiply the growth rate calculated in this paragraph (b)(2)(ii) by a regional risk score growth cap adjustment factor computed as described in § 425.655.

* * * * *

(iv) * * *

(A) Calculating the county-level share of assignable beneficiaries that are assigned to the ACO for each county in the ACO's regional service area. The assignable population of beneficiaries is identified for the performance year using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

* * * * *

■ 103. Section 425.654 is amended by revising paragraph (a)(1)(i) to read as follows:

§ 425.654 Calculating county expenditures and regional expenditures.

(a) * * *

(1) * * *

(i) Determines average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area. The assignable population of beneficiaries is identified for the relevant benchmark or performance year using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

* * * * *

■ 104. Section 425.655 is added to subpart G to read as follows:

§ 425.655 Calculating the regional risk score growth cap adjustment factor.

(a) *General.* This section describes the methodology for calculating the regional risk score growth cap adjustment factor that will be applied to the regional growth rate component of the three-way blend used to update the historical benchmark as described in § 425.652(b) for agreement periods beginning on January 1, 2024, and in subsequent years.

(b) *Calculating county risk scores.* CMS does all of the following to determine county prospective HCC and demographic risk scores for use in calculating the ACO's regional risk scores:

(1) Determines average county prospective HCC and demographic risk scores for the assignable population of beneficiaries in each county in the ACO's regional service area. The assignable population of beneficiaries is identified for the relevant benchmark or performance year using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

(2) Makes separate risk score calculations for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(c) *Calculating regional risk scores.* CMS calculates an ACO's regional prospective HCC and demographic risk scores by:

(1) Weighting the county-level risk scores determined under paragraph (b) of this section according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries in the applicable population (according to Medicare enrollment type) residing in the county in relation to the ACO's total number of assigned beneficiaries in the applicable population (according to Medicare enrollment type) for the relevant benchmark or performance year for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Aggregating the values determined under paragraph (c)(1) of this section for each population of beneficiaries (according to Medicare enrollment type) across all counties within the ACO's regional service area.

(d) *Determining aggregate growth in regional risk scores.* CMS determines aggregate growth in regional prospective HCC and demographic risk scores by:

(1) Determining growth in regional prospective HCC and demographic risk scores determined in paragraph (c) of this section (expressed as a ratio of the performance year regional risk score to the BY3 regional risk score) for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Determines the aggregate growth in regional risk scores by calculating a weighted average of the growth in regional prospective HCC risk scores or demographic risk scores, as applicable, across the populations described in paragraph (d)(1) of this section. When calculating the weighted average growth in prospective HCC risk scores or demographic risk scores, as applicable, the weight applied to the growth in risk scores for each Medicare enrollment type is equal to the product of the ACO's regionally adjusted historical benchmark expenditures for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type.

(e) *Determining the cap on regional risk score growth.* CMS determines the cap on regional prospective HCC risk score growth by:

(1) Computing the sum of the aggregate growth in regional demographic risk scores as determined in paragraph (d)(2) of this section and 3 percentage points.

(2) Calculating the ACO's aggregate market share by calculating the weighted average of the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO for the performance year as determined in § 425.652(b)(2)(iv) across the populations described in § 425.652(b)(1). In calculating this weighted average, the weight applied to the share for each Medicare enrollment type is equal to the ACO's performance year assigned beneficiary person years for that enrollment type.

(3) Adding to the sum computed in paragraph (e)(1) of this section an amount equal to the product of:

(i) The ACO's aggregate market share as determined in paragraph (e)(2) of this section.

(ii) The difference between the aggregate growth in regional prospective HCC risk scores as determined in paragraph (d)(2) of this section and the sum determined in paragraph (e)(1) of this section. This difference is subject to a floor of zero.

(f) *Determining the regional risk score growth cap adjustment factor.* CMS determines the regional risk score growth cap adjustment factor for each Medicare enrollment type to be applied in calculating the regional growth rate described in § 425.652(b) by comparing the aggregate growth in regional prospective HCC risk scores determined in paragraph (d)(2) of this section and, if applicable, the growth in regional prospective HCC risk scores for individual Medicare enrollment types as determined in paragraph (d)(1) of this section with the cap determined in paragraph (e) of this section.

(1) If the aggregate growth in regional prospective HCC risk scores determined in paragraph (d)(2) of this section does not exceed the cap on regional risk score growth determined in paragraph (e) of this section, CMS will set the regional risk score growth cap adjustment factor equal to 1 for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) If the aggregate growth in regional prospective HCC risk scores determined in paragraph (d)(2) of this section exceeds the cap determined in paragraph (e) of this section, CMS will compare the growth in regional prospective HCC risk scores for each Medicare enrollment type as determined in paragraph (d)(1) of this section with the cap on regional risk score growth determined in paragraph (e) of this section.

(i) If the growth in regional prospective HCC risk scores for the enrollment type determined in paragraph (d)(1) of this section does not exceed the cap on regional risk score growth determined in paragraph (e) of this section, CMS will set the regional risk score growth cap adjustment factor equal for that enrollment type equal to 1.

(ii) If the growth in regional prospective HCC risk scores determined in paragraph (d)(1) for the enrollment type exceeds the cap on regional risk score growth determined in paragraph (e) of this section, CMS will set the regional risk score growth cap adjustment factor for that enrollment type equal to the growth in regional

prospective HCC risk scores for the enrollment type determined in paragraph (d)(1) of this section divided by the cap on regional risk score growth determined in paragraph (e) of this section.

■ 105. Section 425.656 is amended—

■ a. By revising paragraph (b)(3);

■ b. In paragraph (c)(2), by removing the phrase ''paragraph (d) of this section'' and adding in its place the phrase ''paragraph (e) of this section'';

■ c. By redesignating paragraphs (d) and (e) as paragraphs (e) and (f), respectively;

■ d. By adding new paragraph (d);

■ e. In newly redesignated paragraph (e)(5)(ii), by removing the phrase ''paragraph (d)(5)(i) of this section'' and adding in its place the phrase ''paragraph (e)(5)(i) of this section'';

■ f. In newly redesignated paragraph (e)(5)(iv), by removing the phrase ''paragraphs (d)(1) through (3)'' and adding in its place the phrase ''paragraphs (e)(1) through (3)''; and

■ g. In newly redesignated paragraph (f) introductory text, by removing the phrase ''paragraphs (b) through (d)'' and adding in its place the phrase ''paragraphs (b) through (e)''.

The revision and addition read as follows:

§ 425.656 Calculating the regional adjustment to the historical benchmark.

* * * * *

(b) * * *

(3) Adjusts for differences in severity and case mix between the ACO's assigned beneficiary population for BY3 and the assignable population of beneficiaries for the ACO's regional service area for BY3. The assignable population of beneficiaries is identified for BY3 using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

* * * * *

(d) *Expression of the regional adjustment as a single value.* (1) CMS expresses the regional adjustment as a single value by taking a person-year weighted average of the Medicare enrollment type-specific regional adjustment values determined in paragraph (c) of this section.

(2) CMS uses the regional adjustment expressed as a single value for purposes of determining the adjustment, if any, that will be applied to the benchmark in accordance with § 425.652(a)(8).

* * * * *

■ 106. Section 425.658 is amended—

■ a. In paragraph (b)(3)(i), by removing the sentence ''The ACO will receive the regional adjustment to its benchmark as described in § 425.656.'';

■ b. By redesignating paragraph (c) as paragraph (d);

■ c. By adding new paragraph (c);

■ d. By revising newly redesignated paragraph (d); and

■ e. By adding new paragraph (e).

The revision and additions read as follows:

§ 425.658 Calculating the prior savings adjustment to the historical benchmark.

* * * * *

(c) *Calculate the per capita savings adjustment.*

(1) If an ACO is eligible for the prior savings adjustment as determined in paragraph (b)(3) of this section, the prior savings adjustment will equal the lesser of the following:

(i) 50 percent of the pro-rated average per capita amount computed in paragraph (b)(3)(ii) of this section.

(ii) 5 percent of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary and expressed as a single value by taking a person-year weighted average of the Medicare enrollment type-specific values.

(2) [Reserved]

(d) *Applicability of the prior savings adjustment.* CMS compares the per capita prior savings adjustment determined in paragraph (c)(1) of this section with the regional adjustment, expressed as a single value as described in § 425.656(d), to determine the adjustment, if any, that will be applied to the ACO's benchmark in accordance with § 425.652(a)(8).

(e) *Recalculation of the prior savings adjustment during an agreement period.*

(1) The ACO's prior savings adjustment is recalculated for changes to the ACO's savings or losses for a performance year used in the prior savings adjustment calculation in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315.

(2) For a new ACO identified as a re-entering ACO, the prior savings adjustment is recalculated for changes to savings or losses for a performance year used in the prior savings adjustment calculation, if the savings or losses of the ACO in which the majority of the new ACO's participants were participating change in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315.

■ 107. Section 425.659 is added to subpart G to read as follows:

§ 425.659 Calculating risk scores used in Shared Savings Program benchmark calculations.

(a) *General.* CMS accounts for differences in severity and case mix of the ACO's assigned beneficiaries and assignable beneficiaries (as defined under § 425.20) in calculations used in establishing, adjusting and updating the ACO's historical benchmark.

(b) *Prospective Hierarchical Condition Category (HCC) risk score calculation.* In determining Medicare FFS beneficiary prospective HCC risk scores for a performance year and each benchmark year of the ACO's agreement period, CMS does the following:

(1) CMS specifies the CMS–HCC risk adjustment methodology used to calculate prospective HCC risk scores for Medicare FFS beneficiaries (as defined under § 425.20) for use in Shared Savings Program calculations as follows:

(i) In calculating risk scores for Medicare FFS beneficiaries for a performance year, CMS applies the CMS–HCC risk adjustment methodology applicable for the corresponding calendar year.

(ii) For agreement periods beginning before January 1, 2024, CMS applies the CMS–HCC risk adjustment methodology for the calendar year corresponding to benchmark year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year of the agreement period.

(iii) For agreement periods beginning on January 1, 2024, and in subsequent years, CMS applies the CMS–HCC risk adjustment methodology for the calendar year corresponding to the performance year, as specified under paragraph (b)(1)(i) of this section, in calculating risk scores for Medicare FFS beneficiaries for each benchmark year of the agreement period.

(2) CMS does the following to calculate the prospective HCC risk scores identified in paragraph (b)(1) of this section for a benchmark or performance year:

(i) Removes the Medicare Advantage coding intensity adjustment, if applicable.

(ii) Renormalizes prospective HCC risk scores by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) based on a national assignable FFS population for

the relevant benchmark or performance year.

(iii) Calculates the average prospective HCC risk score by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries).

■ 108. Section 425.702 is amended—

■ a. In paragraph (c)(1)(ii) introductory text, by removing the phrase ''process development'' and adding in its place the phrase ''protocol development'';

■ b. By revising paragraph (c)(1)(ii)(A)(*3*); and

■ c. By adding paragraph (c)(1)(iii).

The revision and addition read as follows:

§ 425.702 Aggregate reports.

* * * * *

(c) * * *

(1) * * *

(ii) * * *

(A) * * *

(*3*) Beneficiary identifier.

* * * * *

(iii) For performance year 2024 and subsequent performance years, at the beginning of the quality submission period, CMS, upon the ACO's request for the data for purposes of population-based activities relating to improving health or reducing growth in health care costs, protocol development, case management, and care coordination, provides the ACO with information about its fee-for-service population.

(A) The following information is made available to ACOs regarding beneficiaries eligible for Medicare CQMs as defined at § 425.20:

(*1*) Beneficiary name.

(*2*) Date of birth.

(*3*) Beneficiary identifier.

(*4*) Sex.

(B) Information in the following categories, which represents the minimum data necessary for ACOs to conduct health care operations work, is made available to ACOs regarding beneficiaries eligible for Medicare CQMs as defined at § 425.20:

(*1*) Demographic data such as enrollment status.

(*2*) Health status information such as risk profile and chronic condition subgroup.

(*3*) Utilization rates of Medicare services such as the use of evaluation and management, hospital, emergency, and post-acute services, including the dates and place of service.

* * * * *

PART 455—PROGRAM INTEGRITY: MEDICAID

■ 109. The authority citation for part 455 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 110. Section 455.416 is amended by revising paragraph (c) to read as follows:

§ 455.416 Termination or denial of enrollment.

* * * * *

(c) Must deny enrollment or terminate the enrollment of any provider that is terminated on or after January 1, 2011, under title XVIII of the Act and under the Medicaid program or CHIP of any other State, and is currently included in the termination database under § 455.417.

* * * * *

■ 111. Section 455.417 is added to read follows:

§ 455.417 Termination periods and termination database periods.

(a)(1) Subject to paragraph (c) of this section, a provider remains in the termination notification database referenced in section 1902(ll) of the Act for a period that is the lesser of:

(i) The length of the termination period imposed by the State that initially terminated the provider or the reenrollment bar (as described in § 424.535(c) of this chapter) imposed by the Medicare program in the case of a Medicare revocation; or

(ii) 10 years (for those Medicaid or CHIP terminations that are greater than 10 years).

(2) All other State Medicaid agencies or CHIPs must terminate or deny the provider from their respective programs (pursuant to § 455.416(c)) for at least the same length of time as the termination database period described in paragraph (a)(1) of this section.

(b)(1) Nothing in paragraph (a) of this section prohibits:

(i) The initially terminating State from imposing a termination period of greater than 10 years consistent with that State's laws, or

(ii) Another State from terminating the provider, based on the original State's termination, for a period:

(A) Of greater than 10 years; or

(B) That is otherwise longer than that imposed by the initially terminating State.

(2) The period established under paragraph (b)(1)(ii) of this section must be no shorter than the period in which the provider is to be included in the termination database under paragraph (a) of this section.

(c)(1) If the initially terminating State agency or the Medicare program reinstates the provider prior to the end of the termination period originally imposed by the initially terminating State agency or Medicare, CMS removes the provider from the termination database after the reinstatement has been reported to CMS.

(2) If the provider is removed from the database pursuant to paragraph (c)(1), CMS may immediately reinclude the provider in the database (with no interval between the two periods) if a basis for doing so exists under part 455 or 424 of this chapter.

(d) For purposes of this section only, terminations under § 455.416(c) are not considered ''for cause'' terminations and therefore need not be reported to CMS for inclusion in the termination database.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 112. The authority citation for part 489 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh.

■ 113. Section 489.30 is amended by—

■ a. Revising paragraph (b)(1); and

■ b. Adding paragraphs (b)(6) and (7).

The revision and additions read as follows:

§ 489.30 Allowable charges: Deductibles and coinsurance.

* * * * *

(b) * * *

(1) The basic allowable charges are the Part B annual deductible and 20 percent of the customary (insofar as reasonable) charges in excess of that deductible, except as specified in paragraphs (b)(6) and (7) of this section.

* * * * *

(6) In the case of a rebatable drug (as defined in section 1847A(i)(2)(A) of the Act), including a selected drug (as defined in section 1192(c) of the Act), furnished on or after April 1, 2023, in a calendar quarter in which the payment amount for such drug as specified in section 1847A(i)(3)(A)(ii)(I)(aa) or (bb), as applicable, exceeds the inflation-adjusted amount (as defined in section 1847A(i)(3)(C) of the Act) for such drug, the basic allowable charges are the Part B annual deductible and 20 percent of the of the inflation-adjusted payment amount for the rebatable drug in excess of that deductible, which is applied as a percent to the payment amount for such calendar quarter.

(7) In the case of insulin furnished on or after July 1, 2023 through an item of durable medical equipment covered under section 1861(n) of the Act, the coinsurance amount shall not exceed $35 for a month's supply of such insulin

each calendar month. This limitation on the coinsurance amount shall apply for the duration of the calendar month in which the date of service (or services) occurs. In addition, the coinsurance amount shall not exceed $105.00 for three months' supply of insulin. This limitation on the coinsurance amount shall apply for the duration of the calendar month in which the date of service (or services) occurs and the two following calendar months.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

■ 114. The authority citation for part 491 continues to read as follows:

Authority: 42 U.S.C. 263a and 1302.

■ 115. Section 491.2 is amended by—
■ a. Adding the definitions of ''Certified nurse-midwife (CNM)'', ''Clinical psychologist (CP)'', ''Clinical social worker'', ''Marriage and family therapist'', and ''Mental health counselor'' in alphabetical order; and
■ b. Revising the definition of ''Nurse practitioner''.

The additions and revisions read as follows:

§ 491.2 Definitions.

* * * * *

Certified nurse-midwife (CNM) means an individual who meets the applicable education, training, and other requirements at § 410.77(a) of this chapter.

Clinical psychologist (CP) means an individual who meets the applicable education, training, and other requirements of § 410.71(d) of this chapter.

Clinical social worker means an individual who meets the applicable education, training, and other requirements at § 410.73(a) of this chapter.

* * * * *

Marriage and family therapist means an individual who meets the applicable education, training, and other requirements at 410.53 of this chapter.

Mental health counselor means an individual who meets the applicable education, training, and other requirements at 410.54 of this chapter.

Nurse practitioner means a person who meets the applicable State requirements governing the qualifications for nurse practitioners, and who meets at least one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners and possesses a master's degree in nursing or a Doctor of Nursing Practice (DNP) doctoral degree.

* * * * *

■ 116. Section 491.8 is amended by revising paragraphs (a)(3) and (6) to read as follows:

§ 491.8 Staffing and staff responsibilities.

(a) * * *

(3) The physician assistant, nurse practitioner, certified nurse-midwife, clinical social worker,-clinical psychologist, marriage and family therapist, or mental health counselor member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the clinic or center. In the case of a clinic, at least one physician assistant or nurse practitioner must be an employee of the clinic.

* * * * *

(6) A physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, clinical psychologist, marriage and family therapist, or a mental health counselor is available to furnish patient care services at all times the clinic or center operates. In addition, for RHCs, a nurse practitioner, physician assistant, or certified nurse-midwife is available to furnish patient care services at least 50 percent of the time the RHC operates.

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 117. The authority citation for part 495 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 118. Section 495.4 is amended in the definition of ''Certified electronic health record technology (CEHRT)'' by revising paragraph (2) introductory text to read as follows:

§ 495.4 Definitions.

* * * * *

Certified electronic health record technology (CEHRT) * * *

(2) For 2019 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition, or subsequent Base EHR definition (as defined at 45 CFR 170.102) and has been certified to the ONC health IT certification criteria, as adopted and updated in 45 CFR 170.315—

* * * * *

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 119. The authority citation for part 498 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7j, and 1395hh.

■ 120. In § 498.2 amend the definition of ''Supplier'' by revising paragraph (6) to read as follows:

§ 498.2 Definitions.

* * * * *

Supplier * * *

(6) For purposes of this part, a physical therapist in private practice, an occupational therapist in private practice, or a speech-language pathologist.

* * * * *

PART 600—ADMINISTRATION, ELIGIBILITY, ESSENTIAL HEALTH BENEFITS, PERFORMANCE STANDARDS, SERVICE DELIVERY REQUIREMENTS, PREMIUM AND COST SHARING, ALLOTMENTS, AND RECONCILIATION

■ 121. The authority citation for part 600 continues to read as follows:

Authority: Section 1331 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, 124 Stat. 119), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, 124 State. 1029).

■ 122. Revise § 600.125 to read as follows:

§ 600.125 Revisions to a certified BHP Blueprint.

(a) *Submission of revisions.* A State may seek to revise its certified Blueprint in whole or in part at any time through the submission of a revised Blueprint to HHS. A State must submit a revised Blueprint to HHS whenever necessary to reflect—

(1) Changes in Federal law, regulations, policy interpretations, or court decisions that affect provisions in the certified Blueprint;

(2) Significant changes that alter core program operations under 600.145(f) or the BHP benefit package; or

(3) Changes to enrollment, disenrollment, and verification policies described in the certified Blueprint.

(b) *Submission and effective dates.* The effective date of a revised Blueprint may not be earlier than the first day of the quarter in which an approvable

revision is submitted to HHS. A revised Blueprint is deemed received when HHS receives an electronic copy of a cover letter signed by the Governor or Governor's designee and a copy of the currently approved Blueprint with proposed changes in track changes.

(c) *Timing of HHS review.* (1) A revised Blueprint will be deemed approved unless HHS, within 90 calendar days after receipt of the revised Blueprint, sends the State—

(i) Written notice of disapproval; or

(ii) Written notice of additional information it needs in order to make a final determination.

(2) If HHS requests additional information, the 90-day review period for HHS action on the revised Blueprint—

(i) Stops on the day HHS sends a written request for additional information or the next business day if the request is sent on a Federal holiday or weekend; and

(ii) Resumes on the next calendar day of the original 90-day review period after HHS receives an a complete response from the State of all the requested additional information, unless the information is received after 5 p.m. eastern standard time on a day prior to a non-business day or any time on a non-business day, in which case the review period resumes on the following business day.

(3) The 90-day review period cannot stop or end on a non-business day. If the 90th calendar day falls on a non-business day, HHS will consider the 90th day to be the next business day.

(4) HHS may send written notice of its need for additional information as many times as necessary to obtain the complete information necessary to review the revised Blueprint.

(5) HHS may disapprove a Blueprint that is not consistent with section 1331 of the ACA or the regulations set forth in this Part at any time during the review process, including when the 90-day review clock is stopped due to a request for additional information.

(d) *Continued operation.* The State is responsible for continuing to operate under the terms of the existing certified Blueprint until and unless—

(1) The State adopts a revised Blueprint by obtaining approval by HHS under this section;

(2) The State follows the procedures described in § 600.140(a) for terminating a BHP;

(3) The State follows the procedures described in § 600.140(b) for suspending a BHP;

(4) The Secretary withdraws certification of a BHP under 600.142.

(e) *Withdrawal of a revised Blueprint.* A State may withdraw a proposed Blueprint revision during HHS' review if the State has not yet implemented the proposed changes and provides written notice to HHS.

(f) *Reconsideration of decision.* HHS will accept a State request for reconsideration of a decision not to certify a revised Blueprint and provide an impartial review against the standards for certification if requested.

(g) *Public health emergency.* For the Public Health Emergency, as defined in § 400.200 of this chapter, the State may submit to the Secretary for review and certification a revised Blueprint, in the form and manner specified by HHS, that makes temporary significant changes to its BHP that are directly related to the Public Health Emergency and would increase enrollee access to coverage. Such revised Blueprints may have an effective date retroactive to the first day of the Public Health Emergency and through the last day of the Public Health Emergency, or a later date if requested by the State and certified by HHS. Such revised Blueprints are not subject to the public comment requirements under § 600.115(c).

■ 123. Section 600.135 is amended by revising the section heading and paragraph (a) to read as follows:

§ 600.135 Notice and timing of HHS action on an initial BHP Blueprint submission.

(a) *Timely response.* HHS will act on all initial Blueprint certification requests in a timely manner.

* * * * *

■ 124. Section 600.140 is amended by adding introductory text and paragraphs (b) through (d) to read as follows:

§ 600.140 State termination or suspension of a BHP.

A State that no longer wishes to operate a BHP may terminate or suspend its BHP:

* * * * *

(b) If a State decides to suspend its BHP, or to request an extension of a previously-approved suspension, the State must:

(1) Submit to the Secretary a suspension application or a suspension extension application, as applicable. The suspension or suspension extension application must:

(i) Demonstrate that the benefits BHP-eligible individuals will receive during the suspension are equal to the benefits provided under the certified BHP Blueprint in effect on the effective date of suspension;

(ii) Demonstrate that the median actuarial value of the coverage provided to the BHP-eligible individuals during the suspension is no less than the median actuarial value of the coverage under the certified BHP Blueprint in effect on the effective date of suspension;

(iii) Demonstrate that the premiums imposed on BHP-eligible individuals during the suspension are no higher than the premiums charged under the certified BHP Blueprint in effect on the effective date of suspension, except that premiums imposed during the suspension may be adjusted for inflation, as measured by the Consumer Price Index;

(iv) Demonstrate that the eligibility criteria for coverage during the suspension is not more restrictive than the criteria described in § 600.305;

(v) Describe the period, not to exceed 5 years, that the State intends to suspend its BHP or to extend a previously-approved suspension;

(vi) Be submitted at least 9 months in advance of the proposed effective date of the suspension or extension, except for States seeking to suspend a BHP in the first plan year that begins following publication of this rule must submit an application within 30 days of publication of this rule; and

(vii) Include an evaluation of the coverage provided to BHP eligible individuals during the suspension period, if the State is seeking an extension.

(2) Resolve concerns expressed by HHS and obtain approval by the Secretary of the suspension or suspension extension application. Suspensions may not be in effect prior to approval by HHS, except for States seeking to suspend a BHP in the first plan year that begins following publication of this rule.

(3) At least 90 days prior to the effective date of the suspension, submit written notice to all enrollees and participating standard health plan offerors that it intends to suspend the program, if the enrollees will experience a change in coverage, or standard health plan offerors will experience a change in the terms of coverage. The notices to enrollees must include information regarding the State's assessment of their eligibility for all other insurance affordability programs in the State. Notices must meet the accessibility and readability standards at 45 CFR 155.230(b).

(4) Within 12 months of the suspension effective date, submit to HHS the data required by § 600.610 needed to complete the financial reconciliation process with HHS.

(5) Submit the annual report required by § 600.170(a)(2), describing the

balance of the trust fund, and any interest accrued on such amount.

(6) Annually, remit to HHS any interest that has accrued on the balance of the BHP trust fund during the suspension period in the form and manner specified by HHS.

(7) At least 9 months before the end of the suspension period described in paragraph (b)(1)(iv) of this section, or earlier date elected by the State, the State must submit to HHS a transition plan that describes how the State will be reinstate its BHP consistent with the requirements of this part, or terminate the program in accordance with paragraph (a) of this section. The State must meet the noticing requirements of paragraph (b)(3) of this section prior to terminating or reinstating the BHP.

(c) The State cannot implement the suspension or extension of the suspension without prior approval by the Secretary.

(d) The Secretary may withdraw approval of the suspension plan, if the terms of paragraph (b) of this section are not met, if the State ends implementation of the alternative coverage program for any reason, or if HHS finds significant evidence of beneficiary harm, financial malfeasance, fraud, waste, or abuse by the BHP agency or the State consistent with § 600.142 of this part. If HHS withdraws the approved suspension plan, the State must reinstate its BHP under the terms of this Part, or terminate the program under paragraph (a) of this section.

(1) Withdrawal of approval of a suspension under this section must occur only after the Secretary provides the State with notice of the findings upon which the Secretary is basing the withdrawal; a reasonable period for the State to address the finding; and an opportunity for a hearing before issuing a final finding.

(2) The Secretary must make every reasonable effort to work with the State to resolve proposed findings without withdrawing approval of a suspension and in the event of a decision to withdraw approval, will accept a request from the State for reconsideration.

(3) The effective date of an HHS determination withdrawing approval of the suspension plan shall not be earlier than 120 days following issuance of a final finding under paragraph (b)(6)(i) of this section.

(4) Within 30 days following a final finding under paragraph (b)(6)(i) of this section, the State must submit a transition plan to HHS.

■ 125. Section 600.145 is amended by revising paragraphs (a) and (f)(2) to read as follows:

§ 600.145 State program administration and operation.

(a) *Program operation.* The State must implement its BHP in accordance with:

(1) The approved and fully certified State BHP Blueprint, any approved modifications to the State BHP Blueprint and the requirements of this chapter and applicable law; or

(2) The approved suspension application described in § 600.140.

* * * * *

(f) * * *

(2) Eligibility and health services appeals as specified in 600.335.

* * * * *

■ 126. Section 600.170 amended by revising paragraph (a) to read as follows:

§ 600.170 Annual report content and timing.

(a) *Content.* (1) The State that is operating a BHP must submit an annual report that includes any evidence of fraud, waste, or abuse on the part of participating providers, plans, or the State BHP agency known to the State, and a detailed data-driven review of compliance with the following:

(i) Eligibility verification requirements for program participation as specified in § 600.345.

(ii) Limitations on the use of Federal funds received by the BHP as specified in § 600.705.

(iii) Requirements to collect quality and performance measures from all participating standard health plans focusing on quality of care and improved health outcomes as specified in sections 1311(c)(3) and (4) of the Affordable Care Act and as further described in § 600.415.

(iv) Requirements specified by the Secretary at least 120 days prior to the date of the annual report as requiring further study to assess continued State compliance with Federal law, regulations and the terms of the State's certified Blueprint, based on a Federal review of the BHP pursuant to § 600.200, and/or a list of any outstanding recommendations from any audit or evaluation conducted by the HHS Office of Inspector General that have not been fully implemented, including a statement describing the status of implementation and why implementation is not complete.

(2) A State that has suspended its BHP under § 600.140(b) of this part must submit an annual report that includes the following:

(i) The balance of the BHP trust fund and any interest accrued on that balance;

(ii) An assurance that the coverage provided to individuals who would be eligible for a BHP under § 600.305 of this part continues to meet the standards described in § 600.140(b)(1)(i), (ii), and (iii) of this part; and

(iii) Any additional information specified by the Secretary at least 120 days prior to the date of the annual report.

* * * * *

■ 127. Section 600.330 is amended by adding paragraph (f) to read as follows:

§ 600.330 Coordination with other insurance affordability programs.

* * * * *

(f) *Accessibility.* Eligibility notices must be written in plain language and be provided in a manner which ensures individuals with disabilities are provided with effective communication and takes steps to provide meaningful access to eligible individuals with limited English proficiency.

■ 128. Section 600.335 is amended by revising paragraph (b) to read as follows:

§ 600.335 Appeals.

* * * * *

(b) *Appeals process.* Individuals must be given the opportunity to appeal through the appeals rules of the State's Medicaid program:

(1) BHP eligibility determinations; and

(2) Delay, denial, reduction, suspension, or termination of health services, in whole or in part, including a determination about the type or level of service.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

BILLING CODE 4120–01–P

The following appendices will not appear in the Code of Federal Regulations.

APPENDIX 1: MIPS QUALITY MEASURES

Except as otherwise noted in this proposed rule, previously finalized measures and specialty measures sets will continue to apply for the CY 2024 performance period/2026 MIPS payment year and future years. Previously finalized measures and specialty measures sets are located in the CY 2017 through CY 2023 PFS final rules: 81 FR 77558 through 77816, 82 FR 53966 through 54174, 83 FR 60097 through 60285, 84 FR 63205 through 63513, 85 FR 85045 through 85369, 86 FR 65687 through 65968, and 87 FR 70250 through 70633. In addition, electronic clinical quality measures (eCQMs) that are endorsed by a consensus-based entity (CBE) are shown in Table A of this Appendix as follows: CBE # / eCQM CBE #.

Table Group A: New Quality Measures Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

A.1. Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level)

Category	Description
CBE # / eCQM CBE #:	CBE 3633e (clinician level) CBE 3662e (clinician group level)
Quality #:	TBD
Description:	This measure provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses, a risk factor for cancer, while preserving image quality. It is expressed as a percentage of CT exams that are out-of-range based on having either excessive radiation dose or inadequate image quality relative to evidence-based thresholds based on the clinical indication for the exam. All diagnostic CT exams of specified anatomic sites performed in inpatient, outpatient and ambulatory care settings are eligible. This eCQM requires the use of additional software to access primary data elements stored within radiology electronic health records and translate them into data elements that can be ingested by this eCQM. Additional details are included in the Guidance field.
Measure Steward:	Alara Imaging, Inc. in collaboration with the University of California, San Francisco (UCSF)
Numerator:	Calculated CT size-adjusted dose greater than or equal to a threshold specific to the CT dose and Image Quality Category, or Calculated CT Global Noise value greater than or equal to a threshold specific to the CT Dose and Image Quality Category.
Denominator:	All CT scans in adults aged 18 years and older at the start of the measurement period that have a CT Dose and Image Quality Category and were performed during the measurement period.
Exclusions:	Denominator, where a CT scan with a CT Dose and Image Quality Category = full body.
Measure Type:	Intermediate Outcome
High Priority Measure:	Yes
Collection Type:	eCQM Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure to enhance patient safety and drive quality care in diagnostic radiology and assess outcomes of care for patients undergoing diagnostic CT imaging. This measure would improve patient safety by supporting clinician actions that are associated with a reduction in population-level cancer risks, in addition to associated cancer-related morbidity and mortality. As a result, this measure may also reduce the cost of caring for these patients. In the U.S., over 80 million CT scans are performed annually, and the radiation doses associated with these exams are a safety issue, as unnecessarily high radiation doses lead to harm by exposing patients to elevated cancer risk.[397] Numerous consensus-based clinical recommendations and guidelines ask radiologists to track, optimize, and lower the radiation doses they use for CT. These recommendations and guidelines are based on evidence that radiation doses are highly variable across institutions, higher than needed for diagnosis, and can lead to excessive patient harm. These recommendations and guidelines also indicate that physicians collect and compare their doses to benchmarks and reduce their doses if they are found to routinely exceed these

[397] Harvard Health Publishing (2021). Radiation Risk from Medical Imaging. *https://www.health.harvard.edu/cancer/radiation-risk-from-medical-imaging.*

	benchmarks.[398] [399] This measure would support radiologists with a clinically relevant outcome measure within MIPS and meet the high priority definition for MIPS reporting as an outcome and patient safety measure. This measure received support for rulemaking from the Measure Applications Partnership (MAP) and was endorsed by a CBE (CBE 3633e/3662e). This measure would enhance the accessibility of data contained in electronic clinical data systems for increased efficiency, which could decrease clinician burden. Using electronic and standardized data already collected as part of routine clinical care, this measure assesses the radiation dose for every exam with complete information and assessment of imaging quality to ensure that efforts to reduce radiation dose do not result in poor image quality. It is also consistent with our emphasis on expanding the use of digital quality measures. The measure steward has created "as low as reasonably achievable" (ALARA) translation software that ingests radiology variables from Picture Archiving and Communication System (PACS), Radiology Information System (RIS), and electronic health records (EHR) systems for use with this quality measure. The software translates data from these systems into new variables that are specified in Logical Observation Identifiers Names and Codes (LOINC®), reflecting radiation dose and image quality information for each scan, that can then be used for reporting this measure. This translation software would be available to all clinicians and sites without cost, including any updates that need to be completed. Additionally, software tutorials, training, and webinars would also be provided at no cost. This measure is more robust than existing measure Q436: Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques, which is proposed for removal under Table C.12 of this Appendix to reduce duplication concurrent to the proposed adoption of this measure. This proposed measure assesses actual radiation dosing in patients undergoing diagnostic CT imaging, whereas the current measure assesses only utilization of dose optimization techniques (that is, a radiologist's choice of protocol) as documented within the final report. This proposed measure is an intermediate outcome measure of radiation dose, which is strongly associated with cancer risk. This measure covers the two key process of care components that determine the radiation doses: a) the choice of imaging protocol; and b) decisions regarding the technical settings used for that type of CT exam. It assesses radiation dose according to thresholds determined by the underlying clinical indication for imaging and not based upon radiologists' choice of protocol. In addition, this measure includes assessment of image quality as a means of thereby protecting the diagnostic value of CT imaging from unintended consequences of excessive dose reduction. Minimizing dose by adherence to these factors would reduce the number of future cancers that would result from the radiation exposure, and that could in turn lead to a reduction in morbidity, mortality, and health care costs.[400] [401] [402] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[398] Kanal, K. M., Butler, P. F., Sengupta, D., Bhargavan-Chatfield, M., Coombs, L. P., & Morin, R. L. (2017). US Diagnostic Reference Levels and Achievable Doses for 10 Adult CT Examinations. Radiology, 284(1), 120-133. *https://pubs.rsna.org/doi/full/10.1148/radiol.2017161911.*

[399] American College of Radiology, The American Association of Physicists in Medicine, & The Society for Pediatric Radiology. (2022). ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment. *https://www.acr.org/-/media/ACR/Files/Practice-Parameters/CT-Equip.pdf, https://www.aapm.org/pubs/ACRAAPMCollaboration.asp.*

[400] Smith-Bindman, R., Wang, Y., Chu, P., Chung, R., Einstein, A. J., Balcombe, J., Cocker, M., Das, M., Delman, B. N., Flynn, M., Gould, R., Lee, R. K., Nelson, T. R., Schindera, S., Seibert, A., Starkey, J., Suntharalingam, S., Wetter, A., Wildberger, J. E., & Miglioretti, D. L. (2019). International Variation in Radiation Dose for Computed Tomography Examinations: Prospective Cohort Study. BMJ (Clinical research ed.), 364, k4931. *https://doi.org/10.1136/bmj.k4931.*

[401] Smith-Bindman, R., Chu, P., Wang, Y., Chung, R., Lopez-Solano, N., Einstein, A. J., Solberg, L., Cervantes, L. F., Yellen-Nelson, T., Boswell, W., Delman, B. N., Duong, P. A., Goode, A. R., Kasraie, N., Lee, R. K., Neill, R., Pahwa, A., Pike, P., Roehm, J., Schindera, S., … Miglioretti, D. L. (2020). Comparison of the Effectiveness of Single-Component and Multicomponent Interventions for Reducing Radiation Doses in Patients Undergoing Computed Tomography: A Randomized Clinical Trial. *JAMA Internal Medicine*, *180*(5), 666–675. *https://doi.org/10.1001/jamainternmed.2020.0064.*

[402] Berrington de González, A., Mahesh, M., Kim, K. P., Bhargavan, M., Lewis, R., Mettler, F., & Land, C. (2009). Projected Cancer Risks from Computed Tomographic Scans Performed in the United States in 2007. *Archives of Internal Medicine*, *169*(22), 2071–2077. *https://doi.org/10.1001/archinternmed.2009.440.*

A.2. Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.
Measure Steward:	American Academy of Hospice and Palliative Medicine (AAHPM)
Numerator:	The Feeling Heard and Understood (HU) survey is calculated using top-box scoring within 2 months (60 days) of the ambulatory palliative care visit. Numerator 1: Patient felt heard and understood by this provider and team. Numerator 2: Patient felt this provider and team put my best interests first when making recommendations about my care. Numerator 3: Patient felt this provider and team saw me as a person, not just someone with a medical problem. Numerator 4: Patient felt this provider and team understood what is important to me in my life.
Denominator:	Denominator 1, 2, 3, and 4: All patients aged 18 years and older who had an ambulatory palliative care visit.
Exclusions:	Patients who did not complete at least one of the four patient experience HU survey items and return the HU survey within 60 days of the ambulatory palliative care visit. Patients who respond on the patient experience HU survey that they did not receive care by the listed ambulatory palliative care provider in the last 60 days (disavowal). Patients who were deceased when the HU survey reached them. Patients for whom a proxy completed the entire HU survey on their behalf for any reason (no patient involvement).
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this patient-reported outcome measure because it would fill a gap in the current quality measure inventory for patients receiving palliative care. The Feeling Heard and Understood survey was developed to capture patients' assessment of their care for ongoing quality reporting and improvement. This survey measures patients' satisfaction of their ambulatory palliative care experience based on how well they felt heard and understood by physicians, nurses, and other hospital staff. This proposed measure captures the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Assessment of how well patients feel heard and understood complements and adds an important dimension to existing quality measures of care planning by including patient experience of care for this unique patient population.[403] This measure is intended to facilitate and improve effective patient-provider communication that better engenders trust, acknowledgement, and a whole-person orientation to the care that is provided. The outcome of this measure is that the patient feels heard and understood by the ambulatory palliative care provider and team. Through the benefits of enhanced patient-provider communication, this measure would improve the quality of care received and outcomes for patients receiving palliative care. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agree with the MAP that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. This measure is predicated on existing guidelines including the National Consensus Project Clinical Practice Guidelines for Quality Palliative Care and supported by a systematic review of current evidence for palliative care interventions.[404] Evidence from the systematic review supports advanced care planning. Studies have shown that quality palliative care and communication between patients and providers are associated with increased preference-concordant care.[8] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[403] Edelen, M. O., Rodriguez, A., Huang, W., Gramling, R., & Ahluwalia, S. C. (2022). A Novel Scale to Assess Palliative Care Patients' Experience of Feeling Heard and Understood. Journal of Pain and Symptom Management, 63(5), 689–697.e1. *https://doi.org/10.1016/j.jpainsymman.2022.01.002.*

[404] Ahluwalia, S. C., Chen, C., Raaen, L., Motala, A., Walling, A. M., Chamberlin, M., O'Hanlon, C., Larkin, J., Lorenz, K., Akinniranye, O., & Hempel, S. (2018). A Systematic Review in Support of the National Consensus Project Clinical Practice Guidelines for Quality Palliative Care, Fourth Edition. J Pain Symptom Manage, 56(6), 831-870. *https://www.nationalcoalitionhpc.org/ncp/.*

A.3. Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of pregnant or postpartum patients who received a cardiovascular disease (CVD) risk assessment with a standardized instrument.
Measure Steward:	University of California, Irvine
Numerator:	Patients who are assessed for CVD risk via California Maternal Quality Care Collaborative (CMQCC) standardized algorithm. A completed CVD risk assessment will determine the patient to be at low risk or high risk of CVD. Patients will be assessed at their initial encounter with their healthcare provider for pregnancy-related care [prenatal visit, L&D, postpartum visit] and may need to repeat assessments if new symptoms develop.
Denominator:	Patients who have an office visit for prenatal or postpartum care, regardless of gestational age or prior prenatal care at other sites, for any age (including pregnant and postpartum minors), within outpatient obstetric (OB) visit at the hospital or in affiliated clinics; and labor and delivery (L&D) including private providers contracting with the hospital for delivery.
Exclusions:	Patients who have another reason for visiting the clinic [not prenatal or postpartum care] and have a positive pregnancy test but have not established the clinic as OB provider (e.g., plan to terminate the pregnancy or seek prenatal services elsewhere). Prior history of known CVD.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure because it would fill a high priority clinical gap area under the wellness and prevention domain for maternal health. This process measure would address screening and care for pregnant/postpartum patients by assessing for the completion of a standardized CVD risk assessment for this high-risk population. This measure would represent a new quality measure clinical concept for maternal health. CVD is the leading cause of maternal mortality in the U.S., accounting for over one-third of all pregnancy-related deaths.[405] Peripartum cardiomyopathy (PPCM) constitutes the largest group among CVD-related deaths. About 24 percent of all CVD pregnancy-related deaths (and 31 percent of cardiomyopathy deaths) were determined to be potentially preventable.[406] CVD also accounts for many folds higher maternal morbidity, a longer length of hospital stays, intensive care unit (ICU) admissions, and future pregnancy risks.[407] This measure would monitor follow-up to universal cardiovascular risk assessment in all pregnant patients at their first encounter with an obstetrics provider.[408] The measure facilitates clinicians to evaluate pregnant or postpartum patients presenting with symptoms such as shortness of breath, cough, or excessive fatigue in the context of risk factors, vital sign abnormalities, and abnormal physical examination findings.[409] Normal physiological changes in pregnancy lead to signs and symptoms that may be indistinguishable from those of CVD. The overlap of signs and symptoms of normal pregnancy with those of CVD further complicates timely diagnosis. Most women who died from CVD during pregnancy and/or the postpartum period were not suspected of having a cardiac diagnosis and symptoms were attributed to an alternate diagnosis. Roughly 84 percent of pregnant patients who died from CVD presented with symptoms concerning for cardiopulmonary disease. However, only 61.1 percent of these patients were referred to cardiologists, and, of those, only 7 percent were referred antenatally. Given the large proportion of pregnancy-related mortality attributed to cardiovascular disease, these data suggest that an implementation of universal screening may improve overall

[405] Creanga, A. A., Syverson, C., Seed, K., & Callaghan, W. M. (2017). Pregnancy-Related Mortality in the United States, 2011-2013. Obstetrics and Gynecology, 130(2), 366–373. https://doi.org/10.1097/AOG.0000000000002114.

[406] Hameed, A.B., Foster, E., Main, E.K., Khandelwal, A., & Lawton, E.S. (2017). Cardiovascular Disease Assessment in Pregnant and Postpartum Women - California Maternal Quality Care Collaborative. Cardiovascular Disease in Pregnancy Toolkit. *https://www.cmqcc.org/content/cardiovascular-disease-assessment-pregnant-and-postpartum-women.*

[407] Fraser, A., Nelson, S. M., Macdonald-Wallis, C., Cherry, L., Butler, E., Sattar, N., & Lawlor, D. A. (2012). Associations of Pregnancy Complications with Calculated Cardiovascular Disease Risk and Cardiovascular Risk Factors in Middle Age: The Avon Longitudinal Study of Parents and Children. Circulation, 125(11), 1367–1380. *https://doi.org/10.1161/CirculationAHA.111.044784.*

[408] Writing Committee Members, Greenland, P., Alpert, J. S., Beller, G. A., Benjamin, E. J., Budoff, M. J., & Wenger, N. K. (2010). 2010 ACCF/AHA Guideline for Assessment of Cardiovascular Risk in Asymptomatic Adults: Executive Summary: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation, 122(25), 2748-2764. *https://www.ahajournals.org/doi/10.1161/CIR.0b013e3182051bab.*

[409] Abbas, A. E., Lester, S. J., & Connolly, H. (2005). Pregnancy and the Cardiovascular System. International Journal of Cardiology, 98(2), 179-189. *https://www.internationaljournalofcardiology.com/article/S0167-5273(04)00040-3/fulltext.*

Category	Description
	maternal outcomes and lower overall healthcare costs.[410] Use of this measure promotes improvement in the screening of pregnant and postpartum women for the accurate diagnosis of heart failure or CVD versus attributing symptoms of pneumonia or other clinical side effects from pregnancy such as persistent cough, shortness of breath, and/or bilateral infiltrates on a chest x-ray. The intent of assessing the CVD risk during pregnancy/postpartum care is to increase education and awareness in this population and would empower patients to seek early medical care if new signs and symptoms develop that may be suggestive of CVD. It may have implications for long-term health outcomes with improvements in the CVD risk factor profile in the future. The use of a standardized CVD measure to risk-stratify pregnant and postpartum patients may improve the timely identification of CVD, thereby decreasing maternal morbidity and/or mortality. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agree with the MAP that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. The Alliance for Innovation on Maternal Health (AIM) identified the California Maternal Quality Care Collaborative (CMQCC) CVD Assessment Algorithm for Pregnant and Postpartum Patients as an emerging best practice and an important tool for assessing symptoms and risk in a standardized way and advocated for the use of the tool in its Cardiac Conditions in Obstetrical Care Bundle (CCOC).[411] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS *at https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[410] Chambers, M. E., De Zoysa, M. Y., & Hameed, A. B. (2022). Screening for Cardiovascular Disease in Pregnancy: Is There a Need? Journal of cardiovascular development and disease, 9(3), 89. *https://doi.org/10.3390/jcdd9030089.*

[411] Alliance for Innovation on Maternal Health. Cardiac Conditions in Obstetrical Care Bundle. *https://saferbirth.org/psbs/cardiac-conditions-in-obstetric-care/.*

A.4. First Year Standardized Waitlist Ratio (FYSWR)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	The number of incident (newly initiated on dialysis) patients in a practitioner (inclusive of physicians and advanced practice providers) group who are under the age of 75, and were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant within the first year of initiating dialysis. The measure is calculated to compare the observed number of waitlist events in a practitioner group to its expected number of waitlist events. The measure uses the expected waitlist events calculated from a Cox model, adjusted for age, patient comorbidities, and other risk factors at incidence of dialysis.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Patients in the practitioner group's denominator listed on the kidney or kidney-pancreas transplant waitlist or who received living donor transplants within the first year following initiation of dialysis.
Denominator:	The denominator for the First Year Standardized Waitlist Ratio (FYSWR) is the expected number of waitlist or living donor transplant events in the practitioner group according to each patient's treatment history for patients within the first year following initiation of dialysis, adjusted for age, incident comorbidities, dual Medicare-Medicaid eligibility, Area Deprivation Index (from patient's residence zip code) and transplant center characteristics, among patients under 75 years of age who were not already waitlisted and did not have kidney transplantation prior to the initiation of end-stage renal disease (ESRD) dialysis. The number of days at risk (time from start of dialysis to the earliest of being placed on the waitlist, receiving a living donor transplant, death, or one year from start of dialysis) for each patient is used to calculate the expected waitlist or living donor transplant events.
Exclusions:	Patients aged 75 or older on their initiation of dialysis date. Patients admitted to a skilled nursing facility (SNF). Patients in hospice on their initiation of dialysis date or during the month of evaluation. Patients that were on the kidney or kidney-pancreas waitlist prior to initiation of dialysis. Patients who had a transplant prior to initiation of dialysis.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	If a dialysis practitioner group has fewer than 11 patients or 2 expected events, then the dialysis practitioner group is excluded from reporting outcomes.
Rationale:	We are proposing this measure because it addresses a CMS high priority clinical topic: patients with ESRD. ESRD affects nearly 786,000 Americans, and dialysis for ESRD patients represents a significant portion of annual Medicare expenditures (*https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease*). While dialysis is a treatment for ESRD, it is associated with increased mortality and lower quality of life for ESRD patients when compared to kidney transplant (*https://pubmed.ncbi.nlm.nih.gov/34783494/*). This measure assesses whether patients that are in their first year of dialysis were placed on the kidney or kidney-pancreas transplant waitlist or received a living donor kidney transplant. Data submitted by the measure developer indicates a performance gap for a process that can be directly linked to improved patient outcomes. This measure is separate from the other transplant waitlist measure, proposed under Table A.5 of this Appendix, as it is limited to assessing the first year after initiation of dialysis and the timely addition of those patients to the transplant waitlist—a crucial step in driving positive outcomes in the patient population. National and large regional studies provide strong empirical support for the association between processes within the clinical scope and control of dialysis practitioners and subsequent patient transplant wait listing. For example, the clinical assessments, provisions and/or referrals made by a dialysis practitioner are contributing factors for consideration in patient transplant wait listing. In one large regional study conducted on facilities in the state of Georgia, a standardized dialysis facility referral ratio was developed, adjusted for age, demographics, and comorbidities.[412] There was substantial variability across dialysis facilities in referral rates, and a Spearman correlation performed between ranking on the referral ratio and dialysis facility waitlist rates was highly significant ($r=0.35$, $p<0.001$).[16] A national study using registry data (United States Renal Data System) from 2005-2007 examined the association between whether patients were informed about kidney transplantation (based on reporting on the Medical Evidence Form 2728 *(https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS2728.pdf*) and subsequent access to kidney transplantation (wait listing or receipt of a live donor transplant).[413] Approximately 30 percent of patients were uninformed about kidney transplantation, and this was associated with half the rate of access to transplantation compared to patients who were informed.[17] In a related survey study of 388 hemodialysis patients, whether provision of information about transplantation by nephrologists or dialysis staff occurred was directly confirmed with patients.[414] The provision of such information was associated with a near threefold increase in likelihood of wait listing.[18] The intent of this measure is to track the initial placement on the kidney or kidney-pancreas transplantation waitlist or receipt of a living donor transplant within the first year after dialysis initiation, with the intended objective of improving the overall

[412] Paul, S., Plantinga, L. C., Pastan, S. O., Gander, J. C., Mohan, S., & Patzer, R. E. (2018). Standardized Transplantation Referral Ratio to Assess Performance of Transplant Referral among Dialysis Facilities. Clinical Journal of the American Society of Nephrology, 13(2), 282-289. *https://doi.org/10.2215/CJN.04690417.*

[413] Kucirka, L. M., Grams, M. E., Balhara, K. S., Jaar, B. G., & Segev, D. L. (2012). Disparities in Provision of Transplant Information Affect Access to Kidney Transplantation. American Journal of Transplantation, 12(2), 351-357. *https://doi.org/10.1111/j.1600-6143.2011.03865.x.*

[414] Salter, M. L., Orandi, B., McAdams-DeMarco, M. A., Law, A., Meoni, L. A., Jaar, B. G., ... & Segev, D. L. (2014). Patient-and Provider-Reported Information about Transplantation and Subsequent Waitlisting. Journal of the American Society of Nephrology, 25(12), 2871-2877. *https://doi.org/10.1681/ASN.2013121298.*

Category	Description
	health of patients on dialysis. Being waitlisted or receiving a living donor kidney transplant represents a desirable change in health status for patients on dialysis, indicating achievement of a health condition conducive to kidney transplantation. Being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities and may include education of patients about the option of transplantation, referral of patients to a transplant center for evaluation, completion of the evaluation process, and optimizing the health of the patient while on dialysis. These efforts depend heavily and, in many cases, primarily, on dialysis practitioner groups. Aspects that are not directly in the clinician/groups control can be influenced through coordination of care, strong communication with transplant centers, and advocacy for patients. All clinicians should be involved and actively work towards providing patients with high quality care including ensuring placement on the transplant list as quickly as possible. The MAP did not support this measure for rulemaking with the potential for mitigation. The Renal Standing Committee raised concerns regarding the evidence base and specifications and recommended that this measure be resubmitted for endorsement by a CBE. While we agree with the MAP that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. As discussed above, studies suggest a significant association between the clinician activities described above and the addition of patients to a transplant waitlist, which is necessary for patients to receive the improved outcomes associated with kidney transplant. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

A.5. Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	The percentage of patients in each dialysis practitioner group practice who were on the kidney or kidney-pancreas transplant waitlist (all patients or patients in active status). Results are averaged across patients prevalent on the last day of each month during the reporting year. The measure is a directly standardized percentage, which is adjusted for covariates (e.g., age and risk factors).
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Numerator 1: Percentage of Prevalent Patients Waitlisted (PPPW): The adjusted count of patient months in which the patient at the dialysis practitioner or practitioner group practice is on any kidney or kidney-pancreas transplant waitlist as of the last day of each month during the reporting year. Numerator 2: Percentage of Prevalent Patients Waitlisted in Active (aPPPW): The adjusted count of patient months in which the patient at the dialysis practitioner or practitioner group practice is on any kidney or kidney-pancreas transplant waitlist in an active status as of the last day of each month during the reporting year.
Denominator:	Denominator 1 and 2: All patient-months for patients who are under the age of 75 in the reporting month and who are assigned to a dialysis practitioner or practitioner group practice according to each patient's treatment history on the last day of each reporting month during the performance year. If a dialysis practitioner group has fewer than 11 patients during the performance year, the dialysis practitioner group is excluded from reporting outcomes.
Exclusions:	Patients who were admitted to a skilled nursing facility (SNF) during the month of evaluation were excluded from that month. Patients who were admitted to a skilled nursing facility (SNF) within one year of dialysis initiation according to the CMS-2728 form. Patients determined to be in hospice were excluded from month of evaluation and the remainder of reporting period. Patients with dementia at any time prior to or during the month.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	If a dialysis practitioner group has fewer than 11 patients during the performance year, the dialysis practitioner group is excluded from reporting outcomes.
Rationale:	We are proposing this measure because it addresses a CMS priority clinical topic: patients with ESRD. ESRD affects nearly 786,000 Americans, and dialysis for ESRD patients represents a significant portion of annual Medicare expenditures *(https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease)*. While dialysis is a treatment for ESRD, it is associated with increased mortality and lower quality of life for ESRD patients when compared to kidney transplant *(https://pubmed.ncbi.nlm.nih.gov/34783494/)*. This measure captures the adjusted count of patient months on the kidney and kidney-pancreas transplant waitlist for all dialysis patients in a dialysis practitioner or group practice by assessing patient status on the last day of each month during the reporting year and those on the transplant waitlist in active status as of the last day of the month during the reporting year. This process measure is directly linked to driving positive outcomes and measure data indicates a performance gap. Most ESRD patients have to wait to eventually access a deceased donor transplant (national median of roughly 4 years).[415] Maintenance of 'active status' on the transplant list requires ongoing collaboration between dialysis practitioners, transplant centers, and transplant networks, thereby ensuring sustained suitability for a transplant while optimizing the health of patients.[20] This maintenance process is associated with higher transplantation rates and lowered mortality rates while on the waitlist.[416] In addition, the maintenance of 'active status' is an important health equity issue. Research has found disparities in access to kidney transplant by race.[417] Race-neutral efforts by clinicians to encourage maintenance of patients on the waitlist may reduce such disparities while improving their performance on this measure.[21] This measure assesses monthly wait listing in active status of patients. It also evaluates and encourages maintenance of patients on the waitlist. This is an important area to which dialysis practitioners can contribute through ensuring patients remain healthy and complete any ongoing testing activities required to remain active on the waitlist. In contrast to this measure, the First Year Standardized Waitlist Ratio measure proposed under Table A.4 of this Appendix focuses solely on new wait listings and living donor kidney transplants to incentivize early action, rather than ongoing maintenance on the waitlist, which this measure assesses. The MAP conditionally supported this measure for rulemaking pending an update of the measure's specifications to include only the PPPW (CBE 3695) rate that was recommended for endorsement by the CBE's Renal Standing Committee. While we agree with the MAP that full CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets

[415] Johansen, K. L., Chertow, G. M., Foley, R. N., Gilbertson, D. T., Herzog, C. A., Ishani, A., ... & Wetmore, J. B. (2021). US Renal Data System 2020 Annual Data Report: Epidemiology of Kidney Disease in the United States. American Journal of Kidney Diseases, 77(4), A7-A8. *https://www.ajkd.org/article/S0272-6386(21)00024-X/fulltext.*

[416] Grams, M. E., Massie, A. B., Schold, J. D., Chen, B. P., & Segev, D. L. (2013). Trends in the Inactive Kidney Transplant Waitlist and Implications for Candidate Survival. American Journal of Transplantation, 13(4), 1012-1018. *https://onlinelibrary.wiley.com/doi/pdf/10.1111/ajt.12143.*

[417] Kulkarni, S., Ladin, K., Haakinson, D., Greene, E., Li, L., & Deng, Y. (2019). Association of Racial Disparities with Access to Kidney Transplant after the Implementation of the New Kidney Allocation System. JAMA surgery, 154(7), 618-625. *https://jamanetwork.com/journals/jamasurgery/fullarticle/2729436.*

Category	Description
	the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. The CBE recommended endorsement for the PPPW subset of this measure. It is important to include the aPPPW rate in this measure as well to capture patients in active waitlist status and the full scope of the transplant list and the movement of patients between active and inactive status. The studies cited above provide the evidentiary basis for the adoption of this measure. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

A.6. Preventive Care and Wellness (composite)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Numerator 1: Patients who received an influenza immunization OR who reported previous receipt of an influenza immunization. Numerator 2: Patients who were administered any pneumococcal conjugate vaccine or polysaccharide vaccine on or after their 19th birthday and before the end of the measurement period. Numerator 3: Women with one or more mammograms any time on or between October 1 two years prior to the measurement period and the end of the measurement period. Numerator 4: Patients with one or more screenings for colorectal cancer. Appropriate screenings are defined by any one of the following criteria: - Fecal occult blood test (FOBT) during the measurement period. – Flexible sigmoidoscopy during the measurement period or the four years prior to the measurement period. – Colonoscopy during the measurement period or the nine years prior to the measurement period. – Computed tomography (CT) colonography during the measurement period or the four years prior to the measurement period. – Stool DNA (sDNA) with Fecal immunochemical test (FIT) during the measurement period or the two years prior to the measurement period. Numerator 5: Patients with a documented BMI during the encounter or during the previous twelve months, AND when the BMI is outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the encounter. Numerator 6: - Patients who were screened for tobacco use at least once within the measurement period. – Patients who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period. – Patients who were screened for tobacco use at least once within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user. Numerator 7: 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 elevated or hypertensive.
Denominator:	Denominator 1: All patients aged 6 months and older seen for a visit during the measurement period. Denominator 2: Patients 65 years of age and older with a visit during the measurement period. Denominator 3: Women 41 – 74 years of age with a visit during the measurement period. Denominator 4: Patients 45-75 years of age with a visit during the measurement period. Denominator 5: All patients aged 18 and older on the date of the encounter with at least one qualifying encounter during the measurement period. Denominator 6: - All patients aged 12 years and older seen for at least two visits or at least one preventive visit during the measurement period. – All patients aged 12 years and older seen for at least two visits or at least one preventive visit during the measurement period who were screened for tobacco use during the measurement period and identified as a tobacco user. – All patients aged 12 years and older seen for at least two visits or at least one preventive visit during the measurement period. Denominator 7: All patient visits for patients aged 18 years and older at the beginning of the measurement period.
Exclusions:	Denominator Exclusion Population 1: Hospice services provided to patient any time during the measurement period. Anaphylaxis due to the vaccine on or before the date of the encounter. Denominator Exclusion Population 2: Patient received hospice services any time during the measurement period. Patient had anaphylaxis due to the pneumococcal vaccine any time during or before the measurement period. Denominator Exclusion Population 3: - Women who had a bilateral mastectomy or who have a history of a bilateral mastectomy or for whom there is evidence of a right and a left unilateral mastectomy. Hospice services used by patient any time during the measurement period. – Palliative care services used by patient any time during the measurement period. 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. – Patients 66 years of age and older 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. – Patients 66 years of age and older 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. Denominator Exclusion Population 4: - Patients with a diagnosis or past history of total colectomy or colorectal cancer. – Patient was provided hospice services any time during the measurement period. – Patient was provided palliative care services any time during the measurement period. Patient 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. – Patients 66 years of age and older 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. – Patients 66 years of age and older 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. Denominator Exclusion Population 5: - Documentation stating the patient has received or is currently receiving palliative or hospice care. – Documentation of patient pregnancy anytime during the measurement period prior to and including the current encounter. Denominator Exclusion Population 6: Hospice services provided to patient any time during the measurement period (applicable to each of the 3 performance rates). Denominator Exclusion Population 7: Patient not eligible due to active diagnosis of hypertension.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications

Category	Description
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
	We are proposing this composite measure which combines seven current preventive care measures with age and sex appropriate preventive screenings and wellness services to create a robust, broadly encompassing preventive care assessment. The measure developer submitted data demonstrating a performance gap for the composite measure. In testing, the developer identified a performance gap, where median performance on the combined measure was 52.7 percent, with a standard deviation of 11.2 percent. Initially, this measure would be implemented as a weighted average analytic, representing performance for quality actions linked to positive patient outcomes. This measure would set a more stringent performance standard by requiring a comprehensive set of preventive care standards be completed for each patient, working to drive quality care while ensuring more all-inclusive preventive care. By setting a more stringent performance standard through use of a single composite measure compared to the prior framework, under which each quality action was reported through a separate quality measure, we gain a better picture of overall preventive care practices as each component is important to either prevention of or early detection of disease (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4678940/*). This allows for early diagnosis of disease, thereby leading to earlier treatment, improved health outcomes, and a reduction in healthcare associated costs (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4265933/.*
Rationale:	This measure consists of seven preventive care and screening processes that are consistent with guidelines from the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices (ACIP), the American Association of Clinical Endocrinology (AACE), and the American College of Endocrinology (ACE). The seven screening processes are influenza immunization, pneumococcal immunization, breast and colorectal cancer screening, body mass index screening, tobacco use screening and cessation intervention, and screening for high blood pressure with follow-up. Each process received a recommendation of at least "Strong" or an equivalent rating from the corresponding body identified above.[418] The basis for each constituent measure was previously described in our prior rulemaking under the 2013 Physician Quality Reporting System (PQRS) in the CY 2012 PFS final rule (77 FR 69215 through 69267: Table 95 and 77 FR 69269 through 69271: Table 96), and each measure was retained with the implementation of MIPS (81 FR 77558 through 77675). In connection with the proposal of this measure, we also propose to remove measures Q112: Breast Cancer Screening, Q113: Colorectal Cancer Screening, and Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan from traditional MIPS, while retaining those three measures for use in relevant MVPs as discussed under Table Group CC of this Appendix. The MAP conditionally supported this measure for rulemaking pending endorsement of the measure by a CBE. While we agree with the MAP that full CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the

[418] Component 1: Grohskopf, L. A., Alyanak, E., Ferdinands, J. M., Broder, K. R., Blanton, L. H., Talbot, H. K., & Fry, A. M. (2021). Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices, United States, 2021–22 Influenza Season. MMWR Recommendations and Reports, 70(5), 1. *http://dx.doi.org/10.15585/mmwr.rr7005a1.*
Component 2: Kobayashi, M., Farrar, J. L., Gierke, R., Britton, A., Childs, L., Leidner, A. J., ... & Pilishvili, T. (2022). Use of 15-valent Pneumococcal Conjugate Vaccine and 20-valent Pneumococcal Conjugate Vaccine Among US Adults: Updated Recommendations of the Advisory Committee on Immunization Practices—United States, 2022. Morbidity and Mortality Weekly Report, 71(4), 109-117. *https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7104a1-H.pdf.*
Component 3: Siu, A. L., & US Preventive Services Task Force. (2016). Screening for Breast Cancer: US Preventive Services Task Force Recommendation Statement. Annals of Internal Medicine, 164(4), 279-296. *https://www.acpjournals.org/doi/10.7326/M15-2886.*
Component 4: Davidson, K. W., Barry, M. J., Mangione, C. M., Cabana, M., Caughey, A. B., Davis, E. M., ... & US Preventive Services Task Force. (2021). Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. JAMA, 325(19), 1965-1977. *https://doi.org/10.1001/jama.2021.6238.*
Component 5: Garvey, W. T., Mechanick, J. I., Brett, E. M., Garber, A. J., Hurley, D. L., Jastreboff, A. M., Nadolsky, K., Pessah-Pollack, R., Plodkowski, R., & Reviewers of the AACE/ACE Obesity Clinical Practice Guidelines (2016). American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity. Endocrine Practice: Official Journal of the American College of Endocrinology and the American Association of Clinical Endocrinologists, 22 Suppl 3, 1–203. *https://doi.org/10.4158/EP161365.GL.*
Component 6: Krist, A. H., Davidson, K. W., Mangione, C. M., Barry, M. J., Cabana, M., Caughey, A. B., ... & US Preventive Services Task Force. (2021). Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons: US Preventive Services Task Force Recommendation Statement. JAMA, 325(3), 265-279. *https://doi.org/10.1001/jama.2020.25019.*
Component 7: Krist, A. H., Davidson, K. W., Mangione, C. M., Cabana, M., Caughey, A. B., Davis, E. M., ... & US Preventive Services Task Force. (2021). Screening for Hypertension in Adults: US Preventive Services Task Force Reaffirmation Recommendation Statement. JAMA, 325(16), 1650-1656. *https://doi.org/10.1001/jama.2021.4987.*

Category	Description
	statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. The preventive care and wellness composite measure is supported based upon the evidence discussed and cited within the respective rules in which each constituent measure was proposed and finalized as indicated previously in the rationale. A study of preventive services covered under the Affordable Care Act examined the extent to which lives could be saved if adults over 18 received them, including some addressed by this measure. The authors found preventive services ameliorate 9 of the 10 leading causes of death in America and could save at least 100,000 lives,[419] providing support for this composite measure. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[419] Fox, J.B., & F.E. Shaw. (2015). Clinical Preventive Services Coverage and the Affordable Care Act. American Journal of Public Health, 105(1), e7-e10.

A.7. Connection to Community Service Provider

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.
Measure Steward:	Oregon Community Health Information Network (OCHIN)
Numerator:	Patients who had contact with a CSP for at least one of their HRSNs within 60 days after screening.
Denominator:	Patients aged 18 or older who screened positive for at least 1 of the 5 HRSNs domains (food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety) during the measurement period.
Exclusions:	Patients who are counseled on connection with a CSP and explicitly opt-out.
Measure Type:	Process
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure because it would address five social and economic determinants we have identified as both a measurement priority and performance gap. Addressing this gap is a central part of our Health Equity strategic plan pillar, as discussed in the 2023 PFS final rule (87 FR 70253 through 70259) for previously finalized measure Q487: Screening for Social Drivers of Health. This proposed measure assesses patients who screen positive for one or more of the five HRSNs for contact with a CSP for at least one of their HRSNs within 60 days of the screening. The five HRSNs are food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety. A CSP is defined as any independent, for-profit, non-profit, state, territorial, or local agency capable of addressing core or supplemental HRSNs. This measure excludes patients who opt out of contact with a CSP. Studies have shown that social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health (*https://doi.org/10.7326/M17-2441*). Thus, systematically screening patients for social drivers of health and referring them to community-based resources as needed can result in improved health outcomes (*https://doi.org/10.7326/M17-2441*). Furthermore, improving the clinician's understanding of the social obstacles their patients face beyond the clinical realm – but which may affect their clinical outcomes – can provide critical insights, catalyze prevention and/or early identification and prompt referral, improve a patient's overall health and well-being (*https://doi.org/10.31478/201705b*). As an example, early findings from the CMMI Accountable Health Communities (AHC) Model shows those patients within the "Assistance Track" (the intervention group offering navigation assistance to connect patients with the community services they need) had 9 percent fewer emergency department visits as compared to their control group counterparts who did not receive navigation assistance during the first year following screening (*https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*). The USPSTF also recently released a technical brief on screening and interventions for social risk factors, which notes that social risk factors are mentioned in two-thirds of USPSTF recommendation statements, and six other professional medical organizations explicitly promote clinician engagement in social risk screening and referrals.[420] The report highlights that, in studies reporting these outcomes, there were few if any unintended consequences resulting from the implementation of social risk screening and intervention despite perceived barriers to implementation.[24] This measure leverages the data and experience from the AHC Model (*https://innovation.cms.gov/innovation-models/ahcm*), which has screened nearly one million beneficiaries for HRSNs. The AHC Model requires that all AHC-screened beneficiaries with unmet HRSNs receive community referral summaries tailored to their needs (*https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*). This measure is consistent with our priority to advance health equity throughout our various programs. We are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our enrollees need to thrive (*https://www.cms.gov/pillar/health-equity*). The MAP conditionally supported this measure for rulemaking pending testing indicating the measure is reliable, valid, and feasible, and endorsement by a CBE. While we agree with the MAP that the full CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. As discussed above, studies show that social drivers of health contribute to poorer health. Referrals to CSPs provide a direct means through which clinicians can assist patients in overcoming social drivers of health. As we have previously stated, we request that interested parties consider when submitting a quality measure for possible inclusion whether the measure is "beyond the measure concept phase of development and [has] started testing, at a minimum, with strong encouragement and preference for measures that have completed or are near completion of reliability and validity testing" (83 FR 53636; 84 FR 62954). While we consider whether or not a measure is fully tested, it is not the only relevant

[420] Eder, M., Henninger, M., Durbin, S., Iacocca, M. O., Martin, A., Gottlieb, L. M., & Lin, J. S. (2021). Screening and Interventions for Social Risk Factors: Technical Brief to Support the US Preventive Services Task Force. JAMA, 326(14), 1416–1428. *https://doi.org/10.1001/jama.2021.12825.*

Category	Description
	standard. This measure builds upon measure Q487, collecting data on positive screening and subsequent connection to a CSP for assistance. Having both measures in MIPS allows for assessment of two critical steps in addressing health equity; first ensuring that screening is completed on all patients and the second connecting patients who are facing a HRSN with resources that can help address these needs. Addressing health equity is a pressing issue which deserves serious focus and rapid action. This measure is an important next step for use of drivers of health (DOH) data, which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Clinicians choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. This is vital to allow further testing and development of additional health equity outcome measures. While we would encourage submission of health equity related measures, MIPS does allow for clinician choice in quality measure selection and would not require submission of this measure. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

A.8. Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients who had an intravitreal or periocular corticosteroid injection (e.g., triamcinolone, preservative-free triamcinolone, dexamethasone, dexamethasone intravitreal implant, or fluocinolone intravitreal implant) who, within seven (7) weeks following the date of injection, are screened for elevated intraocular pressure (IOP) with tonometry with documented IOP =<25 mm Hg for injected eye OR if the IOP was >25 mm Hg, a plan of care was documented.
Measure Steward:	American Society of Retina Specialists
Numerator:	Number of patients who, within seven (7) weeks following the date of injection, are screened for elevated intraocular pressure (IOP) with tonometry with documented IOP =<25 mm Hg for injected eye listed in chart OR if the IOP was >25 mm Hg, a plan of care was documented.
Denominator:	Patients who had an intravitreal or periocular corticosteroid injection (e.g., triamcinolone, preservative-free triamcinolone, dexamethasone, dexamethasone intravitreal implant, or fluocinolone intravitreal implant) with a patient encounter during the performance period.
Exclusions:	Patients with a diagnosis of hypotony.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this process measure because it would address the MIPS priority area of patient safety. Patients treated with corticosteroid therapy are at increased risk for elevated IOP leading to steroid-induced glaucoma and their quality of life may be negatively impacted due to visual impairments.[421] Ensuring that appropriate monitoring is conducted to detect and treat this complication is important to prevent significant visual morbidity. Researchers who completed a systemic review identified that 10.9 percent to 79.0 percent of patients will develop clinically significant IOP elevations and should have a follow-up within 7 weeks, based upon randomized controlled trials.[422] This measure would directly measure IOP after corticosteroid injections. The intent of this measure encourages clinicians to screen and treat patients identified with an elevated IOP in a timely manner. Currently there are no measures in MIPS that address the screening and plan of care for elevated IOP following intravitreal or periocular steroid therapy. This measure would also provide a clinically relevant measure option for retinal specialists. The MAP conditionally supported this measure for rulemaking pending endorsement of the measure by a CBE. While we agree with the MAP that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. Current clinical guidelines do not address the need to assess for elevated IOP following corticosteroid injection; however, data has demonstrated that patients treated with corticosteroid therapy are at increased risk for elevated IOP leading to steroid induced glaucoma, visual impairment, and overall poor quality of life.[423] [424] Several randomized clinical trials and a systematic review identified that IOPs typically peak around 7 to 9 weeks.[26] [425] [426] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[421] American Academy of Ophthalmology. (2022, March 29). Steroid-Induced Glaucoma. EyeWiki. *https://eyewiki.aao.org/Steroid-Induced_Glaucoma.*

[422] Kiddee, W., Trope, G. E., Sheng, L., Beltran-Agullo, L., Smith, M., Strungaru, M. H., ... & Buys, Y. M. (2013). Intraocular Pressure Monitoring Post Intravitreal Steroids: A Systematic Review. Survey of Ophthalmology, 58(4), 291-310. *https://doi.org/10.1016/j.survophthal.2012.08.003.*

[423] Breusegem, C., Vandewalle, E., Van Calster, J., Stalmans, I., & Zeyen, T. (2009). Predictive Value of a Topical Dexamethasone Provocative Test Before Intravitreal Triamcinolone Acetonide Injection. Investigative Ophthalmology & Visual Science, 50(2), 573–576. *https://doi.org/10.1167/iovs.08-2625.*

[424] Haller, J. A., Bandello, F., Belfort, R., Jr, Blumenkranz, M. S., Gillies, M., Heier, J., Loewenstein, A., Yoon, Y. H., Jiao, J., Li, X. Y., Whitcup, S. M., Ozurdex GENEVA Study Group, & Li, J. (2011). Dexamethasone Intravitreal Implant in Patients with Macular Edema Related to Branch or Central Retinal Vein Occlusion Twelve-Month Study Results. Ophthalmology, 118(12), 2453–2460. *https://doi.org/10.1016/j.ophtha.2011.05.014.*

[425] Haller, J. A., Bandello, F., Belfort, R., Jr, Blumenkranz, M. S., Gillies, M., Heier, J., Loewenstein, A., Yoon, Y. H., Jacques, M. L., Jiao, J., Li, X. Y., Whitcup, S. M., & OZURDEX GENEVA Study Group (2010). Randomized, Sham-Controlled Trial of Dexamethasone Intravitreal Implant in Patients with Macular Edema due to Retinal Vein Occlusion. Ophthalmology, 117(6), 1134–1146.e3. *https://doi.org/10.1016/j.ophtha.2010.03.032.*

[426] Aref, A. A., Scott, I. U., Oden, N. L., Ip, M. S., Blodi, B. A., & Van Veldhuisen, P. C. (2015). Incidence, Risk Factors, and Timing of Elevated Intraocular Pressure After Intravitreal Triamcinolone Acetonide Injection for Macular Edema Secondary to Retinal Vein Occlusion SCORE Study Report 15. JAMA Ophthalmology, 133(9), 1022-1029. *https://doi.org/10.1001/jamaophthalmol.2015.1823.*

A.9. Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 8 weeks
Measure Steward:	American Society of Retina Specialists
Numerator:	Patients who were appropriately evaluated during the initial exam and were re-evaluated no later than 8 weeks.
Denominator:	Patients with a diagnosis of acute PVD in either eye and eligible encounter during measurement period.
Exclusions:	Patients with a post-operative encounter of the eye with the acute PVD within 2 weeks before the initial encounter or 8 weeks after initial acute PVD encounter. Patients with a diagnosis of acute vitreous hemorrhage.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this process measure because it addresses the appropriate screening and follow-up for patients with PVD. PVD puts patients at an increased risk of retinal tears.[427] PVD complicated by retinal tear may result in retinal detachment or epiretinal membrane, causing loss of vision.[31] When retinal tears are treated promptly, the risk of detachment decreases driving positive health outcomes. While the onset of PVD is generally not preventable, it is critical to identify and treat any associated retinal tears through a prompt and appropriate initial exam and re-evaluation.[32] Prompt identification of complications will allow for expedient treatment, minimizing the potential for further complications such as retinal detachment improving a patient's quality of life.[32] Currently there are no measures in MIPS that address care improvement for patients at risk of retinal tearing due to PVD. This measure is intended to assess compliance with the current guidelines published by the American Academy of Ophthalmology on PVD and retinal breaks, which calls for re-evaluation of patients within eight weeks of their diagnosis of PVD.[428] Such re-evaluations are associated with prompt identification of complications which will allow for expedient onset of treatment, minimizing the potential for further complications, such as retinal detachment improving a patient's quality of life.[32] This measure would also provide a clinically relevant measure option for retinal specialists. The MAP conditionally supported this measure for rulemaking pending endorsement of the measure by a CBE, with a specific review of the validity of the measure specifications and performance gap of the measure. While we agree with the MAP that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. As stated above, PVD is not preventable; however, with prompt evaluations, and expedited treatment, these complications may be lessened, supporting the need for this measure. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[427] American Society of Retinal Specialists. (2016). Retina Health Series: Posterior Vitreous Detachment. Available at: *https://www.asrs.org/content/documents/fact_sheet_1_posterior_vitreous_detachment_new.pdf.*

[428] American Academy of Ophthalmology Retina/Vitreous Preferred Practice Pattern Panel. (2019). Preferred Practice Pattern® Guidelines. Posterior Vitreous Detachment, Retinal Breaks, and Lattice Degeneration PPP 2019. San Francisco, CA: American Academy of Ophthalmology. Available at *www.aao.org/ppp*.

A.10. Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) and acute vitreous hemorrhage in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 2 weeks
Measure Steward:	American Society of Retina Specialists
Numerator:	Patients who were appropriately evaluated during the initial exam and were re-evaluated no later than 2 weeks
Denominator:	Patients with a diagnosis of acute PVD and acute vitreous hemorrhage in either eye and eligible encounter during performance period.
Exclusions:	Patients with a post-operative encounter of the eye with the acute PVD within 2 weeks before the initial encounter or 2 weeks after initial acute PVD encounter.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure because it addresses appropriate screening and follow-up for patients with PVD and acute vitreous hemorrhage, due to the increased risk for complications such as retinal tears and subsequent retinal detachment in this population. This measure would address the MIPS priority area of patient safety by incentivizing physicians to see patients in a timely manner. It was found that two-thirds of PVD patients presenting with associated vitreous hemorrhage, had at least one retinal break and therefore, require a more expedient follow-up evaluation. This measure would also provide a clinically relevant measure option for retinal specialists. The MAP conditionally supported this measure for rulemaking pending endorsement of the measure by a CBE. While we agree with the MAP that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. When retinal tears are treated promptly, the risk of detachment decreases driving positive health outcomes. While the onset of PVD is generally not preventable, it is critical to identify and treat any associated retinal tears through a prompt and appropriate evaluation. Prompt identification of complications will allow for expedient onset of treatment, minimizing the potential for further complications such as retinal detachment improving a patient's quality of life. The current guideline published by the American Academy of Ophthalmology on posterior vitreous detachment (PVD) and retinal breaks supports this measure. The guideline states, "selected patients, particularly those with any degree of vitreous pigment, vitreous or retinal hemorrhage, or visible vitreoretinal traction, should be asked to return for a second examination promptly if they have new symptoms or within 6 weeks following the onset of PVD symptoms."[32] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports*.

A.11. Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.
Measure Steward:	American Psychiatric Association
Numerator:	Patients who demonstrated improvement or maintenance of functioning, as demonstrated by results of follow-up assessment using the 12-item WHODAS 2.0 or Sheehan Disability Scale 30 to 180 days after the index assessment during the performance period.
Denominator:	Patients aged 18 and older with a mental and/or substance use disorder and an encounter with an index assessment completed using the 12-item WHODAS 2.0 or Sheehan Disability Scale (SDS) during the denominator identification period.
Exclusions:	Patient situations, at any point during the denominator identification period, where the patient's functional capacity or motivation (or lack thereof) to improve may impact the accuracy of results of validated tools, such as delirium, dementia, intellectual disabilities, and pervasive and specific development disorders, - Patients who died during the performance period.
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure because it would address a high priority specialty area and a high priority clinical topic, mental health and substance use disorders and is not duplicative of any existing measure within MIPS. The mental and substance use disorders captured by this measure are among the 25 leading causes of years lived with disabilities as well as contributing significantly to the global burden of disease.[429] Twenty-two percent of U.S. adults (57.8 million individuals aged 18 and older) have a mental illness diagnosis and 17.3 percent (44 million individuals aged 18 and older) have a substance use disorder diagnosis (*https://www.samhsa.gov/data/release/2021-national-survey-drug-use-and-health-nsduh-releases#annual-national-report*). Individuals with mental disorders are more likely to report severe impairment in functioning when compared to patients with chronic medical conditions.[430] Improvement or maintaining functioning is strongly predictive of a positive outcome.[34] Patients afflicted with mental disorders show increased rates of morbidity from general medical conditions in addition to a higher risk of premature mortality.[34] Considering these factors and the contribution of mental health disorders to the global burden of disease, gaps persist in healthcare. This necessitates improvement in the overall quality of mental health care.[34 431] Outcome measures are critical to evaluating patient improvements based on current patient care, assisting clinicians in planning, monitoring, and adjusting care plans and treatment options.[432] This measure is comprehensive and broadly inclusive of mental health and substance use disorders. It uses a measurement-based care framework for implementation across various settings and populations to assess the outcome of care for patients with mental health and substance use disorders. The MAP conditionally supported this measure for rulemaking pending endorsement of the measure by a CBE. While we agree with the MAP that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. A measure focused on functioning is linked to a decrease in negative symptoms and a reduction in resources utilized, making it have the potential to reduce economic burden. Using a screening tool will allow clinicians to better assess patient functioning over time and adjustment treatment accordingly. Measurement-based care with the use of a valid and reliable tool provides valuable information about functioning.[35] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[429] The U.S. Burden of Disease Collaborators. (2018). The State of US Health, 1990-2016: Burden of Diseases, Injuries, and Risk Factors Among US States. Journal of the American Medical Association, 319(14), 1444–1472. *https://doi.org/10.1001/jama.2018.0158.*

[430] Druss, B. G., Hwang, I., Petukhova, M., Sampson, N. A., Wang, P. S., & Kessler, R. C. (2009). Impairment in Role Functioning in Mental and Chronic Medical Disorders in the United States: Results from the National Comorbidity Survey Replication. Molecular Psychiatry, 14(7), 728-737. *https://doi.org/10.1038/mp.2008.13.*

[431] Scott, K., & Lewis, C. C. (2015). Using Measurement-Based Care to Enhance Any Treatment. Cognitive and Behavioral Practice, 22(1), 49–59. *https://doi.org/10.1016/j.cbpra.2014.01.010.*

[432] Kilbourne, A. M., Beck, K., Spaeth-Rublee, B., Ramanuj, P., O'Brien, R. W., Tomoyasu, N., & Pincus, H. A. (2018). Measuring and Improving Quality of Mental Health Care: A Global Perspective. World Psychiatry, 17(1), 30-38. *https://doi.org/10.1002/wps.20482.*

A.12. Gains in Patient Activation Measure (PAM®) Scores at 12 Months

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	The Patient Activation Measure® (PAM®) is a 10 or 13 item questionnaire that assesses an individual's knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.
Measure Steward:	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
Numerator:	Numerator 1: Patients with a Baseline PAM® score and then a second score taken within 12 months of the baseline (but not less than 6 months). Numerator 2: Percentage of eligible patients who achieved a net increase in PAM® score of at least 3 points in a 6 to 12 month period (passing). Numerator 3: Percentage of eligible patients who achieved a net increase in PAM® score of at least 6 points in a 6 to 12 month period (excellent). Numerator 4: The average change (net difference) for all eligible patients between the baseline PAM® score and the second score taken within 12 months of the baseline (but not less than 6 months).
Denominator:	Denominator 1: Patients aged 14 and older with a qualifying visit at least once during the performance period. Denominator 2, 3 and 4: Patients aged 14 years and older with Performance Met for Submission Criteria 1 who had a baseline PAM® score and a second score within 6 to 12 month of baseline PAM® score and who were seen for a qualifying visit at least once during the performance period.
Exclusions:	Denominator 1, 2, 3: Diagnosis of Dementia; Diagnosis of Huntington's disease; Diagnosis of Cognitive Impairment or Alzheimer's disease Denominator 4: None
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	1.Clinicians must have collected a follow-up PAM® survey on at least 50 percent of all eligible patients during the performance period 2.Clinicians must have administered a follow-up PAM® survey to a minimum of 40 unique patients
Rationale:	We are proposing this measure because this measure, while disease agnostic, addresses chronic conditions and patient reported outcomes, both of which are high priority areas for measure consideration for MIPS. This PRO-PM provides a standardized method for clinicians to assess patient activation through the continuum of care. The PAM® survey[433] collects information directly from patients regarding their knowledge, skill, and confidence in managing their health and healthcare. This measure has been used with a wide variety of chronic conditions, as well as with people with no medical diagnosis. The intent of the PAM® is to assess an individual's ability to manage their own health and health care. According to the measure developer, the PAM® is predictive of most health outcomes, including such diverse outcomes as how a patient fares after orthopedic surgery; remission of depression over time; the likelihood of hospital re-admission or ambulatory care sensitive (ACS) utilization; the trajectory of a chronic disease over time; and even the likelihood of a new chronic disease diagnosis in the coming year.[434] [435] [436] [437] The PAM® surveys the knowledge, skill, and confidence necessary for self-management on a 0-100 point scale that can be broken down into four levels from low activation to high activation. The 13 (or 10) item survey has strong measurement properties and is predictive of most health behaviors and many clinical outcomes.[438] PAM® scores are also predictive of health care costs, with lower scores predictive of higher costs.[37] The PAM® is in use both in the U.S. and internationally in research as well as clinical settings and has been translated into

[433] PAM Survey: *https://www.phreesia.com/patient-activation-measure/ ?utm_source=google&utm_ medium=paid_ search&utm_ destinationmedium=mql_form&utm_campaign=payer_care_management_paid_search&utm_vendor=phreesia&ut m_audience1=payer&utm_content=648172611574&utm_destinationco.*

[434] Greene, J., Hibbard, J. H., Sacks, R., Overton, V., & Parrotta, C. D. (2015). When Patient Activation Levels Change, Health Outcomes and Costs Change Too. Health Affairs, 34(3), 431-437. *https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.0452.*

[435] Mitchell, S. E., Gardiner, P. M., Sadikova, E., Martin, J. M., Jack, B. W., Hibbard, J. H., & Paasche-Orlow, M. K. (2014). Patient Activation and 30-day Post-discharge Hospital Utilization. Journal of General Internal Medicine, 29(2), 349–355. *https://doi.org/10.1007/s11606-013-2647-2.*

[436] Sacks, R. M., Greene, J., Hibbard, J. H., & Overton, V. (2014). How Well Do Patient Activation Scores Predict Depression Outcomes One Year Later? Journal of Affective Disorders, 169, 1-6. *https://doi.org/10.1016/j.jad.2014.07.030.*

[437] Hibbard, J. H., Greene, J., Sacks, R. M., Overton, V., & Parrotta, C. (2017). Improving Population Health Management Strategies: Identifying Patients Who Are More Likely to Be Users of Avoidable Costly Care and Those More Likely to Develop a New Chronic Disease. Health Services Research, 52(4), 1297–1309. *https://doi.org/10.1111/1475-6773.12545.*

[438] Hibbard, J. H., Stockard, J., Mahoney, E. R., & Tusler, M. (2004). Development of the Patient Activation Measure (PAM): Conceptualizing and Measuring Activation in Patients and Consumers. Health Services Research,

Category	Description
	more than 30 languages.[37] The measure developer has been able to validate the instrument with people of different racial and ethnic backgrounds, and with people from different socio-economic levels, owing to the widespread utilization of PAM® by researchers all over the world.[37 42] A version of this measure, as well as the PAM® survey, is used in a number of Federal quality and payment programs.[37] Additionally, it is currently a required assessment in the CMMI Kidney Care Choices (KCC) *(https://innovation.cms.gov/innovation-models/kidney-care-choices-kcc-model*) and Maternal Opioid Misuse (*https://innovation.cms.gov/innovation-models/maternal-opioid-misuse-model*) alternative payment models. This measure received support for rulemaking from the MAP. The MAP discussed concerns regarding the potential proprietary nature of the assessment, costs to integrate the measure into EHRs, and the licensing for integration into EHRs. The measure developer clarified the measure would be available without licensing costs for implementation. MAP also raised concerns regarding the specificity of the denominator definition/population. However, this measure is currently implemented in other Federal quality and payment programs. The measure is also aligned with the CBE endorsed measure CBE 2483: Gains in Patient Activation (PAM®) Scores at 12 Months, which is applicable to the "Group/Practice" level of analysis. Overall, the MAP agreed this measure contributes to patient-centered care and supported the measure as a PRO-PM. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports*.

A.13. Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.
Measure Steward:	American Psychiatric Association
Numerator:	Numerator 1: Patients for whom a completed suicide safety plan is initiated, reviewed, or updated in collaboration between the patient and their clinician at the time the suicidal ideation behavior or risk is identified (concurrent or within 24 hours of index clinical encounter), during the measurement period. Numerator 2: Patients for whom a suicide safety plan is initiated, reviewed, or updated in collaboration between the individual and their clinician at the time the suicidal ideation, behavior or risk is identified (concurrent or within 24 hours of clinical encounter) AND reviewed and updated within 120 days after the index clinical encounter after initiation.
Denominator:	Denominator 1 and 2: Patients aged 18 and older with a mental and/or substance use disorder with suicidal ideation and/or behavior symptoms or suicide risk at a clinical encounter during the denominator identification period.
Exclusions:	Denominator 1 and 2: Patients whose functional capacity or motivation (or lack thereof) to improve may impact the accuracy of results of validated tools such as delirium, dementia, intellectual disabilities, and pervasive and specific development disorders. Patients who died during the measurement period.
Measure Type:	Process
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure because it focuses on a process where initiating and reviewing a suicide safety plan with a patient at risk of suicide is a proxy for the clinical outcome of a reduction in suicides, suicide attempts, and suicidal ideation; thereby, addressing behavioral health. Incorporating this measure into MIPS would encourage measure adoption, which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder. This measure represents a high priority area for MIPS due to its focus on improved outcomes in mental health. The use of standardized patient-reported outcome measures (PROMs) associated with suicide ideation and behavior and clinician-rated assessments of suicide risk, including the use of safety plans, varies within and across behavioral health specialties as well as primary care and emergency care settings, where suicidal persons often present for care. Currently, only hard-copy versions of safety planning documents have been used in most settings, with slow uptake of electronic versions.[43] Hard-copy safety plans provided to patients are prone to misplacement, creating a barrier to their use and follow-up.[439] Even with use of suicide safety plans at an index visit, research has found that less than 50 percent of suicidal persons had explicit evidence of ongoing review or utilization of the safety plan in ongoing treatments.[440] The implementation of this proposed quality measure is intended to incentivize quality care that addresses the low rate of (re)assessment and poor outcomes. This quality measure would help to advance the Zero Suicide initiative set forth in the National Strategy for Suicide Prevention (*https://theactionalliance.org/our-strategy/national-strategy-suicide-prevention*) and ultimately improve the quality of care for patients with suicide ideation, behaviors, or suicide risk. There is one existing measure in MIPS that addresses suicide: measure Q107: Adult Major Depressive Disorder (MDD): Suicide Risk Assessment. Though conceptually related, the proposed measure distinguishes itself from measure Q107 by focusing on a care process that is directly designed to mitigate suicide risk, as opposed to merely completely screening for it. There is an outcome measure in MIPS focused on a related mental health area: measure Q370: Depression Remission at Twelve Months. While PHQ-9, the assessment used in measure Q370[441], does include one question about self-harm, this measure is specific to depression. The proposed measure would include patients with other behavioral health conditions who are at risk of suicide and appropriate for assessment of the clinical quality action within the measure. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agree with the MAP that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. This suicide prevention measure could be clinically useful for clinicians treating individuals at increased risk for suicide as it is associated with reduction in suicidal behaviors and may improve quality of care for at risk patients.

[439] Little, V., Neufeld, J., & Cole, A. R. (2018). Integrating Safety Plans for Suicidal Patients into Patient Portals: Challenges and Opportunities. Psychiatric services (Washington, D.C.), 69(6), 618–619. *https://doi.org/10.1176/appi.ps.201700458*.

[440] Gamarra, J. M., Luciano, M. T., Gradus, J. L., & Wiltsey Stirman, S. (2015). Assessing Variability and Implementation Fidelity of Suicide Prevention Safety Planning in a Regional VA Healthcare System. Crisis, 36(6), 433–439. *https://doi.org/10.1027/0227-5910/a000345*.

[441] *See https://www.apa.org/depression-guideline/patient-health-questionnaire.pdf.*

Category	Description
	Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

A.14. Reduction in Suicidal Ideation or Behavior Symptoms

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit', within 120 days after an index assessment.
Measure Steward:	American Psychiatric Association
Numerator:	Patients who demonstrated a reduction in suicidal ideation and/or behavior symptoms as demonstrated by results of a follow-up assessment using the C-SSRS within 120 days after the index assessment during the measurement period.
Denominator:	Patients aged 18 and older with a mental and/or substance use disorder with suicidal ideation and/or behavior symptoms OR deemed a suicide risk based on their clinician's evaluation at an encounter with an index assessment completed using the C-SSRS during the denominator identification period.
Exclusions:	Patients whose functional capacity or motivation (or lack thereof) to improve may impact the accuracy of results of validated tools such as delirium, dementia, intellectual disabilities, and pervasive and specific development disorders. Patients who died during the measurement period
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this PRO-PM because this measure focuses on mental health and substance use disorder (SUD), which are CMS high priority areas for MIPS measure consideration. This measure collects information related to a demonstrated reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' *(https://www.cms.gov/files/document/cssrs-screen-version-instrument.pdf)* versus 'Since Last Visit', taken within 120 days after an index assessment. Incorporating this measure into MIPS would encourage and support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder. This measure would represent another valuable PRO-PM measure for interested parties to report within MIPS, representing the continuum of care and improved health outcomes for individuals with suicidal ideation, behavior, or risk. This clinical outcome measure assesses reductions in suicidal ideation that are likely associated with reductions in suicides and suicide attempts. Suicide is a preventable cause of lost lives, yet each year over 40,000 Americans die by suicide (*https://www.cdc.gov/nchs/products/databriefs/db330.htm*). Safety planning, means reduction, and connecting suicidal persons to treatment are effective and critical elements in suicide prevention (*https://theactionalliance.org/sites/default/files/action_alliance_recommended_standard_care_final.pdf*), as discussed in the most updated clinical practice guidelines for assessment and treatment of suicidal persons (*https://www.healthquality.va.gov/guidelines/MH/srb/VADoDSuicideRiskFullCPGFinal5088212019.pdf*). This measure, which focuses on the reduction of suicidal ideation, conceptually addresses behavioral health, and is a high priority area for MIPS. There is one existing measure in MIPS that addresses suicide: measure Q107: Adult Major Depressive Disorder (MDD): Suicide Risk Assessment. Though conceptually related, this measure distinguishes itself by focusing on the relevant clinical outcome. There is an outcome measure in MIPS focused on a related mental health area: measure Q370: Depression Remission at Twelve Months. The instrument used to assess remission in measure Q370, the PHQ-9, does include one question about self-harm; however, this measure is specific to depression. This proposed measure would include patients with other behavioral health conditions who are at risk of suicide and appropriate for assessment of the clinical quality action within the measure. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agree with the MAP that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

Table Group B: Modifications to Previously Finalized Specialty Measures Sets Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

We are proposing to modify the below previously finalized specialty measures sets based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and feedback provided by specialty societies. There may be instances where the quality measures within a specialty set remain static, but the individual measures have proposed substantive changes in Table Group D of this Appendix. In the first column, existing measures with substantive changes described in Table Group D of this Appendix 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 the regulatory definition of high priority measures. In addition, electronic clinical quality measures (eCQMs) that are endorsed by a CBE are shown in Table Group B of this Appendix as follows: CBE # / eCQM CBE #.

Under § 414.1305, a high priority measure means an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, opioid, or health equity-related quality measure. Further details of these types of measures are located in the CMS Measures Management System Hub (*mmshub.cms.gov*).

It should be noted that for the CY 2024 performance period/2026 MIPS payment year (and prior CY 2023 performance period/2025 MIPS payment year), the CMS Web Interface as a collection type is only available for APM Entities, specifically Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs), reporting through the APM Performance Pathway (APP) (the CMS Web Interface measures as a collection type is no longer available under traditional MIPS). Thus, the CMS Web Interface collection type is not listed in any specialty set under Table Group B of this Appendix. For further information regarding the Shared Savings Program requirements under the APP and the CMS Web Interface collection type available under the APP, see section III.G.2.c.(2) of this proposed rule. For information regarding proposed changes to the CMS Web Interface measures available for the CY 2024 performance period/2026 MIPS payment year, see Table Group E of this Appendix.

Note: The following specialty sets have no addition tables, no removal tables, and no substantive changes proposed for the CY 2024 performance period/2026 MIPS payment year: Anesthesiology, Electrophysiology Cardiac Specialist, and Pathology.

Note: Previously finalized measures that have no substantive changes are not open for comment under this proposed rule. We seek comment on proposed additions and proposed removals under applicable specialty sets in Table Group B of this Appendix.

B.1. Allergy/Immunology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Allergy/Immunology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Allergy/Immunology specialty set.

B.1. Allergy/Immunology							
PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	**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	**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	338	N/A	MIPS CQMs Specifications	Outcome	**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)	N/A / N/A	340	N/A	MIPS CQMs Specifications	Process	**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

B.1. Allergy/Immunology							
PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	374	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	**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
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.1. Allergy/Immunology

MEASURES PROPOSED FOR **ADDITION** TO THE ALLERGY/IMMUNOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Allergy/Immunology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of drivers of health (DOH) data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10- or 13-item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Allergy/Immunology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.1. Allergy/Immunology

MEASURES PROPOSED FOR **ADDITION** TO THE ALLERGY/IMMUNOLOGY SPECIALTY SET													
Indicator						**CBE # / eCQM CBE #**		**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
						to follow-up measurement.								

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE ALLERGY/IMMUNOLOGY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.													
CBE # / eCQM CBE #							**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.						

B.2. Anesthesiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Anesthesiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 and this specialty set has no proposed changes.

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES IN THE ANESTHESIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	404	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Anesthesiology Smoking Abstinence:** The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists
! (Outcome)	N/A / N/A	424	N/A	MIPS CQMs Specifications	Outcome	**Perioperative Temperature Management:** Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was achieved within the 30 minutes immediately before or 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists
! (Patient Safety)	N/A / N/A	430	N/A	MIPS CQMs Specifications	Process	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
! (Patient Safety)	N/A / N/A	463	N/A	MIPS CQMs Specifications	Process	**Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics):** Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
! (Opioid)	N/A / N/A	477	N/A	MIPS CQMs Specifications	Process	**Multimodal Pain Management:** Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.	American Society of Anesthesiologists

B.3. Audiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Audiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Audiology specialty set.

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 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	MIPS CQMs Specifications	Process	**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 within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Care Coordination)	NA / NA	261	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	CMS139v12	eCQM Specifications	Process	**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
* §	2152/ N/A	431	N/A	MIPS CQMs Specifications	Process	**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
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.3. Audiology

MEASURES PROPOSED FOR **ADDITION** TO THE AUDIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	317	CMS2 2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Audiology specialty set. We agree with interested parties' feedback that adding this measure to this specialty set would help to broaden the patient population being screened for high blood pressure. There is known risk of adverse effects on the auditory system due to high blood pressure making this an important aspect of care for audiologists. Given the close correlation of adverse effects on the auditory system due to hypertension, interdisciplinary care is vital, and it should be the responsibility of all clinician types to address health promotion and wellness, and prevention, delay, or management of acute or chronic diseases and conditions. This measure would support the comprehensive evaluation of compliance of screening for and proper treatment of high blood pressure that can improve quality care and prevent disease for the general population. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule.

B.3. Audiology

MEASURES PROPOSED FOR **ADDITION** TO THE AUDIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Audiology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.4a. Cardiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Cardiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Cardiology specialty set.

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS13 5v12	eCQM Specifications, MIPS CQMs Specifications	Process	**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	**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	CMS14 5v12	eCQM Specifications, MIPS CQMs Specifications	Process	**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	CMS14 4v12	eCQM Specifications, MIPS CQMs Specifications	Process	**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.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	**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 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS16 5v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Inter-mediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
* ! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	**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	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Efficiency)	N/A / N/A	322	N/A	MIPS CQMs Specifications	Efficiency	**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
* §	N/A / N/A	326	N/A	MIPS CQMs Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	**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	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**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	CMS347v7	eCQM Specifications, MIPS CQMs Specifications	Process	**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: *All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes.	Centers for Medicare & Medicaid Services

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	**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
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: • Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.4a. Cardiology

MEASURES PROPOSED FOR **ADDITION** TO THE CARDIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Cardiology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for

B.4a. Cardiology

MEASURES PROPOSED FOR **ADDITION** TO THE CARDIOLOGY SPECIALTY SET														
Indicator			**CBE # / eCQM CBE #**					**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
														rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months**: The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Cardiology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.					

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE CARDIOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE CARDIOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	324	N/A	MIPS CQMs Specifications	Efficiency	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE CARDIOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.													
CBE # / eCQM CBE #							**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.						

B.4b. Electrophysiology Cardiac Specialist

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Electrophysiology Cardiac Specialist specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 and this specialty set has no proposed changes.

B.4b. Electrophysiology Cardiac Specialist

PREVIOUSLY FINALIZED MEASURES IN THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	2474 / N/A	392	N/A	MIPS CQMs Specifications	Outcome	**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	**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.5. Certified Nurse Midwife

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Certified Nurse Midwife specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Certified Nurse Midwife specialty set.

B.5. Certified Nurse Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	335	N/A	MIPS CQMs Specifications	Outcome	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQMs Specifications	Process	**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 12 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
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**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	475	CMS349v6	eCQM Specifications	Process	**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 Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention

B.5. Certified Nurse Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.5. Certified Nurse Midwife

MEASURES PROPOSED FOR **ADDITION** TO THE CERTIFIED NURSE MIDWIFE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**CVD Risk Assessment Measure – Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument:** Percentage of pregnant or postpartum patients who received a cardiovascular disease (CVD) risk assessment with a standardized instrument.	University of California, Irvine	We propose to include this measure in the Certified Nurse Midwife specialty set as it would be clinically relevant to this clinician type. This measure fills a high priority clinical gap area under the wellness and prevention domain for maternal health by addressing screening and care for pregnant/postpartum patients by assessing for a standardized CVD risk assessment for this high-risk population cared for by clinicians in this specialty. Given the close correlation of CVD risks and pregnant/postpartum patients, interdisciplinary care is vital. The addition of this quality measure to this specialty set would incentivize thorough assessment for patient risk and increase education and awareness in this population. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.3 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Certified Nurse Midwife specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this

B.5. Certified Nurse Midwife

MEASURES PROPOSED FOR **ADDITION** TO THE CERTIFIED NURSE MIDWIFE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								measure in MIPS.

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Certified Nurse Midwife specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
! (Safety)			N/A /	TBD	N/A	MIPS CQM	Process	**Initiation,**	American	We propose to include this measure in the

	N/A			s Specifications		**Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	Psychiatric Association	Certified Nurse Midwife specialty set as it would be clinically relevant to this clinician type. The incorporation of this measure in this specialty set would help promote interventions and best practices that are effective at symptoms reduction and improving functional status and quality of life. This measure is a high priority area for MIPS and by adding the measure to this specialty set it would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder, while also reinforcing our commitment that all clinicians should be actively engaging in addressing mental health and substance use disorders across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.13 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
! (Outcome)	N/A /	TBD	N/A	MIPS CQM	Patient-	**Reduction in**	American	We propose to include this measure in the

B.5. Certified Nurse Midwife

MEASURES PROPOSED FOR **ADDITION** TO THE CERTIFIED NURSE MIDWIFE SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**		**Measure Steward**	**Rationale for Inclusion**
	N/A			s Specifications	Reported Outcome-Based Performance Measure	**Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit', within 120 days after an index assessment.	Psychiatric Association	Certified Nurse Midwife specialty set as it would be clinically relevant to this clinician type. This patient reported outcome measure focuses on mental health and substance use disorder (SUD) and the reduction of suicidal ideation, conceptually addressing behavioral health which are a CMS high priority area. Incorporating this clinical outcome measure in this specialty set would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and SUD. The addition of this quality measure for this specialty would reinforce our commitment that all clinicians should be actively engaging in addressing mental health and SUDs across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.14 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.6. Chiropractic Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Chiropractic Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Chiropractic Medicine specialty set.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**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 within two days of 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-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) 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 FOTO Elbow/Wrist/Hand FS 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.6. Chiropractic Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE CHIROPRACTIC MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Chiropractic Medicine specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.7. Clinical Social Work

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Clinical Social Work specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Clinical Social Work specialty set.

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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)	N/A / N/A	130	CMS68v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v1 3	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 or up to two days after the date of the qualifying 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	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 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	226	CMS138 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / 2872e	281	CMS149 v12	eCQM Specifications	Process	**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.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	**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
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	**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	**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 v12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**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 / N/A	382	CMS177 v12	eCQM Specifications	Process	**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 (MDD) with an assessment for suicide risk.	Mathematica
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	**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.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**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
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.7. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Opioid)	N/A / N/A	305	CMS137v12	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance	We propose to include this measure in the Clinical Social Work specialty set as it would be clinically relevant to this clinician type. We agree with interested parties' feedback that this measure would be beneficial for clinical social workers to address the complex psychosocial challenges that accompany those with substance use disorders. Behavioral health clinicians, such as clinical social workers, are instrumental in ensuring that services address the needs of these individuals. The measure being added to this specialty set would be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule.

B.7. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SPECIALTY SET														
Indicator				**CBE # / eCQM CBE #**				**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Clinical Social Work specialty set. We agree with interested parties' feedback that this measure would be clinically relevant to this clinician type as this profession has historically addressed social needs through screening and evaluation, providing referrals, and connecting patients to community services and falls within their scope of care. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.				

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association	We propose to include this measure in the Clinical Social Work specialty set. We agree with interested parties' feedback that this measure would be clinically relevant to this clinician type. Clinical social workers are vital in helping those with mental health and substance use disorders (SUD). Social work practice is in a unique position to influence the delivery of services by addressing the acute and chronic needs of clients with SUDs, including co-occurring disorders and polysubstance patterns. By developing and applying evidence-informed approaches that incorporate established interventions and evolving techniques based on emerging research findings, clinical social workers can markedly improve treatment services for clients and their families. The measure being added to this specialty set

B.7. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**		**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**		**Measure Steward**	**Rationale for Inclusion**
									would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.11 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.	

! (Safety)	N/A/N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association	We propose to include this measure in the Clinical Social Worker specialty set as this measure would be clinically relevant to this clinician type. We agree with interested parties' feedback that incorporating this measure in this specialty set would help promote interventions and best practices that are effective at symptoms reduction and improving functional status and quality of life. This measure is a high priority area for MIPS and adding it would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder, while also reinforcing our commitment that all clinicians should be actively engaging in addressing mental health and

B.7. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**		**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
									substance use disorders across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.13 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.7. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SPECIALTY SET										
Indicator	**CBE # / eCQM CBE #**	**Quality #**		**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**		**Measure Steward**	**Rationale for Inclusion**
! (Outcome)		N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit', within 120 days after an index assessment.	American Psychiatric Association	We propose to include this measure in the Clinical Social Work specialty set. We agree with interested parties' feedback that this measure would be clinically relevant to this clinician type. The interested parties noted that this measure could provide meaningful data that could be used to support evidence-based treatment and promote better quality of care. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.14 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE CLINICAL SOCIAL WORK SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	**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/ American Psychiatric Association	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.8. Dentistry

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Dentistry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Dentistry specialty set.

B.8. Dentistry

PREVIOUSLY FINALIZED MEASURES IN THE DENTISTRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	378	CMS75v12	eCQM Specifications	Outcome	**Children Who Have Dental Decay or Cavities:** Percentage of children, 6 months to 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period as determined by a dentist.	Centers for Medicare & Medicaid Services
*	N/A / N/A	379	CMS74v13	eCQM Specifications	Process	**Primary Caries Prevention Intervention as Offered by Dentists:** Percentage of children, 6 months to 20 years of age, who received a fluoride varnish application during the measurement period as determined by a dentist.	Centers for Medicare & Medicaid Services

B.9. Dermatology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Dermatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Dermatology specialty set.

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A / N/A	137	N/A	MIPS CQMs Specifications	Structure	**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
	N/A/ N/A	176	N/A	MIPS CQMs Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	410	N/A	MIPS CQMs Specifications	Outcome	**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	**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
* ! (Outcome)	N/A / N/A	485	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Psoriasis – Improvement in Patient-Reported Itch Severity:** The percentage of patients, aged 18 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit.	American Academy of Dermatology
* ! (Outcome)	N/A / N/A	486	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Dermatitis – Improvement in Patient-Reported Itch Severity:** The percentage of patients, aged 18 years and older, with a diagnosis of dermatitis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit.	American Academy of Dermatology
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.9. Dermatology

MEASURES PROPOSED FOR **ADDITION** TO THE DERMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Dermatology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.9. Dermatology

MEASURES PROPOSED FOR **ADDITION** TO THE DERMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Dermatology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE DERMATOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.									
CBE # / eCQM CBE #					**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A					138	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.10. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Diagnostic Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Diagnostic Radiology specialty set.

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**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	**Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices.	American College of Radiology
! (Appropriate Use)	N/A / N/A	360	N/A	MIPS CQMs Specifications	Process	**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	**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
! (Appropriate Use)	N/A / N/A	405	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	406	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.10. Diagnostic Radiology

MEASURES PROPOSED FOR **ADDITION** TO THE DIAGNOSTIC RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

! (Outcome)				3633e / N/A				TBD	CMS1056v1	eCQM Specifications	Intermediate Outcome	**Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level):** This measure provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses, a risk factor for cancer, while preserving image quality. It is expressed as a percentage of CT exams that are out-of-range based on having either excessive radiation dose or inadequate image quality relative to evidence-based thresholds based on the clinical Indication for the exam. All diagnostic CT exams of specified anatomic sites performed in inpatient, outpatient and ambulatory care settings are eligible. This eCQM requires the use of additional software to access primary data elements stored within radiology electronic health records and translate them into data elements that can be ingested by this eCQM. Additional details are included in the Guidance field.	Alara Imaging, Inc. in collaboration with the University of California, San Francisco (UCSF)	We propose to include this measure in the Diagnostic Radiology specialty set as it would be clinically relevant to this clinician type. This measure would provide radiologists with a clinically relevant outcome measure within MIPS and meets the high priority definition for MIPS reporting as an outcome and patient safety measure. It aligns with numerous consensus-based clinical recommendations and guidelines and is also consistent with the CMS emphasis on expanding digital quality measures with reduction in clinician burden. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.1 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or	OCHIN	We propose to include this measure in the Diagnostic Radiology specialty set as it's clinically screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data					

B.10. Diagnostic Radiology

MEASURES PROPOSED FOR **ADDITION** TO THE DIAGNOSTIC RADIOLOGY SPECIALTY SET														
Indicator				**CBE # / eCQM CBE #**				**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
						older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.		capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.					

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE DIAGNOSTIC RADIOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	147	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	436	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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/ National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.11. Emergency Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Emergency Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Emergency Medicine specialty set.

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069/ N/A	065	CMS154v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**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 order.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	**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	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	**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 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
*	N/A / N/A	254	N/A	MIPS CQMs Specifications	Process	**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	CMS22v1 2	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	**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	**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	**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	MIPS CQMs Specifications	Efficiency	**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
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.11. Emergency Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE EMERGENCY MEDICINE SPECIALTY SET													
Indicator					**CBE # / eCQM CBE #**			**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Emergency Medicine specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.							

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE EMERGENCY MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE EMERGENCY MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	107	CMS161v12	eCQM Specifications	Process	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit.	Mathematica	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.12. Endocrinology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Endocrinology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Endocrinology specialty set.

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**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	**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 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of 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 in any part of 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	**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
	N/A / N/A	126	N/A	MIPS CQMs Specifications	Process	**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.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of 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	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	438	CMS347 v7	eCQM Specifications, MIPS CQMs Specifications	Process	**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: *All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • *Patients aged 40-75 years with a diagnosis of diabetes.	Centers for Medicare & Medicaid Services
	N/A / N/A	462	CMS645 v7	eCQM Specifications	Process	**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
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	488	CMS951 v2	eCQM Specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.12. Endocrinology

MEASURES PROPOSED FOR **ADDITION** TO THE ENDOCRINOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Endocrinology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity within all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.12. Endocrinology

MEASURES PROPOSED FOR **ADDITION** TO THE ENDOCRINOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10–- or 13–- item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Endocrinology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE ENDOCRINOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.													
CBE # / eCQM CBE #							**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.						

B.13. Family Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Family Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Family Medicine specialty set.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**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	CMS135v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**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	**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	CMS145v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**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	CMS144v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**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.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	009	CMS128v 12	eCQM Specifications	Process	**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 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	**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	**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	**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.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	**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	CMS154v12	eCQM Specifications, MIPS CQMs Specifications	Process	**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 order.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	**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	CMS131v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of 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 in any part of 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
	N/A / N/A	126	N/A	MIPS CQMs Specifications	Process	**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.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	176	N/A	MIPS CQMs Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 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	MIPS CQMs Specifications	Process	**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 within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS165v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of 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	CMS156v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
* ! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	**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
! (Opioid)	N/A / N/A	305	CMS137v 12	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	309	CMS124v 12	eCQM Specifications	Process	**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
! (Patient Safety)	0101 / N/A	318	CMS139v 12	eCQM Specifications	Process	**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	**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 CBE 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 CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
* §	N/A / N/A	326	N/A	MIPS CQMs Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	**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	**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	338	N/A	MIPS CQMs Specifications	Outcome	**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)	0710 / 0710e	370	CMS159v 12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**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	CMS50v1 2	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	377	CMS90v1 3	eCQM Specifications	Process	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with 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	**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

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	**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
§	N/A / N/A	394	N/A	MIPS CQMs Specifications	Process	**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	**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
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	**One-Time Screening for Hepatitis C Virus (HCV) for all Patients:** Percentage of patients age >= 18 years 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	**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
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or 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	**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

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	438	CMS347v 7	eCQM Specifications, MIPS CQMs Specifications	Process	**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: *All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	**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	**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
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	**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

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	**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	CMS249v 6	eCQM Specifications	Process	**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	CMS349v 6	eCQM Specifications	Process	**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 Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Outcome)	N/A / N/A	476	CMS771v 5	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**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
! (Outcome)	3568 / N/A	483	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM Patient Reported Outcome Measure (PROM) a comprehensive and parsimonious set of 11 patient-reported items – to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the clinician or practice.	The American Board of Family Medicine
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	488	CMS951v2	eCQM Specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

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MEASURES PROPOSED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care provider and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We propose to include this measure in the Family Medicine specialty set as it would be clinically relevant to this clinician type. This patient-reported outcome measure would help to fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Patients feeling heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. This measure is predicated on existing guidelines and conceptual models. In addition, it can facilitate and improve effective patient-provider communication that engenders trust, acknowledgement, and a whole-person orientation to the care that is provided. This is an important patient-centered measure that helps patients feel heard and understood which can effectively improve the quality of care received and outcomes for patients in palliative care. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.2 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
			N/A /	TBD	N/A	MIPS CQMs	Process	**Preventive Care and Wellness**	Centers for Medic	We propose to include this measure in the Family

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MEASURES PROPOSED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**		**Measure Steward**	**Rationale for Inclusion**
	N/A			Specifications		**(composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	are and Medicaid Services	Medicine specialty set as it would be clinically relevant to this clinician type. The addition of this quality measure to this specialty set would reinforce our commitment that all clinicians should be actively engaging in activities that address preventive care and wellness and is in alignment with our priorities to support overall patient health. The measure would set a more stringent performance standard by requiring a set of preventive care for the general population in one composite measure and aligns with evidence-based recommendations. The measure would help incentivize a more broadly encompassing preventive care assessment to guide clinicians. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.6 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Family Medicine specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity within all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Meas	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use	American Psychiatric Association	We propose to include this measure in the Family Medicine specialty set as it would be clinically relevant to this clinician type. This measure addresses a high priority specialty area and high priority clinical

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MEASURES PROPOSED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
					ure	disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.		condition for MIPS. It's an important comprehensive PRO-PM encompassing a broad behavioral health patient population. It utilizes a measurement-based care framework for implementation across various settings and populations. This measure would help to broaden the patient population being assessed for mental and/or substance use disorders and their maintenance and recovery. Adding this measure to the Family Medicine specialty set would reinforce the important role this clinician type plays in addressing patient mental health and substance use disorders. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.11 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.13. Family Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**		**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Family Medicine specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

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MEASURES PROPOSED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Safety)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association	We propose to include this measure in the Family Medicine specialty set as it would be clinically relevant to this clinician type. The incorporation of this measure in this specialty set would help promote interventions and best practices that are effective at symptoms reduction and improving functional status and quality of life. This measure is a high priority area for MIPS and by adding the measure to this specialty set it would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder, while also reinforcing our commitment that all clinicians should be actively engaging in addressing mental health and substance use disorders across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.13 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

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MEASURES PROPOSED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET															
Indicator								**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version" or "Since Last Visit", within 120 days after an index assessment.	American Psychiatric Association								We propose to include this measure in the Family Medicine specialty set as it would be clinically relevant to this clinician type. This patient reported outcome measure focuses on mental health and substance use disorder (SUD) and the reduction of suicidal ideation, conceptually addressing behavioral health which are a CMS high priority area. Incorporating this clinical outcome measure in this specialty set would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and SUD. The addition of this quality measure for this specialty would reinforce our commitment that all clinicians should be actively engaging in addressing mental health and SUDs across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.14 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE FAMILY MEDICINE SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #		Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	107	CMS161v12	eCQM Specifications	Process	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit.	Mathematica	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE FAMILY MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
2372 / N/A	112	CMS 125v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group CC of this Appendix for rationale.
0034 / N/A	113	CMS 130v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Colorectal Cancer Screening:** Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group CC of this Appendix for rationale.
N/A / N/A	128	CMS 69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE FAMILY MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.													
CBE # / eCQM CBE #							**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal from the *Family Medicine* specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is proposed to be included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set would be duplicative.					

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE FAMILY MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
CBE # / eCQM CBE #		**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from the Family Medicine specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is proposed to be included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set would be duplicative.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.14. Gastroenterology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Gastroenterology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Gastroenterology specialty set.

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	185	N/A	MIPS CQMs Specifications	Process	**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 Gastroenterological Association
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* §	NA / N/A	275	N/A	MIPS CQMs Specifications	Process	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastroenterological Association

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated 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	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 45 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	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	**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
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**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	**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
* ! (Equity	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.14. Gastroenterology

MEASURES PROPOSED FOR **ADDITION** TO THE GASTROENTEROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Gastroenterology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity within all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.14. Gastroenterology

MEASURES PROPOSED FOR **ADDITION** TO THE GASTROENTEROLOGY SPECIALTY SET														
Indicator					**CBE # / eCQM CBE #**			**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10–- or 13–- item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia							We propose to include this measure in the Gastroenterology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE GASTROENTEROLOGY SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	128	CMS 69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.15. General Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the General Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed General Surgery specialty set.

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	264	N/A	MIPS CQMs Specifications	Process	**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	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	354	N/A	MIPS CQMs Specifications	Outcome	**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	**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	**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	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**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 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.15. General Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE GENERAL SURGERY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the General Surgery specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity within all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE GENERAL SURGERY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.16. Geriatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Geriatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Geriatrics specialty set.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	**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	**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	MIPS CQMs Specifications	Process	**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
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v1 3	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 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	CMS156 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / 2872e	281	CMS149 v12	eCQM Specifications	Process	**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	**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
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	**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	**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 v12	eCQM Specifications	Process	**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)	0710 / 0710e	370	CMS159 v12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**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

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	476	CMS771 v5	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**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
* ! (Equity	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	488	CMS951 v2	eCQM Specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
	1662/ N/A	489	N/A	MIPS CQMs Specifications	Process	**Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy**: Percentage of patients aged 18 years and older with a diagnosis of (CKD (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.	Renal Physicians Association
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.16. Geriatrics

MEASURES PROPOSED FOR **ADDITION** TO THE GERIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services	We propose to include this measure in the Geriatrics specialty set as it would be clinically relevant to this clinician type. The addition of this quality measure to this specialty set would reinforce our commitment that all clinicians should be actively engaging in activities that address preventive care and wellness and is in alignment with our priorities to support overall patient health. The measure would set a more stringent performance standard by requiring a set of preventive care for the general population in one composite measure and aligns with evidence-based recommendations. The measure would help incentivize a more broadly encompassing preventive care assessment to guide clinicians. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.6 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.16. Geriatrics

MEASURES PROPOSED FOR **ADDITION** TO THE GERIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Geriatrics specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity within all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE GERIATRICS SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	226	CMS 138v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal from the Geriatrics specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is proposed to be included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set would be duplicative.
N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	**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/ American Psychiatric Association	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.17. Hospitalists

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Hospitalists specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Hospitalists specialty set.

B.17. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135v12	eCQM Specifications, MIPS CQMs Specifications	Process	**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	CMS144v12	eCQM Specifications, MIPS CQMs Specifications	Process	**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	**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)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.18. Infectious Disease

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Infectious Disease specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Infectious Disease specialty set.

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**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 order.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
* §	N/A / N/A	205	N/A	MIPS CQMs Specifications	Process	**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.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	226	CMS138 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* §	N/A / N/A	240	CMS117 v12	eCQM Specifications	Process	**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
* § ! (Outcome)	N/A / N/A	338	N/A	MIPS CQMs Specifications	Outcome	**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)	N/A / N/A	340	N/A	MIPS CQMs Specifications	Process	**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	387	N/A	MIPS CQMs Specifications	Process	**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
§	N/A / N/A	394	N/A	MIPS CQMs Specifications	Process	**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
* §	N/A / N/A	475	CMS349 v6	eCQM Specifications	Process	**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 Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility	Centers for Medicare & Medicaid Services

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
						difficulties, and interpersonal safety.	
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.18. Infectious Disease

MEASURES PROPOSED FOR **ADDITION** TO THE INFECTIOUS DISEASE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Infectious Disease specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity within all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.19. Internal Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Internal Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Internal Medicine specialty set.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**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	CMS135v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**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	**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	CMS145v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**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 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**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.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	009	CMS128 v12	eCQM Specifications	Process	**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 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	**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	**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	**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.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	**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)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	**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	CMS131 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Diabetes: Eye Exam**: Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of 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 in any part of 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
	N/A / N/A	126	N/A	MIPS CQMs Specifications	Process	**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
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v1 3	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	176	N/A	MIPS CQMs Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 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
* § ! (Outcome)	N/A / N/A	236	CMS165 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of 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 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
* ! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	**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

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	**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), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	**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	CMS137 v12	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
§	N/A / N/A	309	CMS124 v12	eCQM Specifications	Process	**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
! (Patient Safety)	0101 / N/A	318	CMS139 v12	eCQM Specifications	Process	**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

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	**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 CBE 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 CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
* §	N/A / N/A	326	N/A	MIPS CQMs Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an 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	**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	**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

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	338	N/A	MIPS CQMs Specifications	Outcome	**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)	0710 / 0710e	370	CMS159 v12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**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 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	377	CMS90v 13	eCQM Specifications	Process	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with 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	**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	**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	**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
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	**One-Time Screening for Hepatitis C Virus (HCV) for all Patients:** Percentage of patients age >= 18 years who received one-time screening for Hepatitis C Virus (HCV) infection.	American Gastroenterological Association

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	**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
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or 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	**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 v7	eCQM Specifications, MIPS CQMs Specifications	Process	**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: • All patients with an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or ever had an ASCVD procedure; OR • Patients aged ≥ 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40-75 years with a diagnosis of diabetes.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	**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	**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
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	**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 v6	eCQM Specifications	Process	**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 v6	eCQM Specifications	Process	**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 Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Outcome)	N/A / N/A	476	CMS771 v5	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**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

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	3568 / N/A	483	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM Patient Reported Outcome Measure (PROM) a comprehensive and parsimonious set of 11 patient-reported items – to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the clinician or practice.	The American Board of Family Medicine
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	488	CMS951 v2	eCQM specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

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MEASURES PROPOSED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care provider and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We propose to include this measure in the Internal Medicine specialty set as it would be clinically relevant to this clinician type. This patient-reported outcome measure would help to fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Patients feeling heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. This measure is predicated on existing guidelines and conceptual models. In addition, it can facilitate and improve effective patient-provider communication that engenders trust, acknowledgement, and a whole-person orientation to the care that is provided. This is an important patient-centered measure that helps patients feel heard and understood which can effectively improve the quality of care received and outcomes for patients in palliative care. The measure being added to

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MEASURES PROPOSED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.2 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services	We propose to include this measure in the Internal Medicine specialty set as it would be clinically relevant to this clinician type. The addition of this quality measure to this specialty set would reinforce our commitment that all clinicians should be actively engaging in activities that address preventive care and wellness and is in alignment with our priorities to support overall patient health. The measure would set a more stringent performance standard by requiring a set of preventive care for the general population in one composite measure and aligns with evidence-based recommendations. The measure would help incentivize a more broadly encompassing preventive care assessment to guide clinicians. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.6 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specif	Process	**Connection to Community Service Provider:**	OCHIN	We propose to include this measure in the Internal

				ication s		Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.		Medicine specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this

B.19. Internal Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								measure in MIPS.

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association	We propose to include this measure in the Internal Medicine specialty set as it would be clinically relevant to this clinician type. This measure addresses a high priority specialty area and high priority clinical condition for the MIPS. It's an important comprehensive PRO-PM encompassing a broad behavioral health patient population. It utilizes a measurement-based care framework for implementation across various settings and populations. This measure would help to broaden the patient population being assessed for mental and/or substance use disorders and their maintenance and recovery. Adding this measure to the Internal Medicine specialty set would reinforce the important role this clinician type plays in addressing patient mental health and substance use disorders. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.11 of this Appendix for rationale, including clinical evidence supporting the inclusion of this

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MEASURES PROPOSED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								measure in MIPS.

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MEASURES PROPOSED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**		**Collection Type**	**Measure Type**	**Measure Title And Description**		**Measure Steward**	**Rationale for Inclusion**
! (Outcome)		N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10– or 13– item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Internal Medicine specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

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MEASURES PROPOSED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET													
Indicator				**CBE # / eCQM CBE #**				**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Safety)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association	We propose to include this measure in the Internal Medicine specialty set as it would be clinically relevant to this clinician type. The incorporation of this measure in this specialty set would help promote interventions and best practices that are effective at symptoms reduction and improving functional status and quality of life. This measure is a high priority area for MIPS and by adding the measure to this specialty set it would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder, while also reinforcing our commitment that all clinicians should be actively engaging in addressing mental health and substance use disorders across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.13 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.					

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PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INTERNAL MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
CBE # / eCQM CBE #		**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.	
N/A / N/A		107	CMS 161v12	eCQM Specifications	Process	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit.	Mathematica	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

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PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INTERNAL MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal from the Internal Medicine specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is proposed to be included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set would be duplicative.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INTERNAL MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.												
CBE # / eCQM CBE #							**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from the Internal Medicine specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is proposed to be included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set would be duplicative.						

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE INTERNAL MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
CBE # / eCQM CBE #		**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	**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 provider. 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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.	

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INTERNAL MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
CBE # / eCQM CBE #		**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**		**Measure Steward**	**Rationale for Removal**
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.		

B.20. Interventional Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Interventional Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Interventional Radiology specialty set.

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**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	**Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices.	American College of Radiology
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	409	N/A	MIPS CQMs Specifications	Outcome	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a Modified Rankin Score (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	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	420	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**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	**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	**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
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.20. Interventional Radiology

MEASURES PROPOSED FOR **ADDITION** TO THE INTERVENTIONAL RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Interventional Radiology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.21. Mental/Behavioral Health and Psychiatry

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Mental/Behavioral Health and Psychiatry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Mental/Behavioral Health and Psychiatry specialty set.

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	009	CMS128v12	eCQM Specifications	Process	**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
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 or up to two days after the date of the qualifying 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	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 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	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / 2872e	281	CMS149v12	eCQM Specifications	Process	**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	**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
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	**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	**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
! (Opioid)	N/A / N/A	305	CMS137v12	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive	Centers for Medicare and Medicaid Services

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	366	CMS13 6v13	eCQM Specifications	Process	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly prescribed 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	CMS15 9v12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**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 / N/A	382	CMS17 7v12	eCQM Specifications	Process	**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 (MDD) with an assessment for suicide risk.	Mathematica
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	**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
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**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	**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.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.21. Mental/Behavioral Health and Psychiatry

MEASURES PROPOSED FOR **ADDITION** TO THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Mental/Behavioral Health and Psychiatry specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or**	American Psychiatric Association	We propose to include this measure in the Mental/Behavioral Health and Psychiatry specialty set as it would be clinically relevant to this clinician type. This measure

B.21. Mental/Behavioral Health and Psychiatry

MEASURES PROPOSED FOR **ADDITION** TO THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
					Performance Measure	**Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.		addresses a high priority specialty and high priority clinical condition for the MIPS. It's an important comprehensive PRO- PM encompassing a broad behavioral health patient population. It utilizes a measurement-based care framework for implementation across various settings and populations. This measure would help to broaden the patient population being assessed for mental and/or substance use disorders and their maintenance and recovery. Adding this measure to the Mental/ Behavioral Health specialty set would reinforce the important role this clinician type plays in addressing patient mental health and substance use disorders. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.11 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.21. Mental/Behavioral Health and Psychiatry

MEASURES PROPOSED FOR **ADDITION** TO THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET															
Indicator								**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Safety)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association	We propose to include this measure in the Mental/Behavioral Health and Psychiatry specialty set as it would be clinically relevant to this clinician type. The incorporation of this measure in this specialty set would help promote interventions and best practices that are effective at symptoms reduction and improving functional status and quality of life. This measure is a high priority area for MIPS and by adding the measure to this specialty set it would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder, while also reinforcing our commitment that all clinicians should be actively engaging in addressing mental health and substance use disorders across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.13 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.						

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit', within 120 days after an index assessment.	American Psychiatric Association	We propose to include this measure in the Mental/Behavioral Health and Psychiatry specialty set as it would be clinically relevant to this clinician type. This patient reported outcome measure focuses on mental health and substance use disorder (SUD) and the reduction of suicidal ideation, conceptually addressing behavioral health which are a CMS high priority area. Incorporating this clinical outcome measure in this specialty set would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and SUD. The addition of this quality measure for this specialty would reinforce our commitment that all

B.21. Mental/Behavioral Health and Psychiatry

MEASURES PROPOSED FOR **ADDITION** TO THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**	
								clinicians should be actively engaging in addressing mental health and SUDs across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.14 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.	

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	107	CMS161v12	eCQM Specifications	Process	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit.	Mathematica	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	**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/ American Psychiatric Association	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	**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 provider. 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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.22. Nephrology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Nephrology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Nephrology specialty set.

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**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	**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)	N/A / N/A	130	CMS68v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**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 within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139 v12	eCQM Specifications	Process	**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	**One-Time Screening for Hepatitis C Virus (HCV) for all Patients:** Percentage of patients age >= 18 years who received one-time screening for Hepatitis C Virus (HCV) infection.	American Gastroenterological Association
! (Outcome)	N/A/ N/A	482	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate**: Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access attributable to an individual practitioner or group practice.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	488	CMS951 v2	eCQM specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
	1662/ N/A	489	N/A	MIPS CQMs Specifications	Process	**Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of CKD (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.	Renal Physicians Association
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.22. Nephrology

MEASURES PROPOSED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**First Year Standardized Waitlist Ratio (FYSWR):** The number of incident (newly initiated on dialysis) patients in a practitioner (inclusive of physicians and advanced practice providers) group who are under the age of 75, and were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant within the first year of initiating dialysis. The measure is calculated to compare the observed number of waitlist events in a practitioner group to its expected number of waitlist events. The measure uses the expected waitlist events calculated from a Cox model, adjusted for age, patient comorbidities, and other risk factors at incidence of dialysis.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Nephrology specialty set as it would be clinically relevant to this clinician type. The measure's intended objective consists of improving the overall health of patients on dialysis, with Nephrologists at the forefront of caring for this patient population. Clinicians within this specialty are responsible for the education of patients about the option of transplantation, referral of patients to a transplant center for evaluation, completion of the evaluation process, and optimizing the health of the patient while on dialysis. All clinicians should be involved and actively work towards providing patients with high quality care including ensuring placement on the transplant list as quickly as possible. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.4 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.22. Nephrology

MEASURES PROPOSED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	Percentage of **Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW):** The percentage of patients in each dialysis practitioner group practice who were on the kidney or kidney-pancreas transplant waitlist (all patients or patients in active status). Results are averaged across patients prevalent on the last day of each month during the reporting year. The measure is a directly standardized percentage, which is adjusted for covariates (e.g., age and risk factors).	Centers for Medicare & Medicaid Services	We propose to include this measure in the Nephrology specialty set as would be clinically relevant to this clinician type. The maintenance of end stage renal disease patients on active status on the waitlist is additionally important given demonstrated disparities and positive association with subsequent transplantation. These practices are important for Nephrologists who are at the forefront of caring for this patient population. This is an important area to which dialysis practitioners can contribute through ensuring patients remain healthy and complete any ongoing testing activities required to remain active on the waitlist. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.22. Nephrology

MEASURES PROPOSED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Nephrology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.22. Nephrology

MEASURES PROPOSED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Nephrology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.23. Neurology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Neurology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Neurology specialty set.

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 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	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	268	N/A	MIPS CQMs Specifications	Process	**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 / N/A	277	N/A	MIPS CQMs Specifications	Process	**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), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	**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 / 2872e	281	CMS149v 12	eCQM Specifications	Process	**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	**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
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	**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	**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.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	290	N/A	MIPS CQMs Specifications	Process	**Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for depression, anxiety, apathy, AND psychosis once during the measurement period.	American Academy of Neurology
*	N/A / N/A	291	N/A	MIPS CQMs Specifications	Process	**Assessment of Cognitive Impairment or Dysfunction 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 during the measurement period.	American Academy of Neurology
! (Care Coordination)	N/A / N/A	293	N/A	MIPS CQMs Specifications	Process	**Rehabilitative Therapy Referral for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were referred to physical, occupational, speech, or recreational therapy once during the measurement period.	American Academy of Neurology
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare and Medicaid Services
! (Care Coordination)	N/A / N/A	374	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A / N/A	386	N/A	MIPS CQMs Specifications	Process	**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
! (Efficiency)	N/A / N/A	419	N/A	MIPS CQMs Specifications	Process	**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
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**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.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.23. Neurology

MEASURES PROPOSED FOR **ADDITION** TO THE NEUROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Neurology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.23. Neurology

MEASURES PROPOSED FOR **ADDITION** TO THE NEUROLOGY SPECIALTY SET														
Indicator							**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia							We propose to include this measure in the Neurology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE NEUROLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	**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/ American Psychiatric Association	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.24. Neurosurgical

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Neurosurgical specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Neurosurgical specialty set.

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	**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 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	NA / NA	260	N/A	MIPS CQMs Specifications	Outcome	**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
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	**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	409	N/A	MIPS CQMs Specifications	Outcome	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology
§ ! (Outcome)	N/A / N/A	459	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Back Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion 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 or a numeric pain scale at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Leg Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or 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 or a numeric pain scale at three months (6 to 20 weeks) for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	471	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status After Lumbar Surgery:** For patients age 18 and older who had lumbar discectomy/laminectomy or fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy or fusion procedure.	Minnesota Community Measurement
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.24. Neurosurgical

MEASURES PROPOSED FOR **ADDITION** TO THE NEUROSURGICAL SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Neurosurgical specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.25. Nutrition/Dietician

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Nutrition/Dietician specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Nutrition/Dietician specialty set.

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**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
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 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	226	CMS138 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§	N/A / N/A	239	CMS155 v12	eCQM Specifications	Process	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/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. • 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

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**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
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.25. Nutrition/Dietician

MEASURES PROPOSED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Nutrition/Dietician specialty set. We agree with interested parties' feedback that depression continues to be a major public health concern and all Medicare clinicians should be doing their part to address the issue. Screening for depression is often a routine part of the comprehensive nutrition assessment performed by Registered Dieticians/ Nutritionists (RDNs) as nutrition status is closely linked to mental health. Optimizing the nutrition status of an individual with mental illness has been shown to improve both cognitive and emotional functioning. The measure being added to this specialty set would be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule.

B.25. Nutrition/Dietician

MEASURES PROPOSED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Nutrition/Dietician specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE NUTRITION/DIETICIAN SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

B.26. Obstetrics/Gynecology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Obstetrics/Gynecology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Obstetrics/Gynecology specialty set.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	**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	**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	MIPS CQMs Specifications	Process	**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
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* § ! (Outcome)	N/A / N/A	236	CMS165v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	309	CMS124v 12	eCQM Specifications	Process	**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	CMS153v 12	eCQM Specifications	Process	**Chlamydia Screening in 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
! (Outcome)	N/A / N/A	335	N/A	MIPS CQMs Specifications	Outcome	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQMs Specifications	Process	**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 12 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	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	2063 / N/A	422	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**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	**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	**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
* § ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	**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	**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	CMS249v6	eCQM Specifications	Process	**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	CMS349v6	eCQM Specifications	Process	**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 Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.26. Obstetrics/Gynecology

MEASURES PROPOSED FOR **ADDITION** TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**CVD Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument:** Percentage of pregnant or postpartum patients who received a cardiovascular disease (CVD) risk assessment with a standardized instrument.	University of California, Irvine	We propose to include this measure in the Obstetrics/Gynecology specialty set as it would be clinically relevant to this clinician type. This measure fills a high priority clinical gap area under the wellness and prevention domain for maternal health by addressing screening and care for pregnant/postpartum patients by assessing for a standardized CVD risk assessment for this high-risk population cared for by clinicians in this specialty. Given the close correlation of CVD risks and pregnant/postpartum patients, interdisciplinary care is vital. The addition of this quality measure to this specialty set would incentivize thorough assessment for patient risk and increase education and awareness in this population. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.3 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.26. Obstetrics/Gynecology

MEASURES PROPOSED FOR **ADDITION** TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services	We propose to include this measure in the Obstetrics/Gynecology specialty set as it would be clinically relevant to this clinician type. The addition of this quality measure to this specialty set would reinforce our commitment that all clinicians should be actively engaging in activities that address preventive care and wellness and is in alignment with our priorities to support overall patient health. The measure would set a more stringent performance standard by requiring a set of preventive care for the general population in one composite measure and aligns with evidence-based recommendations. The measure would help incentivize a more broadly encompassing preventive care assessment to guide clinicians. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.6 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.26. Obstetrics/Gynecology

MEASURES PROPOSED FOR **ADDITION** TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET														
Indicator			**CBE # / eCQM CBE #**					**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Obstetrics/Gynecology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.													

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual's knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Obstetrics/Gynecology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale,

B.26. Obstetrics/Gynecology

MEASURES PROPOSED FOR **ADDITION** TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								including clinical evidence supporting the inclusion of this measure in MIPS.

! (Safety)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association	We propose to include this measure in the Obstetrics/Gynecology specialty set as it would be clinically relevant to this clinician type. The incorporation of this measure in this specialty set would help promote interventions and best practices that are effective at symptoms reduction and improving functional status and quality of life. This measure is a high priority area for MIPS and by adding the measure to this specialty set it would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder, while also reinforcing our commitment that all clinicians should be actively engaging in addressing mental

B.26. Obstetrics/Gynecology

MEASURES PROPOSED FOR **ADDITION** TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								health and substance use disorders across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.13 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit', within 120 days after an index assessment.	American Psychiatric Association	We propose to include this measure in the Obstetrics/Gynecology specialty set as it would be clinically relevant to this clinician type. This patient reported outcome measure focuses on mental health and substance use disorder (SUD) and the reduction of suicidal ideation, conceptually addressing behavioral health which are a CMS high priority area. Incorporating this clinical outcome measure in this specialty set would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder. The addition of this quality measure for this specialty would reinforce our commitment that all clinicians

B.26. Obstetrics/Gynecology

MEASURES PROPOSED FOR **ADDITION** TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**	
								should be actively engaging in addressing mental health and substance use disorders across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.14 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.	

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE OBSTETRICS/GYNECOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
2372 / N/A	112	CMS 125v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group CC of this Appendix for rationale.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE OBSTETRICS/GYNECOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal from the Obstetrics/Gynecology specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is proposed to be included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set would be duplicative.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE OBSTETRICS/GYNECOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.												
CBE # / eCQM CBE #							**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from the *Obstetrics/Gynecology* specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is proposed to be included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set would be duplicative.					
N/A / N/A	402						N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.	

B.27a. Oncology/Hematology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Oncology/Hematology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Oncology/Hematology specialty set.

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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)	N/A / N/A	102	CMS129 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**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 Safety)	N/A / N/A	130	CMS68v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v1 3	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
§ ! (Patient Experience)	0384 / 0384e	143	CMS157 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**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

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	0383 / N/A	144	N/A	MIPS CQMs Specifications	Process	**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
* §	N/A / N/A	226	CMS138 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
*	N/A / N/A	317	CMS22v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	**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 CBE 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 CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A / N/A	374	CMS50v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**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	**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

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	1859 / N/A	451	N/A	MIPS CQMs Specifications	Process	**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
§ ! (Appropriate Use)	1860 / N/A	452	N/A	MIPS CQMs Specifications	Process	**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	**Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0216 / N/A	457	N/A	MIPS CQMs Specifications	Outcome	**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 v7	eCQM Specifications	Process	**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
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	490	N/A	MIPS CQMs Specifications	Process	**Appropriate Intervention of Immune-related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors:** Percentage of patients, aged 18 years and older, with a diagnosis of cancer, on immune checkpoint inhibitor therapy, and grade 2 or above diarrhea and/or grade 2 or above colitis, who have immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered.	Society for Immunotherapy of Cancer (SITC)
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.27a. Oncology/Hematology

MEASURES PROPOSED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care provider and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We propose to include this measure in the Oncology/ Hematology specialty set as it would be clinically relevant to this clinician type. This patient-reported outcome measure would help to fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Patients feeling heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. This is an important patient-centered measure that helps patients feel heard and understood which can effectively improve the quality of care received and outcomes for patients in palliative care. See Table A.2 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.27a. Oncology/Hematology

MEASURES PROPOSED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Oncology/Hematology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.27a. Oncology/Hematology

MEASURES PROPOSED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Oncology/Hematology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE ONCOLOGY/HEMATOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.													
CBE # / eCQM CBE #							Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.						

B.27b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Radiation Oncology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Radiation Oncology specialty set.

B.27b. Radiation Oncology

PREVIOUSLY FINALIZED MEASURES IN THE RADIATION ONCOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A / N/A	102	CMS12 9v13	eCQM Specifications, MIPS CQMs Specifications	Process	**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	CMS15 7v12	eCQM Specifications, MIPS CQMs Specifications	Process	**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	**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
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.28. Ophthalmology/Optometry

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Ophthalmology/Optometry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Ophthalmology/Optometry specialty set.

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / 0086e	012	CMS143v12	eCQM Specifications	Process	**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
* ! (Care Coordination)	N/A / N/A	019	CMS142v12	eCQM Specifications, MIPS CQMs Specifications	Process	**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	CMS131v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of 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 in any part of 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)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	0563 / N/A	141	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Outcome	**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	CMS133v12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**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
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	303	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	American Academy of Ophthalmology

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	304	N/A	MIPS CQMs Specifications	Patient Engagement/Experience	**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
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	384	N/A	MIPS CQMs Specifications	Outcome	**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	**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	**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
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.28. Ophthalmology/Optometry

MEASURES PROPOSED FOR **ADDITION** TO THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Ophthalmology/Optometry specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.28. Ophthalmology/Optometry

MEASURES PROPOSED FOR **ADDITION** TO THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET																
Indicator								**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy:** Percentage of patients who had an intravitreal or periocular corticosteroid injection (e.g., triamcinolone, preservative-free triamcinolone, dexamethasone, dexamethasone intravitreal implant, or fluocinolone intravitreal implant) who, within seven (7) weeks following the date of injection, are screened for elevated intraocular pressure (IOP) with tonometry with documented IOP =<25 mm Hg for injected eye OR if the IOP was >25 mm Hg, a plan of care was documented.	American Society of Retina Specialists								We propose to include this measure in the Ophthalmology and Optometry specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given the high rates that patients are assessed, treated, and managed for this condition in the Ophthalmology and Optometry care setting. This measure addresses the MIPS priority area of patient safety. This measure would help to incentivize timely initiation of the appropriate screening for these patients and ensure there is a plan of care for elevated IOP following intravitreal or periocular steroid therapy. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.8 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up:** Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 8 weeks	American Society of Retina Specialists	We propose to include this measure in the Ophthalmology and Optometry specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given the high rates that patients are assessed, treated, and managed for this condition in the Ophthalmology and Optometry care setting. This measure is guideline based and addresses the MIPS priority area of patient safety. It's also linked to health outcomes by appropriate care for acute PVD, which can prevent retinal tears. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.9 of this Appendix for rationale, including clinical evidence supporting the inclusion of this

B.28. Ophthalmology/Optometry

MEASURES PROPOSED FOR **ADDITION** TO THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								measure in MIPS.

B.28. Ophthalmology/Optometry

MEASURES PROPOSED FOR **ADDITION** TO THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.10 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0087 / N/A	014	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.29. Orthopedic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Orthopedic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Orthopedic Surgery specialty set.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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 Measure Specifications, MIPS CQMs Specifications	Process	**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)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	**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	**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	MIPS CQMs Specifications	Process	**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 within two days of 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-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) 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 FOTO Elbow/Wrist/Hand FS 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS13 9v12	eCQM Specifications	Process	**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	**Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients regardless of age undergoing a total knee or total hip 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

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	351	N/A	MIPS CQMs Specifications	Process	**Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients regardless of age undergoing a total knee or total hip 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
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**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 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	N/A / N/A	376	CMS56 v12	eCQM Specifications	Process	**Functional Status Assessment for Total Hip Replacement:** Percentage of patients 19 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
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	459	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Back Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion 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 or a numeric pain scale at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Leg Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or 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 or a numeric pain scale at three months (6 to 20 weeks) for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	470	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**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-Based Performance Measure	**Functional Status After Lumbar Surgery:** For patients age 18 and older who had lumbar discectomy/laminectomy or fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy or fusion procedure.	Minnesota Community Measurement

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	3493 / N/A	480	N/A	Administrative Claims	Outcome	**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):** 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.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers** of **Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.29. Orthopedic Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE ORTHOPEDIC SURGERY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Orthopedic Surgery specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE ORTHOPEDIC SURGERY SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.30. Otolaryngology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Otolaryngology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Otolaryngology specialty set.

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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)	N/A / N/A	066	CMS146 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Service
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	226	CMS138 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	**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), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicin
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	**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 Medicin

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Service
! (Patient Safety)	0101 / N/A	318	CMS139v12	eCQM Specifications	Process	**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	**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	**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	355	N/A	MIPS CQMs Specifications	Outcome	**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	357	N/A	MIPS CQMs Specifications	Outcome	**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	**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	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Service
* ! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	**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	**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	**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. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.30. Otolaryngology

MEASURES PROPOSED FOR **ADDITION** TO THE OTOLARYNGOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Otolaryngology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE OTOLARYNGOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE OTOLARYNGOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.													
CBE # / eCQM CBE #							**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.						

B.31. Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 and this specialty set has no proposed changes.

B.31. Pathology

PREVIOUSLY FNALIZED MEASURES IN THE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	249	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	**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	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on lung biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type following the International Association for the Study of Lung Cancer (IASLC) guidance 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	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on lung 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	**Melanoma Reporting:** Pathology reports for primary malignant cutaneous melanoma that include the pT category, thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors.	College of American Pathologists
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQMs Specifications	Process	**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
! (Care Coordination)	3661 / N/A	491	N/A	MIPS CQMs Specifications	Process	**Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma:** Percentage of surgical pathology reports for primary colorectal, endometrial, gastroesophageal or small bowel carcinoma, biopsy or resection, that contain impression or conclusion of or recommendation for testing of mismatch repair (MMR) by immunohistochemistry (biomarkers MLH1, MSH2, MSH6, and PMS2), or microsatellite instability (MSI) by DNA-based testing status, or both	College of American Pathologists

B.32. Pediatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Pediatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Pediatrics specialty set.

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v12	eCQM Specifications, MIPS CQMs Specifications	Process	**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 order.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	**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	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	205	N/A	MIPS CQMs Specifications	Process	**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.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	239	CMS155v12	eCQM Specifications	Process	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/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. • 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	CMS117v12	eCQM Specifications	Process	**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	CMS137v12	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
* §	N/A / N/A	310	CMS153v12	eCQM Specifications	Process	**Chlamydia Screening in 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.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	366	CMS136v13	eCQM Specifications	Process	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly prescribed 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	CMS159v12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**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 / N/A	382	CMS177v12	eCQM Specifications	Process	**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 (MDD) with an assessment for suicide risk.	Mathematica
§	N/A / N/A	394	N/A	MIPS CQMs Specifications	Process	**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	**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
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	**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.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.32. Pediatrics

MEASURES PROPOSED FOR **ADDITION** TO THE PEDIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	We propose to include this measure in the Pediatrics specialty set. Updates are being proposed to measure Q226 to now include patients 12 years of age and older. Therefore, screening for tobacco use and cessation intervention would be an important measure for the pediatric clinician type to utilize. The measure being added to this specialty set would be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule.

B.32. Pediatrics

MEASURES PROPOSED FOR **ADDITION** TO THE PEDIATRICS SPECIALTY SET																
Indicator								**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Pediatrics specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.								

B.32. Pediatrics

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE PEDIATRICS SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	**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 provider. 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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.32. Pediatrics

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PEDIATRICS SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.													
CBE # / eCQM CBE #							**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.						

B.33. Physical Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Physical Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Physical Medicine specialty set.

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	MIPS CQMs Specifications	Process	**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 within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**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	**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
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.33. Physical Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Physical Medicine specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE PHYSICAL MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.34. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Physical Therapy/Occupational Therapy specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Physical Therapy/Occupational Therapy specialty set.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	**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	MIPS CQMs Specifications	Process	**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
	N/A / N/A	126	N/A	MIPS CQMs Specifications	Process	**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	127	N/A	MIPS CQMs Specifications	Process	**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
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v 13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 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	MIPS CQMs Specifications	Process	**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 within two days of 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-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient- Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient- Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient- Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient- Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient- Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) 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 FOTO Elbow/Wrist/Hand FS 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / 2872e	281	CMS14 9v12	eCQM Specifications	Process	**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
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	**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	**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.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0101 / N/A	318	CMS139v12	eCQM Specifications	Process	**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-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers** of **Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.34. Physical Therapy/Occupational Therapy

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	291	N/A	MIPS CQMs Specifications	Process	**Assessment of Cognitive Impairment or Dysfunction 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 during the measurement period.	American Academy of Neurology	We propose to include this measure in the Physical Therapy/Occupational Therapy specialty set. We agree with interested parties' feedback that this measure would be clinically relevant to this clinician type. Occupational therapy services enable clients to participate in their everyday life occupations in their desired roles, contexts, and life situations through evaluation and treatment related to basic activities of daily living and instrumental activities of daily living. Occupational therapy practitioners use their knowledge and skills to help clients conduct or resume daily life occupations that support function and health throughout the lifespan, including patients with dementia and their caregivers. The addition of this quality measure in this specialty set would make room for more clinician choice by making more measures available that are reflective of the services delivered to this patient population. The measure being added to this specialty set would be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule.

B.34. Physical Therapy/Occupational Therapy

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Physical Therapy/ Occupational Therapy specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association	We propose to include this measure in the Physical Therapy/ Occupational Therapy (OT) specialty set as it would be clinically relevant to this clinician type. We agree with interested parties' feedback that this measure would help to broaden the patient population being assessed for mental and/or substance use disorders and their maintenance and recovery. In addition, Occupational therapy practitioners provide services to people across the lifespan who experience a range of mental health and ill health based on genetic predisposition and/or life stressors (e.g., disability, injury, trauma). Occupational therapy is used to help support people with mental illness in skill development, activity engagement, and with

B.34. Physical Therapy/Occupational Therapy

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**		**Measure Title And Description**		**Measure Steward**	**Rationale for Inclusion**
										meeting individual recovery goals under an OT Plan of Care. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.11 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.34. Physical Therapy/Occupational Therapy

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET														
Indicator		**CBE # / eCQM CBE #**						**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Physical Therapy/ Occupational Therapy specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.					

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal from the Physical Therapy/Occupational Therapy specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. PT/OT applicable coding has not been added to this measure, so we are proposing to remove this measure from this specialty set.
N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	**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/ American Psychiatric Association	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.35. Plastic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Plastic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Plastic Surgery specialty set.

B.35. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	**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	**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	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons

B.35. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**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
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.35. Plastic Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE PLASTIC SURGERY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Plastic Surgery specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.35. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PLASTIC SURGERY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

B.36. Podiatry

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Podiatry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Podiatry specialty set.

B.36. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	126	N/A	MIPS CQMs Specifications	Process	**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	127	N/A	MIPS CQMs Specifications	Process	**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
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Patient Safety)	0101 / N/A	318	CMS139v12	eCQM Specifications	Process	**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
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.36. Podiatry

MEASURES PROPOSED FOR **ADDITION** TO THE PODIATRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! Outcome	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) 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, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.	We propose to include this measure in the Podiatry specialty set as it would be clinically relevant to this clinician type. The addition of this measure would provide this specialty the opportunity to report on an important PRO-PM that would align with their scope of care consisting of the treatment of the lower extremity. Functional deficits are common in the general population and are costly to the individual, their family and society, and improving functional status has been associated with greater quality of life, self-efficacy, improved financial well-being and lower future medical costs (*https://fotoinc.com/science-of-foto/nqf-measure-specifications/*). Predictive modeling allows for patient-level predictions to help guide treatment decision making and expectations for recovery.

B.36. Podiatry

MEASURES PROPOSED FOR **ADDITION** TO THE PODIATRY SPECIALTY SET															
Indicator								**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services								We propose to include this measure in the Podiatry specialty set. The addition of this measure to this specialty set would help to broaden the patient population being screened for high blood pressure. There is known risk of adverse effects on the circulatory system due to high blood pressure making this an important aspect of care for podiatrists. Hypertension is often related to atherosclerosis and this buildup of plaque in blood vessels can lead to decreased circulation and peripheral arterial disease (PAD) (*https://www.apma.org/hypertension*). Patients with decreased circulation in their lower extremities may develop ulcerations that can lead to amputations. Given the close correlation of hypertension and decreased circulation in lower extremities, interdisciplinary care is vital and should be the responsibility of all clinician types. The addition of this measure to the Podiatry specialty set would help to encourage the comprehensive evaluation of compliance of screening for and proper treatment of high blood pressure that can improve quality care and prevent disease for the general population.

! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**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	We propose to include this measure in the Podiatry specialty set as it would be clinically relevant to this clinician type. Patients undergoing podiatric surgery should receive a thorough perioperative evaluation. Medical "clearance" is no longer sufficient; rather, formal risk assessment should be performed, and risk-reducing strategies communicated. A collaborative, multidisciplinary approach is generally most appropriate, however, expertise and training in this critical dimension of clinical practice varies. Thus, podiatrists should develop independent competence in perioperative evaluation to ensure optimal care for their patients. In preparation for elective foot and ankle surgery, the podiatric surgeon often will refer the patient for a preoperative evaluation. Surgeons rely on the input of that consultant to provide a determination as to the operative risk for the patient (*https://pubmed.ncbi.nlm.nih.gov/12776978/*).
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen	OCHIN	We propose to include this measure in the Podiatry specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with

B.36. Podiatry

MEASURES PROPOSED FOR **ADDITION** TO THE PODIATRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
						positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.		all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data, which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10- or 13-item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Podiatry specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.36. Podiatry

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PODIATRY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

B.37. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Preventive Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Preventive Medicine specialty set.

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**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 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	**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	**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	**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.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	**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	126	N/A	MIPS CQMs Specifications	Process	**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
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	MIPS CQMs Specifications	Process	**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 within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	**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
! (Care Coordination)	N/A / N/A	374	CMS50v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	NA	MIPS CQMs Specifications	Process	**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 v7	eCQM Specifications, MIPS CQMs Specifications	Process	**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: *All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	475	CMS349 v6	eCQM Specifications	Process	**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 Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	488	CMS951 v2	eCQM specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.37. Preventive Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE PREVENTIVE MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services	We propose to include this measure in the Preventive Medicine specialty set as it would be clinically relevant to this clinician type. The addition of this quality measure to this specialty set would reinforce our commitment that all clinicians should be actively engaging in activities that address preventive care and wellness and is in alignment with our priorities to support overall patient health. The measure would set a more stringent performance standard by requiring a set of preventive care for the general population in one composite measure and aligns with evidence-based recommendations. The measure would help incentivize a more broadly encompassing preventive care assessment to guide clinicians. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.6 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.37. Preventive Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE PREVENTIVE MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Preventive Medicine specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.37. Preventive Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE PREVENTIVE MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Preventive Medicine specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PREVENTIVE MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
2372 / N/A	112	CMS125v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group CC of this Appendix for rationale.
0034 / N/A	113	CMS130v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Colorectal Cancer Screening:** Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group CC of this Appendix for rationale.
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PREVENTIVE MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.													
CBE # / eCQM CBE #							**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal from the *Preventive Medicine* specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is proposed to be included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set would be duplicative.						
N/A / N/A							317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from the Preventive Medicine specialty set beginning with the CY 2024 performance period/2026 MIPS payment year.

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PREVENTIVE MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.38. Pulmonology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Pulmonology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Pulmonology specialty set.

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	**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
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of 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 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	**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), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	**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 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	**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	**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
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.38. Pulmonology

MEASURES PROPOSED FOR **ADDITION** TO THE PULMONOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Pulmonology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data, which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule. Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.38. Pulmonology

MEASURES PROPOSED FOR **ADDITION** TO THE PULMONOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Pulmonology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE PULMONOLOGY SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.39. Rheumatology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Rheumatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Rheumatology specialty set.

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	**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	**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)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	2523 / N/A	177	N/A	MIPS CQMs Specifications	Process	**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	**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	**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
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of 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	CMS156v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive	Centers for Medicare & Medicaid Services

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee Quality Assurance

B.39. Rheumatology

MEASURES PROPOSED FOR **ADDITION** TO THE RHEUMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Rheumatology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.39. Rheumatology

MEASURES PROPOSED FOR **ADDITION** TO THE RHEUMATOLOGY SPECIALTY SET														
Indicator				**CBE # / eCQM CBE #**				**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia							We propose to include this measure in the Rheumatology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE RHEUMATOLOGY SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	128	CMS69 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.40. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Skilled Nursing Facility specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Skilled Nursing Facility specialty set.

B.40. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	**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	CMS145v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**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	CMS144v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**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	**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	**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
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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.40. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**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	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 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	CMS156v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	326	N/A	MIPS CQMs Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.40. Skilled Nursing Facility

MEASURES PROPOSED FOR **ADDITION** TO THE SKILLED NURSING FACILITY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Skilled Nursing Facility specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.41. Speech Language Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Speech Language Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Speech Language Pathology specialty set.

B.41. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 or up to two days after the date of the qualifying 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	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 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	MIPS CQMs Specifications	Process	**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 within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.41. Speech Language Pathology

MEASURES PROPOSED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	291	N/A	MIPS CQMs Specifications	Process	**Assessment of Cognitive Impairment or Dysfunction 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 during the measurement period.	American Academy of Neurology	We propose to include this measure in the Speech Language Pathology specialty set. We agree with interested parties' feedback that SLPs are keenly interested in a measure set that includes quality measures that are more reflective of the types of clinical conditions they treat. While the diagnosis of Parkinson's disease is made by a medical team, SLPs are trained to assess cognitive-communication deficits related to this condition, and to identify cultural, linguistic, and environmental influences that have an impact on functioning. The services provided by SLPs contribute to improving the safety and well-being of the individual. Therefore, it would be important to consider SLPs as an integral member of the clinical care team working with patients diagnosed with Parkinson's and include this measure in the speech-language pathology specialty measure set. The addition of this quality measure in this specialty set would make room for more clinician choice by making more measures available that are reflective of the services delivered to this patient population. The measure being added to this specialty set would be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule.

B.41. Speech Language Pathology

MEASURES PROPOSED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**		**Measure Steward**	**Rationale for Inclusion**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Speech Language Pathology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. We agree with interested parties' feedback that SLPs are committed to addressing health equity and play a key role in screening individuals for social risks. When factors are identified, SLPs consider them when establishing a care plan and modifications are made to create achievable, sustainable, and functional goals that are patient-centered. In response to the interested parties' feedback, we are proposing to add this measure to this specialty set if all proposed measures for the specialty set are finalized. This is a screening data collection measure and is voluntary; therefore, clinicians have the flexibility to choose to report this measure and it only looks at the screening of patients. Currently, if all proposed measures for this specialty set are finalized, the SLP specialty set would contain 11 measures allowing clinicians to choose to submit those measures that are most meaningful to their scope of care. Under MIPS, clinicians have the flexibility to choose to report the measures that would work best for their scope of practice and clinical workflow. The measure being added to this specialty set would be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule.

B.41. Speech Language Pathology

MEASURES PROPOSED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**		**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Speech Language Pathology specialty set. We agree with interested parties' feedback that this measure would be clinically relevant to this clinician type as this profession has historically addressed social needs through screening and evaluation, providing referrals, and connecting patients to community services and falls within their scope of care. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. This is a screening measure requiring a connection to the CSP, and is voluntary; therefore, clinicians have the flexibility to choose to report this measure and it only looks at the screening of patients. Currently, if all proposed measures for this specialty set are finalized, the Speech Language Pathology specialty set would contain 11 measures allowing clinicians to choose to submit those measures that are most meaningful to their scope of care. Under MIPS, clinicians have the flexibility to choose to report the measures that would work best for their scope of practice and clinical workflow. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.42. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Thoracic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Thoracic Surgery specialty set.

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Outcome)	0129 / N/A	164	N/A	MIPS CQMs Specifications	Outcome	**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	**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
! (Outcome)	0115 / N/A	168	N/A	MIPS CQMs Specifications	Outcome	**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
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	356	N/A	MIPS CQMs Specifications	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**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 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	0119 / N/A	445	N/A	MIPS CQMs Specifications	Outcome	**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
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.42. Thoracic Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE THORACIC SURGERY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Thoracic Surgery specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE THORACIC SURGERY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.43. Urgent Care

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Urgent Care specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Urgent Care specialty set.

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v12	eCQM Specifications, MIPS CQMs Specifications	Process	**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 order.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	**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)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	**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	**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
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**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	**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
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.43. Urgent Care

MEASURES PROPOSED FOR **ADDITION** TO THE URGENT CARE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Urgent Care specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE URGENT CARE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.44. Urology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Urology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Urology specialty set.

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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	**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	MIPS CQMs Specifications	Process	**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)	N/A / N/A	102	CMS129v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**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
*	N/A / N/A	104	N/A	MIPS CQMs Specifications	Process	**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.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022/ N/A	238	CMS156v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005/ N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	**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 CBE 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 CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**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	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**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.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	432	N/A	MIPS CQMs Specifications	Outcome	**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	**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
§ ! (Appropriate Use)	0210/ N/A	453	N/A	MIPS CQMs Specifications	Process	**Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0216/ N/A	457	N/A	MIPS CQMs Specifications	Outcome	**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	CMS645v7	eCQM Specifications	Process	**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
! (Outcome)	N/A / N/A	476	CMS771v5	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**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.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A/ N/A	481	CMS646v 4	eCQM Specifications	Process	**Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer**: Percentage of patients initially diagnosed with non-muscle invasive bladder cancer and who received intravesical Bacillus-Calmette-Guerin (BCG) within 6 months of bladder cancer staging.	Oregon Urology
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	488	CMS951v 2	eCQM Specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation

B.44. Urology

MEASURES PROPOSED FOR **ADDITION** TO THE UROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Urology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data, which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.44. Urology

MEASURES PROPOSED FOR **ADDITION** TO THE UROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Urology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.44. Urology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE UROLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

B.45. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Vascular Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a 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 are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Vascular Surgery specialty set.

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**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)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of 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	259	N/A	MIPS CQMs Specifications	Outcome	**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

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	NA / NA	260	N/A	MIPS CQMs Specifications	Outcome	**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
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	**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	**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	**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	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	420	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	**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
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.45. Vascular Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE VASCULAR SURGERY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Vascular Surgery specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE VASCULAR SURGERY SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #							Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A							128	CMS 69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**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 the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**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	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.						

Table Group C: Previously Finalized Quality Measures Proposed for Removal in the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

In this proposed rule, we propose to remove 12 previously finalized MIPS quality measures from MIPS for the CY 2024 performance period/2026 MIPS payment year and future years. These measures are discussed in detail below. The CY 2019 PFS final rule (83 FR 59763 through 59765) and CY 2020 PFS final rule (84 FR 62957 through 62959) discusses our incremental approach to removing process measures.

Under our measure removal criteria, consideration is given to the following, but is not limited to:

- Whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the measure addresses a priority area highlighted in the Measure Development Plan at *https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measure-development.*
- Whether the measure promotes positive outcomes in patients.
- Considerations and evaluation of the measure's performance data.
- Whether the measure is designated as high priority or not.
- If they do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods.
- After factoring in other considerations (such as, but not limited to: The robustness of the measure; whether it addresses a measurement gap; if the measure is a patient-reported outcomes; consideration of the measure in developing MVPs).
- If we determine the measure is not available for MIPS reporting by or on behalf of all MIPS eligible clinicians.

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), an additional criterion that we use for the removal of measures includes extremely topped out measures, which means measures that are topped out with an average (mean) performance rate between 98-100 percent.

For a measure that is proposed for removal due to criteria relating to the benchmark and performance data, further information regarding MIPS benchmarking data can be located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip*.

C.1. Age-Related Macular Degeneration (AMD): Dilated Macular Examination

Category	Description
CBE # / eCQM CBE #:	0087 / N/A
Quality #:	014
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
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.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip.*
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.2. Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use

Category	Description
CBE # / eCQM CBE #:	0654 / N/A
Quality #:	093
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.
Measure Steward:	American Academy of Otolaryngology – Head and Neck Surgery
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip.*
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.3. Adult Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	107
CMS eCQM ID:	CMS161v12
Collection Type:	eCQM Specifications
Measure Description:	Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit.
Measure Steward:	Mathematica
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to the Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk measure being proposed in Table A.13 of this Appendix. Measure Q107 is specific to major depressive disorder whereas the new measure would include patients with other behavioral health conditions who are at risk of suicide. Furthermore, the proposed new measure represents a high priority area for MIPS: mental health. It focuses on a care process that is directly designed to mitigate suicide risk, as opposed to just completing the screening. Studies have shown that clinical interventions aimed at suicide prevention, such as initiating and reviewing a suicide safety plan with a patient at risk of suicide, is a proxy for the clinical outcome of a reduction in suicides, suicide attempts, and suicidal ideation (*https://pubmed.ncbi.nlm.nih.gov/29998307/*).
In the Circumstance the Measure is Retained	If the measure is not finalized for removal in the CY 2024 PFS final rule, we propose to apply the following substantive change to the measure specifications: 1) the measure description, initial patient population and guidance would be updated so that the age description in the narrative matches the Clinical Quality Language (CQL) logic of capturing patients who are 17 years and older. This proposal ensures the measure is implemented as specified, and the correct patient population is being captured. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix. The substantive changes outlined above would be applied to the measure specifications.

C.4. Preventive Care and Screening: Influenza Immunization

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	110
CMS eCQM ID:	CMS147v13
Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to a more robust measure Q493: Adult Immunization Status. This measure's clinical concept is included in the Adult Immunization Status measure. Measure Q110 only focuses on the administration of the influenza immunization rather than providing a comprehensive evaluation based on all the recommended age-appropriate immunizations that promote well-being. Furthermore, the measure is currently only available for use within MVPs; however, based upon interested party feedback, measure Q493 is being proposed as a replacement for those MVPs that contain measure Q110. This measure would remain for purposes of the CMS Web Interface collection type available to Shared Savings Program ACOs reporting through the APP.
In the Circumstance the Measure is Retained	If the measure is not finalized for removal in the CY 2024 PFS final rule, we propose to apply the following substantive change to the measure specifications: 1) denominator exclusion for all collection types would be updated to include anaphylaxis due to the vaccine as there is new coding available to capture this data. It is clinically appropriate and prudent to refrain from administering the vaccine to patients who experienced anaphylaxis with a previous vaccine administration. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix. The substantive changes outlined above would be applied to the measure specifications.

C.5. Pneumococcal Vaccination Status for Older Adults

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	111
CMS eCQM ID:	CMS127v12
Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients 66 years of age and older who have received a pneumococcal vaccine.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to a more robust measure Q493: Adult Immunization Status. This measure's clinical concept is included in the Adult Immunization Status measure. Measure Q111 only focuses on the administration of the pneumococcal immunization rather than providing a comprehensive evaluation based on all the recommended age-appropriate immunizations that promote well-being. Furthermore, the measure is currently only available for use within MVPs; however, based upon interested party feedback, measure Q493 is being proposed as a replacement for those MVPs that contain measure Q111.
In the Circumstance the Measure is Retained	If the measure is not finalized for removal in the CY 2024 PFS final rule, we propose to apply the following substantive changes to the measure specifications: 1) for the eCQM Specifications collection type, the denominator exclusion would be updated to include anaphylaxis any time before the end of the measurement period due to new coding availability to capture this data; 2) for the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types, the denominator exclusions for active chemotherapy, bone marrow transplant and history of immunocompromising conditions would be removed; and 3) for all collection types, the initial patient population would be changed from 66 years of age and older to 65 years of age and older while the numerator criteria lookback period would be extended to the 19th birthday for pneumococcal vaccination. These updates would lend to better alignment with the most recent ACIP guidelines *(https://www.cdc.gov/vaccines/vpd/pneumo/hcp/recommendations.html)*. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix. The substantive changes outlined above would be applied to the measure specifications.

C.6. Melanoma: Coordination of Care

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	138
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
Measure Description:	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.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip.*
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.7. Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	147
CMS eCQM ID:	N/A
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
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.
Measure Steward:	Society of Nuclear Medicine and Molecular Imaging
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip.*
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.8. Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	283
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
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.
Measure Steward:	American Academy of Neurology/American Psychiatric Association
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip.*
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.9. Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	324
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
Measure Description:	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.
Measure Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because the quality action being measured 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 measure is 0.81 percent for the MIPS CQMs Specifications collection type. As such, the MIPS CQMs Specifications collection type is 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/2272/2023%20Quality%20Benchmarks.zip.*
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.10. Follow-Up After Hospitalization for Mental Illness (FUH)

Category	Description
CBE # / eCQM CBE #:	0576 / N/A
Quality #:	391
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
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 provider. 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
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because we received feedback from interested parties that it is analytically challenging to implement this measure at the clinician level. The quality action of this measure is to ensure that patients discharged from an acute setting have outpatient follow ups. However, clinicians have provided feedback that patients who receive inpatient care, and are denominator eligible for this measure, may not always seek follow-up care within the inpatient clinician's health system which limits the clinician's or group's ability to document adequate follow up to outpatient encounters. This limitation makes it difficult to attribute the required numerator actions back to the accountable clinician, creating undue burden for MIPS eligible clinicians.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.11. Tobacco Use and Help with Quitting Among Adolescents

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	402
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
Measure Description:	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.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to measure Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention. We are proposing in Table D.22 of this Appendix substantive changes to measure Q226 that would broaden the denominator by lowering the age to 12 years old and would therefore capture the denominator-eligible patient population for this measure.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.12. Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	436
CMS eCQM ID:	N/A
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	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.
Measure Steward:	American College of Radiology/ American Medical Association/ National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to the measure Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level) being proposed in Table A.1 of this Appendix. This new measure is an outcome and digital measure which supports MIPS' focus on quality measures that assess outcomes and reduce clinician burden. The focus of this measure is to reduce radiation doses from computerized tomography (CT) scans, which may increase the risk of cancer. This new measure is more robust than measure Q436 which represents a process measure.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

Table Group CC: Proposed Partial Removal of Three Previously Finalized Quality Measures as Component Measures in Traditional MIPS and Proposed Retention of These Three Measures for Use in Relevant MVPs for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

Beginning with the CY 2024 performance period/2026 MIPS payment year and future years, we propose to maintain 3 quality measures: Q112: Breast Cancer Screening; Q113: Colorectal Cancer Screening; and Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up Plan for MVP development and implementation (and maintain quality measures Q112 and Q113 for purposes of the CMS Web Interface collection type available to Shared Savings Program ACOs reporting through the APP). The clinical concepts represented by these MIPS quality measures would support some specialties in a more targeted approach rather than the broader clinical concept of preventive screenings represented within the proposed Preventive Care and Wellness (composite) measure proposed under Table A.6 of Appendix 1: MIPS Quality Measures. The tables within this section offer the rationale for the proposal to partially remove quality measures Q112, Q113, and Q128, in which such quality measures are proposed for removal from traditional MIPS but retained for use in MVPs.

Therefore, we are proposing to remove the three aforementioned previously finalized quality measures from traditional MIPS due to the proposal of adding the Preventive Care and Wellness (composite) measure in Table A.6 of Appendix 1: MIPS Quality Measures, which includes the concepts of quality measures Q112, Q113, and Q128 as part of the proposed composite Preventive Care and Wellness measure, and retain measures Q112, Q113, and Q128 for use in MVPs (and retain measures Q112 and Q113 for purposes of the CMS Web Interface collection type available to Shared Savings Program ACOs reporting through the APP as discussed in section III.G.2.c.(2) of this proposed rule; see Table Group E of this Appendix for the proposed changes to quality measures Q112 and Q113 available within the CMS Web Interface collection type).

Furthermore, measure Q112 is proposed as an available measure within the proposed Focusing on Women's Health MVP (see Appendix 3: MVP Inventory Table A.1).

Measure Q128 is proposed for removal from traditional MIPS with proposal for retention in MVPs under Table CC.3 of this Appendix. It is noted that measure Q128 is being proposed as an available measure within the following two proposed MVPs: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP and Rehabilitative Support for Musculoskeletal Care MVP (see Appendix 3: MVP Inventory Tables A.2 and A.5). Quality measure Q128 is currently an available measure within the following 2 previously finalized MVPs: Advancing Care for Heart Disease MVP and Improving Care for Lower Extremity Joint Repair MVP (see Appendix 3: MVP Inventory Tables B.5 and B.8).

We request comments on this proposal.

CC.1. Breast Cancer Screening

Category	Description
CBE # / eCQM CBE #:	2372 / N/A
Quality #:	112
CMS eCQM ID:	CMS125v12
Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
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.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from traditional MIPS because we propose a more robust and comprehensive measure under Table A.6: Preventive Care and Wellness (composite) of this Appendix. This clinical concept is included as one of the components of the Preventive Care and Wellness (composite) measure. Measure Q112 only focuses on a single clinical concept of women who have had a mammogram screening for breast cancer rather than a comprehensive preventive care and wellness approach; however, the clinical quality action assessed within measure Q112 is appropriate and applicable for some MVPs, where other components within the composite measure are not, leaving a potential gap within the quality performance category of these MVPs. Therefore, we propose the removal of this measure from traditional MIPS but propose retention of this measure for use in relevant MVPs. Measure Q112 has already been finalized in the Promoting Wellness MVP but is proposed for removal from that MVP due to the proposal of the Preventive Care and Wellness (composite) measure under Table A.6 of this Appendix and proposal of a consolidated MVP titled Value in Primary Care (see Appendix 3: MVP Inventory Table B.11). Measure Q112 is currently proposed as a quality measure within the proposed Focusing on Women's Health MVP (see Appendix 3: MVP Inventory Table A.1). It is also part of the CQMC, Adult Universal Core Set, and in alignment across multiple CMS quality reporting programs. This measure would remain for purposes of the CMS Web Interface collection type available to Share Savings Program ACOs reporting through the APP.
In the Circumstance the Measure is Retained	If measure A.6: Preventive Care and Wellness (composite) of this Appendix is not finalized for the CY 2024 performance period/2026 MIPS payment year and future years, we would retain measure Q112 in traditional MIPS in all applicable specialty sets under Table Group B of this Appendix. See Table Group DD of this Appendix for any substantive changes proposed for this measure.

CC.2. Colorectal Cancer Screening

Category	Description
CBE # / eCQM CBE #:	0034/ N/A
Quality #:	113
CMS eCQM ID:	CMS130v12
Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from traditional MIPS because we propose a more robust and comprehensive measure under Table A.6: Preventive Care and Wellness (composite) of this Appendix. This clinical concept is included as one of the components of the Preventive Care and Wellness (composite) measure. Measure Q113 only focuses on a single clinical concept of patients who have had an appropriate screening for colorectal cancer rather than a comprehensive preventive care and wellness approach; however, the clinical quality action assessed within measure Q113 is appropriate and applicable for some MVPs, where other components within the composite measure are not, leaving a potential gap in these identified MVPs. Therefore, we propose the removal of this measure from traditional MIPS but propose retention of this measure for use in relevant MVPs. This measure has previously been finalized in the Promoting Wellness MVP but is proposed for removal from that MVP due to the proposal of the Preventive Care and Wellness (composite) measure under Table A.6 of this Appendix and proposal of a consolidated MVP titled Value in Primary Care (see Appendix 3: MVP Inventory Table B.11). This measure would remain available for purposes of the CMS Web Interface collection type available to Shared Savings Program ACOs reporting through the APP.
In the Circumstance the Measure is Retained	If measure A.6: Preventive Care and Wellness (composite) of this Appendix is not finalized for the CY 2024 performance period/2026 MIPS payment year and future years, we would retain measure Q113 in traditional MIPS in all applicable specialty sets under Table Group B of this Appendix. See Table Group DD of this Appendix for any substantive changes proposed for this measure.

CC.3. Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up Plan

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	128
CMS eCQM ID:	CMS69v12
Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Measure Description:	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 the most recent BMI was outside of normal parameters
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from traditional MIPS because we propose a more robust and comprehensive measure under Table A.6: Preventive Care and Wellness (composite) of this Appendix. This clinical concept is included as one of the components of the Preventive Care and Wellness (composite) measure. Measure Q128 only focuses on the clinical concept of a documented BMI and follow-up plan if the BMI was outside of normal parameters, rather than a comprehensive preventive care and wellness approach. However, the clinical quality action assessed within measure Q128 is appropriate and applicable for some MVPs, where other components within the composite measure are not, leaving a potential gap in these identified MVPs. Therefore, we propose the removal of this measure from traditional MIPS but propose retention of this measure for use in relevant MVPs. Measure Q128 is currently proposed as a quality measure for use within two proposed MVPs: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP and Rehabilitative Support for Musculoskeletal Care MVP (see Appendix 3: MVP Inventory Tables A.2 and A.5). Measure Q128 is available within two previously finalized MVPs: Advancing Care for Heart Disease MVP and Improving Care for Lower Extremity Joint Repair MVP (see Appendix 3: MVP Inventory Tables B.5 and B.8). This measure has previously been finalized in the Promoting Wellness MVP but is proposed for removal from that MVP due to the proposal of the Preventive Care and Wellness (composite) measure under Table A.6 of this Appendix and proposal of a consolidated MVP titled Value in Primary Care (see Appendix 3: MVP Inventory Table B.11).
In the Circumstance the Measure is Retained	If measure A.6: Preventive Care and Wellness (composite) of this Appendix is not finalized for the CY 2024 performance period/2026 MIPS payment year and future years, we would retain measure Q128 in traditional MIPS in all applicable specialty sets under Table Group B of this Appendix. See Table Group DD of this Appendix for any substantive changes proposed for this measure.

Table Group D: Previously Finalized Quality Measures with Substantive Changes Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

NOTE: Electronic clinical quality measures (eCQMs) that are endorsed by a CBE are shown in Table D of this Appendix as follows: CBE # / eCQM CBE #.

The D Tables within this proposed rule provide the substantive changes proposed for the quality measures in CY 2024. 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 2024 may not be identified within this proposed rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2024 CPT and ICD-10 updates and assessment of these codes' inclusion by the Measure Steward, these changes may be postponed until CY 2025. The 2024 Quality Measure Release Notes provide a comprehensive, detailed reference of exact code 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 website at *https://qpp.cms.gov*.

In addition to the proposed substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but they are important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes would expand or contract the measure's current eligible population. Therefore, please refer to the current year measure specification and the 2024 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation. Language has also been added, to all applicable 2024 quality measure specifications, in the form of an 'Instructions Note' to clarify that telehealth encounters are allowed for determination of denominator eligibility. Only where telehealth encounters previously were not allowed as denominator eligible would the D table corresponding to a measure reflect an update to the denominator allowing for telehealth encounters in the 'Substantive Change' cell.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the proposed substantive changes, there may be revisions within the logic that are not considered substantive in nature, however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow.

Note: For the CY 2024 performance period/2026 MIPS payment year (and prior CY 2023 performance period/2025 MIPS payment year), the CMS Web Interface measures as a collection type is only available for APM Entities, specifically Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs), reporting through the APM Performance Pathway (APP) (the CMS Web Interface measures as a collection type is no longer available under traditional MIPS). Thus, the CMS Web Interface collection type is not listed in any table under Table Group D of this Appendix. For further information regarding the Shared Savings Program requirements under the APP and the CMS Web Interface collection type available under the APP, see section III.G.2.c.(2) of this proposed rule. For information regarding proposed changes to the CMS Web Interface measures available for the CY 2024 performance period/2026 MIPS payment year, see Table Group E of this Appendix.

D.1 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
CBE # / eCQM CBE #:	0059/ N/A
Quality #:	001
CMS eCQM ID:	CMS122v12
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 who had hemoglobin A1c > 9.0% during the measurement period.
Substantive Change:	**Modified collection type:** Medicare CQMs Specifications, Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications collection type. **Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** Dementia combinations: Donepezil-memantine to the list of dementia medication exclusion medications.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose to update the collection types available for this measure to include the Medicare CQMs Specifications collection type to allow choice in submission method for SSP ACOs reporting via the APP. See section IV.A.4.f.(1)(b) and section III.G.2. for further information on the Medicare CQMs Specifications collection type. We propose to update the denominator exclusion to include Donepezil-memantine in the list of dementia exclusion medications, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with the intent of the measure to exclude patients with this condition from the measure.

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
CBE # / eCQM CBE #:	0081 / 0081e
Quality #:	005
CMS eCQM ID:	CMS135v12
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 guidance: For the eCQM Specifications collection type: Added:** In order for the Ejection Fraction result pathway to be recognized as below 40%, the result must be reported as a number with unit of %. A text string of "below 40%" or "ejection fraction between 35 and 40%" will not be recognized through electronic data capture. Although, this criteria can also be met using the Diagnosis pathway if specified as "Moderate or Severe."
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the guidance for the eCQM Specifications collection type by adding documentation requirements for ejection fraction results to ensure the data is being accurately captured. This added statement in the guidance clarifies that the ejection fraction results must be documented as a percentage (for example, 40%) in order to be recognized through electronic capture.

D.3 Coronary Artery Disease (CAD): Antiplatelet Therapy

Category	Description
CBE # / eCQM CBE #:	0067 / N/A
Quality #:	006
CMS eCQM ID:	N/A
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 exception: Removed:** Documentation of system reason(s) for not prescribing aspirin or clopidogrel (e.g., lack of drug availability, other reasons attributable to the health care system). **Updated denominator criteria: Removed:** coding for subsequent myocardial infarction.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove the denominator exception for documentation of system reason(s) as this option is not recommended for this measure due to wide-spread availability of these medications. This would also create alignment within the denominator exceptions across all American Heart Association (AHA) measures. We propose to remove patients with subsequent myocardial infarction (MI) from the denominator criteria as this patient population is duplicative in nature. For the purposes of this measure, those patients with a subsequent MI would already have a diagnosis of CAD from the initial MI. Therefore, these patients would already be correctly included in the denominator eligible patient population.

D.4 Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)

Category	Description
CBE # / eCQM CBE #:	0070 / 0070e
Quality #:	007
CMS eCQM ID:	CMS145v12
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 guidance: For the eCQM Specifications collection type: Added:** In order for the Ejection Fraction result pathway to be recognized as below 40%, the result must be reported as a number with unit of %. A text string of "below 40%" or "ejection fraction between 35 and 40%" will not be recognized through electronic data capture. Although, this criteria can also be met using the Diagnosis pathway if specified as "Moderate or Severe." **Updated denominator criteria: For the MIPS CQMs Specifications collection type: Removed:** For submission criteria 2: coding for subsequent myocardial infarction For all submission criteria: endoscopic procedures on the heart and pericardium. **Updated denominator exception: For all collection types: Removed:** For all submission criteria: Documentation of system reason(s) for not prescribing beta-blocker therapy (e.g., other reasons attributable to the health care system).
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the guidance for the eCQM Specifications collection type by adding documentation requirements for ejection fraction results to ensure the data is being accurately captured. This added statement in the guidance clarifies that the ejection fraction results must be documented as a percentage (for example, 40%) to be recognized through electronic capture. We propose to remove patients with subsequent MI from the denominator criteria for the MIPS CQMs Specifications collection type as this patient population is duplicative in nature. For the purposes of this measure, those patients with a subsequent MI would already have a diagnosis of CAD from the initial MI. Therefore, these patients would already be correctly included in the denominator eligible patient population. Additionally, we propose to remove coding for endoscopic procedures of the heart and pericardium for the MIPS CQMs Specifications collection type as the coding is more related to the harvest of the artery and not the cardiac surgery itself and therefore, these patients may not be appropriate for the quality action. We propose to remove the denominator exception for all collection types for documentation of system reason(s) as this option is not recommended for this measure due to wide-spread availability of beta-blocker therapy. This would also create alignment within the denominator exceptions across all AHA measures.

D.5 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
CBE # / eCQM CBE #:	0083 / 0083e
Quality #:	008
CMS eCQM ID:	CMS144v12
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 guidance: For the eCQM Specifications collection type: Added:** In order for the Ejection Fraction result pathway to be recognized as below 40%, the result must be reported as a number with unit of %. A text string of "below 40%" or "ejection fraction between 35 and 40%" will not be recognized through electronic data capture. Although, this criteria can also be met using the Diagnosis pathway if specified as "Moderate or Severe."
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the guidance for the eCQM Specifications collection type by adding documentation requirements for ejection fraction results to ensure the data is being accurately captured. This added statement in the guidance clarifies that the ejection fraction results must be documented as a percentage (for example, 40%) to be recognized through electronica capture.

D.6 Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	019
CMS eCQM ID:	CMS142v12
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:	**The measure description is revised to read: For the MIPS CQMs Specifications collection type:** 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 during the performance period. **For the eCQM Specifications collection type:** 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 during the measurement period. **The measure numerator is revised to read: For the MIPS CQMs Specifications collection type:** Patients with documentation, at least once within the performance period, of the findings of the dilated macular or fundus exam via communication to the physician who manages the patient's diabetic care. **For the eCQM Specifications collection type:** Patients with documentation, at least once within the measurement period, of the findings of the dilated macular or fundus exam via communication to the physician who manages the patient's diabetic care.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the measure description and numerator to clarify that the "reporting period" is the 12-month performance period of January 1st – December 31st and to maintain consistency across measures in MIPS.

D.7 Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	024
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current 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.
Substantive Change:	**Updated denominator criteria: For all collection types: Added:** coding for initial encounters for age-related osteoporosis with current pathological fractures and periprosthetic fractures around internal prosthetic joints.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add coding for initial encounters for age-related or other osteoporosis with current pathological fractures and periprosthetic fractures around internal prosthetic joints to align with codes in the Healthcare Effectiveness Data and Information Set (HEDIS) Fractures Value Set and create consistency in implementation while ensuring the appropriate patient population is identified for numerator compliance assessment.

D.8 Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	048
CMS eCQM ID:	N/A
Current Collection Type:	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:	**Updated denominator criteria: For all collection types: Added:** coding for physical and occupational therapy clinician types.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add coding for for physical and occupational therapy clinician types as the measure is appropriate and it would be within their scope of care to complete this assessment.

D.9 Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	052
CMS eCQM ID:	N/A
Current Collection Type:	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:	**The measure title is revised from 'Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy' to:** Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy **The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of COPD with a documented FEV1/FVC < 70% measured by spirometry, who are symptomatic, and were prescribed a long-acting inhaled bronchodilator. **Update instructions: Added:** **This measure will be calculated with 2 performance rates:** 1) Percentage of patients aged 18 years and older with a diagnosis of COPD who have a documented airflow obstruction (FEV1/FVC < 70%) as measured by spirometry. 2) Percentage of patients aged 18 years and older with a diagnosis of COPD who have a documented airflow obstruction (FEV1/FVC < 70%) and are symptomatic, who were prescribed a long-acting inhaled bronchodilator. A simple average, which is the sum of the performance rates divided by the number of performance rates will be used for performance. THERE ARE TWO SUBMISSION CRITERIA FOR THIS MEASURE: 1. Patients diagnosed with COPD with who have documented airflow obstruction (FEV1/FVC < 70%) as measured by spirometry in the medical record. 2. Patients diagnosed with COPD who have documented airflow obstruction (FEV1/FVC < 70%) and are symptomatic, who were prescribed a long-acting bronchodilator. This measure contains two submission criteria which together ensure that the proper evaluation and treatment is provided for patients with COPD and that patients without COPD are not provided inappropriate therapy. Submission Criteria 1 evaluates whether spirometry was performed for patients diagnosed with COPD and results confirming airflow obstruction are documented. Submission Criteria 2 evaluates whether a long-acting inhaled bronchodilator was prescribed for COPD patients who have symptoms. NOTE: Submission of the two performance rates is required for this measure. A simple average, which is the sum of the performance rates divided by the number of the performance rates, will be used to calculate performance. **Updated denominator: Added:** DENOMINATOR (SUBMISSION CRITERIA 1): All patients aged 18 and older with a diagnosis of COPD. **Revised:** DENOMINATOR (SUBMISSION CRITERIA 2): All patients aged 18 years and older with a diagnosis of COPD with spirometry results documented (FEV1/FVC < 70%), and have symptoms (e.g., dyspnea, cough/sputum, wheezing). **Updated denominator criteria: Added:** For Submission Criteria 1: Denominator Criteria (Eligible Cases): Patients aged ≥ 18 years on date of encounter AND Diagnosis for COPD AND Patient encounter during the performance period WITHOUT Telehealth Modifier **Revised:** For Submission Criteria 2: Denominator Criteria (Eligible Cases): Patients aged ≥ 18 years on date of encounter AND Diagnosis for COPD AND Spirometry results documented (FEV1/FVC < 70%) AND Patient encounter during the performance period WITHOUT Telehealth Modifier AND Patient has COPD symptoms (e.g., dyspnea, cough/sputum, wheezing) **Updated numerator: Added: For** Submission Criteria 1: Patients with documented spirometry and confirmed airflow obstruction (FEV1/FVC < 70%). **Revised:** For Submission Criteria 2: Symptomatic COPD patients who were prescribed a long-acting inhaled bronchodilator.

Category	Description
	Updated numerator instructions: Added: For Submission Criteria 1: Documentation of spirometry results of (FEV1/FVC < 70%) can take place before the performance period. The intent of Submission Criteria 1 is to ensure accurate diagnosis of COPD in patients with respiratory symptoms such as dyspnea, chronic cough or sputum production, and/or a history of exposure to risk factors for the disease is appropriate by having documentation of spirometry results of FEV1/FVC < 70%, which is required to make the COPD diagnosis. **Updated numerator note: Added:** For Submission Criteria 1: Denominator Exception(s) are determined on the date of the denominator eligible encounter. If there is a diagnosis of COPD, but there is no documented spirometry within five years of the date of the encounter, and the current spirometry result is ≥70%, an exception may be reported. **Updated numerator options: Added:** For Submission Criteria 1: **Performance Met:** Spirometry results with confirmed airflow obstruction (FEV1/FVC < 70%) documented and reviewed. **Denominator Exception:** Documentation of medical reason(s) for not documenting and reviewing spirometry results (e.g., patients with dementia or tracheostomy). **Denominator Exception:** No history of spirometry results with confirmed airflow obstruction (FEV1/FVC < 70%) and present spirometry is ≥ 70%. **Denominator Exception:** Documentation of system reason(s) for not documenting and reviewing spirometry results (e.g., spirometry equipment not available at the time of the encounter). **Performance Not Met:** No spirometry results with confirmed airflow obstruction (FEV1/FVC < 70%) documented and/or no spirometry performed with results documented during the encounter. **Revised:** For Submission Criteria 2: **Denominator Exception:** Documentation of medical reason(s) for not prescribing a long-acting inhaled bronchodilator (e.g., patient intolerance or history of side effects). **Denominator Exception:** Documentation of system reason(s) for not prescribing a long-acting inhaled bronchodilator (e.g., cost of treatment or lack of insurance). **Removed:** For Submission Criteria 2: Denominator Exception for patient reason(s).
Measure Steward:	American Thoracic Society
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise this measure to add a submission criteria and performance rate so all patients are assessed for spirometry evaluation to ensure that the proper evaluation and subsequent treatment is provided for the patients with COPD. We propose to add submission criteria one to evaluate whether spirometry was performed and if there were results confirming airflow obstruction. Submission criteria 2 would evaluate whether a long-acting bronchodilator was prescribed for the COPD patient meeting evaluation criteria and having symptoms. The inclusion of submission criteria one "allows potentially wide application of testing to improve recognition and diagnosis of COPD" which is then complimented in submission criteria 2 with the appropriate care of patients diagnosed with COPD.[442] Additionally, we propose to revise the denominator exceptions for submission criteria two to clarify implementation by giving examples of scenarios that meet the denominator exception intent. We propose to remove the denominator exception for patient reason(s) as it is incumbent upon the clinician to educate the patient on the importance of treatment. In the event the proposed substantive change(s) are 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. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark would be used for scoring.

[442] Johns, D. P., Walters, J. A., & Walters, E. H. (2014). Diagnosis and Early Detection of COPD Using Spirometry. Journal of Thoracic Disease, 6(11), 1557–1569. *https://pubmed.ncbi.nlm.nih.gov/25478197/.*

D.10 Appropriate Treatment for Upper Respiratory Infection (URI)

Category	Description
CBE # / eCQM CBE #:	0069 / N/A
Quality #:	065
CMS eCQM ID:	CMS154v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	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 order.
Substantive Change:	**Updated denominator exclusion: For all collection types: Revised:** Exclude URI episodes where the patient is taking antibiotics in the 30 days prior to the episode date. **Updated value set/coding: For the eCQM Specifications collection type: Added:** coding for malignant neoplasms to the "Comorbid Conditions for Respiratory Conditions" value set, and aggressive periodontitis to the "Competing Conditions for Respiratory Conditions" value set. **Updated denominator: For the MIPS CQMs Specifications collection type: Revised:** Outpatient visits, telephone visits, online assessments (i.e. e-visit or virtual check-in), observation stays or emergency department visits with a diagnosis of upper respiratory infection (URI) from January 1 to December 28 for patients 3 months of age and older. **Updated denominator instructions: For the MIPS CQMs Specifications collection type: Added:** An episode is defined as each eligible encounter for patients aged 3 months of age and older with a diagnosis of upper respiratory infection during the measurement period of January 1 to December 28. **Updated denominator criteria: For the MIPS CQMs Specifications collection type:** Table 1 – Antibiotic medications to be utilized for the denominator exclusion: **Added:** Aminoglycosides: Amikacin, Gentamicin, Streptomycin, Tobramycin To Beta-lactamase inhibitors: Ampicillin-sulbactam, Piperacillin-tazobactam Fourth-generation cephalosporins: Cefepime To Lincomycin derivatives: Lincomycin Miscellaneous antibiotics: Aztreonam, Chloramphenicol, Dalfopristin-quinupristin, Daptomycin, Linezolid, Metronidazole, Vancomycin To Natural penicillins: Penicillin G benzathine, Penicillin G benzathine procaine, Penicillin G procaine To Penicillinase-resistant penicillins: Nafcillin, Oxacillin To Quinolones: Gemifloxacin Rifamycin derivatives: Rifampin To Second generation cephalosporins: Cefotetan, Cefoxitin To Sulfonamides: Sulfadiazine To Third generation cephalosporins: Cefotaxime, Ceftazidime Urinary anti-infectives: Fosfomycin, Nitrofurantoin, Nitrofuantoin macrocrystals-monohydrate, Trimethoprim **Removed:** Folate antagonist From Macrolides: Erythromycin ethylsuccinate, Erythromycin lactobionate, Erythromycin stearate From Third generation cephalosporins: Ceftibuten, Cefditoren
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the denominator exclusion for all collection types to exclude patients who were actively taking antibiotics in the 30 days prior to the encounter. We propose to remove the clause of actively taking antibiotics on the day of the encounter as the measure logic does not check for antibiotic use of the day of the encounter. The revised denominator exclusion would align the measure logic across antibiotic measures and ensure the appropriate patient population is being assessed for antibiotics prescribed on the date of the encounter. We propose to update the value set/coding for the eCQM Specifications collection type by adding coding for 'Aggressive periodontitis' to the "Competing Conditions for Respiratory Conditions (2.16.840.1.113883.3.464.1003.102.12.1017)" value set and coding for 'Neoplasms' to the "Comorbid Conditions for Respiratory Conditions ((2.16.840.1.113883.3.464.1003.102.12.1017)" value set, which would allow clinicians to use the denominator exclusion as it may be appropriate to dispense antibiotics to these patients. Additionally, it would create alignment with NCQA's HEDIS measure. We propose to update the denominator and denominator instructions for the MIPS CQMs Specifications collection type to revise the timeframe for eligible encounters as this would align with the numerator timeframe of 'on or within 3 days of the eligible encounter'. We propose to update the list of antibiotic medications for purposes of determining patients appropriate for the denominator exclusion for the MIPS CQMs Specifications collection type by adding and removing prescriptions to align with the current medication table to ensure the appropriate patient population is being identified for denominator eligibility and ensuring the quality action is applicable.

D.11 Appropriate Testing for Pharyngitis

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	066
CMS eCQM ID:	CMS146v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.
Substantive Change:	**Updated denominator exclusion: For all collection types: Revised:** Exclude URI episodes where the patient is taking antibiotics in the 30 days prior to the episode date. **Updated value set/coding: For the eCQM Specifications collection type: Added:** coding for malignant neoplasms to the 'Competing Conditions for Respiratory Conditions' value set. **Updated denominator: For the MIPS CQMs Specifications collection type: Revised:** Outpatient, telephone, online assessment (i.e. e-visit or virtual check-in), observation, or emergency department (ED) visits with a diagnosis of pharyngitis or tonsilitis from January 1 to December 28 and an antibiotic order on or within 3 days after the episode date among patients 3 years or older. **Updated denominator instructions: For the MIPS CQMs Specifications collection type: Revised:** An episode is defined as each eligible encounter for patients aged 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order during the measurement period of January 1 to December 28. **Updated denominator criteria: For the MIPS CQMs Specifications collection type:** Table 1 – Antibiotic medications to be utilized for the denominator exclusion: **Removed:** From macrolides: Erythromycin ethylsuccinate, Erythromycin lactobionate, Erythromycin stearate Penicillinase resistant penicillins From Third generation cephalosporins: Ceftibuten, Cefditoren
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the denominator exclusion for all collection types to exclude patients who were actively taking antibiotics in the 30 days prior to the encounter. We propose removal of the clause of actively taking antibiotics on the day of the encounter as the measure logic does not check for antibiotic use of the day of the encounter. The revised denominator exclusion would align the measure logic across antibiotic measures and ensure the appropriate patient population is being assessed for antibiotics prescribed on the date of the encounter. We propose to update the value set/coding for the eCQM Specifications collection type by adding coding for malignant neoplasms to the "Competing Conditions for Respiratory Conditions (2.16.840.1.113883.3.464.1003.102.12.1025)" value set which would allow clinicians to use the denominator exclusion as it may be appropriate to dispense antibiotics to these patients. Additionally, it creates alignment with NCQA's HEDIS measure. We propose to update the denominator and denominator instructions for the MIPS CQMs Specifications collection type to revise the timeframe for eligible encounters as this would align with the numerator timeframe of 'through 3 days after the eligible encounter'. We propose to update the list of antibiotic medications for purposes of determining patients appropriate for the denominator exclusion for the MIPS CQMs Specifications collection type by adding and removing prescriptions to align with the current medication table to ensure the appropriate patient population is being identified for denominator eligibility and ensuring the quality action is applicable.

D.12 Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	104
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	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.
Substantive Change:	**The denominator definition is revised to read:** **Risk Strata – Very Low, Low, Intermediate, High, or Very High –** **Very Low Risk** – PSA < 10 ng/mL; AND Gleason score 6 or less/Gleason grade group 1; AND clinical stage T1c; AND presence of disease in fewer than 3 biopsy cores; AND ≤ 50% prostate cancer involvement in each fragment/core; AND PSA density < 0.15 ng/mL/g. **Low Risk** – PSA < 10 ng/mL; AND Gleason score 6 or less/Gleason grade group 1; AND clinical stage T1 to T2a. **Intermediate Risk** – PSA 10 to 20 ng/mL; OR Gleason score 7/Gleason grade group 2-3; OR clinical stage T2b to T2c; AND no high-risk group or very-high-risk group features. **High Risk** – Has one of the following: PSA > 20 ng/mL; OR Gleason score 8 to 10/Gleason grade group 4-5; OR clinically localized stage T3a, without any very-high-risk group features. **Very High Risk** – At least one of the following: Clinical stage T3b to T4; OR primary Gleason pattern 5; OR more than 4 cores with Gleason score 8 to 10/Gleason grade group 4-5 OR 2-3 high-risk features. (NCCN, 2022) **External beam radiotherapy** – "External beam radiotherapy" refers to 3D conformal radiation therapy (3D- CRT), intensity modulated radiation therapy (IMRT), stereotactic body radiotherapy (SBRT), and proton beam therapy.
Measure Steward:	American Urological Association Education and Research
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the denominator definition to better classify risk category for patients receiving treatment for prostate cancer in accordance with revised NCCN guidelines.[443]

[443] Eastham, J. A., Auffenberg, G. B., Barocas, D. A., Chou, R., Crispino, T., Davis, J. W., Eggener, S., Horwitz, E. M., Kane, C. J., Kirkby, E., Lin, D. W., McBride, S. M., Morgans, A. K., Pierorazio, P. M., Rodrigues, G., Wong, W. W., & Boorjian, S. A. (2022). Clinically Localized Prostate Cancer: AUA/ASTRO Guideline, Part I: Introduction, Risk Assessment, Staging, and Risk-Based Management. The Journal of Urology, 208(1), 10–18. *https://doi.org/10.1097/JU.0000000000002757.*

Eastham, J. A., Auffenberg, G. B., Barocas, D. A., Chou, R., Crispino, T., Davis, J. W., Eggener, S., Horwitz, E. M., Kane, C. J., Kirkby, E., Lin, D. W., McBride, S. M., Morgans, A. K., Pierorazio, P. M., Rodrigues, G., Wong, W. W., & Boorjian, S. A. (2022). Clinically Localized Prostate Cancer: AUA/ASTRO Guideline, Part II: Principles of Active Surveillance, Principles of Surgery, and Follow-Up. The Journal of Urology, 208(1), 19–25. *https://pubmed.ncbi.nlm.nih.gov/35536148/.*

Eastham, J. A., Auffenberg, G. B., Barocas, D. A., Chou, R., Crispino, T., Davis, J. W., Eggener, S., Horwitz, E. M., Kane, C. J., Kirkby, E., Lin, D. W., McBride, S. M., Morgans, A. K., Pierorazio, P. M., Rodrigues, G., Wong, W. W., & Boorjian, S. A. (2022). Clinically Localized Prostate Cancer: AUA/ASTRO Guideline. Part III: Principles of Radiation and Future Directions. The Journal of Urology, 208(1), 26–33. *https://pubmed.ncbi.nlm.nih.gov/35536141/.*

D.13 Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis

Category	Description
CBE # / eCQM CBE #:	0058 / N/A
Quality #:	116
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	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.
Substantive Change:	**Updated denominator criteria: Added:** coding for federally qualified health center (FQHC) services. **Updated denominator criteria: For the MIPS CQMs Specifications collection type:** Table 1 – Antibiotic medications to be utilized for the denominator exclusion and numerator components: **Removed:** Ketolides From Third generation cephalosporins: Ceftibuten, Cefditoren
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the denominator criteria to include coding for FQHC services to standardize codes in the value sets and align with the HEDIS version of this measure (*https://www.ncqa.org/hedis/measures/avoidance-of-antibiotic-treatment-for-acute-bronchitis-bronchiolitis/*). We propose to update the list of antibiotic medications, found in Table 1 – Antibiotic Medications, used to determine patients who are appropriate for the denominator exclusion and numerator compliance. This proposed update would ensure the appropriate patient population is being identified for denominator eligibility and ensuring the quality action is assessed appropriately by removing antibiotics that may not fully align with the measure intent and standardizing medication names to maintain alignment with the HEDIS measure.

D.14 Diabetes: Eye Exam

Category	Description
CBE # / eCQM CBE #:	0055 / N/A
Quality #:	117
CMS eCQM ID:	CMS131v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of 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 in any part of 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** MIPS CQMs Specifications collection type**: Added:** Dementia combinations: Donepezil-memantine **to** list of dementia exclusion medications. **Updated numerator note: For the MIPS CQMs Specifications collection type: Added:** reporting of CPT 92229 meets the intent of the quality action for performance met.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator exclusion for the MIPS CQMs Specifications collection type to include Donepezil-memantine in the list of dementia medication list, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with intent of the measure to exclude patients with this condition from the measure. Additionally for the MIPS CQMs Specifications collection type, we propose to update the numerator note to indicate that denominator eligible patients who receive services under CPT code 92229 would meet the intent of the measure and should be included in the appropriate performance met numerator option, based on retinopathy findings.

D.15 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
CBE # / eCQM CBE #:	0066 / N/A
Quality #:	118
CMS eCQM ID:	N/A
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: Removed:** For all submission criteria: coding for subsequent myocardial infarction. **Updated denominator exception: Removed:** For all submission criteria: other reasons attributable to the health care system.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove patients with subsequent MI from the denominator criteria as this patient population is duplicative in nature. For the purposes of this measure, those patients with a subsequent MI would already have a diagnosis of CAD from the initial MI. Therefore, these patients would already be correctly included in the denominator eligible patient population. We propose to remove documentation of system reason(s) from the denominator exception as this option is not recommended for this measure due to wide-spread availability of these medications. This would also create alignment within the denominator exceptions across all AHA measures.

D.16 Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	134
CMS eCQM ID:	CMS2v13
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM 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 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 or up to two days after the date of the qualifying encounter.
Substantive Change:	**Modified collection type:** Medicare CQMs Specifications, Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications collection type. **Updated guidance: For the eCQM Specifications collection type: Revised:** The intent of the measure is to screen for new cases of depression in patients who have never had a diagnosis of bipolar disorder. Patients who have ever been diagnosed with bipolar disorder prior to the qualifying encounter used to evaluate the **numerator** will be excluded from the measure regardless of whether the diagnosis is active or not. **Updated denominator exclusion: For all collection types: Removed:** Diagnosis of depression from the denominator exclusion. **Updated denominator note: For the** MIPS CQMs Specifications **and Medicare Part B Claims Specifications collection types: Removed:** Diagnosis of depression from the denominator note. **Updated denominator definition: For the MIPS CQMs Specifications and Medicare Part B Claims Specifications collection types: Removed:** Diagnosis of depression from the denominator exclusion definition. **Updated denominator criteria: For all collection types: Added:** coding for qualifying encounters for nutritionists/dieticians and home-based health care.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the collection types available for this measure to include the Medicare CQMs Specifications collection type to allow choice in submission method for SSP ACOs reporting via the APP. See section IV.A.4.f.(1)(b) and section III.G.2. for further information on the Medicare CQMs Specifications collection type. We propose to revise the guidance for the eCQM Specifications collection type to reflect inclusion of patients with a previous inactive (or resolved) diagnosis of depression as it is important to identify patients who have been treated for depression in the past but may have re-emerging symptoms. We also propose to revise the denominator exclusion to remove a diagnosis of depression as an applicable exclusion, as patients with a history of depression may require more frequent monitoring and ongoing treatment for reoccurrence of symptoms. We propose to update the denominator to include encounter codes for nutritionists and dieticians, as well as home-based encounter codes, as it is clinically appropriate to conduct depression screenings during these encounters.

D.17 Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care

Category	Description
CBE # / eCQM CBE #:	0563 / N/A
Quality #:	141
CMS eCQM ID:	N/A
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:	**The measure title is revised from 'Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care ' to:** Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care. **The measure description is revised to read: For all collection types:** 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 20% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 20% from the pre-intervention level, a plan of care was documented within the 12 month performance period. **The measure numertor is revised to read: For all collection types:** Patients whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 20% from the pre- intervention level) OR if the most recent IOP was not reduced by at least 20% from the pre-intervention level, a plan of care was documented within the 12 month performance period. **Updated definitions: For all collection types: Revised: Glaucoma Treatment Not Failed** – The most recent IOP was reduced by at least 20% in the affected eye or if both eyes were affected, the reduction of at least 20% occurred in both eyes from pre-intervention levels. **Updated numerator instructions: For all collection types: Revised:** to reflect an IOP reduction goal of 20% or more from pre-intervention levels. **Updated numerator options: For all collection types: Revised:** to reflect an IOP reduction goal of 20% or more from pre-intervention levels.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to revise multiple components of this measure for all collection types to align with the latest scientific evidence that shows that 20 percent reduction in pre-intervention IOP optimizes patient outcomes by reducing the rate of worsening visual fields and is used as a benchmark for treatment outcomes. In a recent randomized clinical trial comparing phaco/Kahook Dual Blade to phaco/iStent, success was defined as at least a 20 percent reduction in IOP or reduction of one or more glaucoma medications from baseline.[444] In the only multicenter randomized clinical trial comparing minimally invasive glaucoma surgery standalone procedures, the COMPARE Study defined success as an unmedicated IOP reduction of at least 20 percent from baseline or unmedicated IOP less than or equal to 18 mmHg.[445]

[444] Falkenberry, S., Singh, I. P., Crane, C. J., Haider, M. A., Morgan, M. G., Grenier, C. P., ... & Dorairaj, S. (2020). Excisional Goniotomy vs. Trabecular Microbypass Stent Implantation: A Prospective Randomized Clinical Trial in Eyes with Mild to Moderate Open-Angle Glaucoma. Journal of Cataract & Refractive Surgery, 46(8), 1165-1171. *https://doi.org/10.1097/j.jcrs.0000000000000229.*

[445] Ahmed, I. I. K., Fea, A., Au, L., Ang, R. E., Harasymowycz, P., Jampel, H. D., ... & COMPARE Investigators. (2020). A Prospective Randomized Trial Comparing Hydrus and iStent Microinvasive Glaucoma Surgery Implants for Standalone Treatment of Open-Angle Glaucoma: The COMPARE Study. *Ophthalmology*, *127*(1), 52-61. *https://www.amedeolucente.it/public/A%20Prospective%20Randomized%20Trial%20Comparing.pdf.*

D.18 Functional Outcome Assessment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	182
CMS eCQM ID:	N/A
Current Collection Type:	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 within two days of the date of the identified deficiencies.
Substantive Change:	**Updated numerator definition: Revised:** Functional Outcome Deficiencies – Impairment, loss of function, or difficulty with participation in daily activities related to physical (e.g., musculoskeletal, cardiovascular, pulmonary, integumentary), sensory, cognitive, behavioral, or visual/perceptual impairments. **Updated denominator criteria: Added:** coding for cognitive assessment.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the numerator definition to describe assessment areas more accurately and completely for physical therapy and occupational therapy clinicians. We also propose to add qualifying encounter coding utilized for cognitive assessment, as the quality action would be appropriate for this patient population.

D.19 Stroke and Stroke Rehabilitation: Thrombolytic Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	187
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.
Substantive Change:	**Updated denominator exception: Removed:** Tenecteplase (TNK) as an example of a denominator exception.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove Tenecteplase (TNK) as one of the examples for the denominator exception as the numerator action is looking at patients for whom IV thrombolytic therapy was initiated within 4.5 hours.

D.20 Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery

Category	Description
CBE # / eCQM CBE #:	0565 / 0565e
Quality #:	191
CMS eCQM ID:	CMS133v12
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 logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic to ensure surgeries on Sep 30 are included in the denominator.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to revise the measure logic for the eCQM Specifications collection type to include cataract surgeries performed on September 30 to align with the measure intent of including all cataract surgeries performed between January 1st and September 30th of the measurement period.

D.21 HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	205
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	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.
Substantive Change:	**Modified collection type:** eCQM Specifications, MIPS CQMs Specifications collection type. **The measure description is revised to read:** Percentage of patients 13 years of age and older with a diagnosis of HIV who had tests for syphilis, gonorrhea, and chlamydia performed within the performance period. **Updated instructions: Removed:** Only patients who had at least two visits during the performance period, with at least 90 days between each visit will be counted in the denominator for this measure. **The denominator is revised to read:** All patients 13 years of age and older at the start of the performance period with a diagnosis of HIV before the end of the performance period with an eligible encounter during the performance period. **Updated denominator criteria: Revised:** age determined at start of the performance period. **Removed:** At Least Two Denominator Eligible Encounters During the Measurement Year, With at Least 90 days Between Each. **Added:** coding for nonphysician, physician, and qualified health care professional (QHP) telephone assessments, residence services, and preventive medicine. **Updated denominator exclusion: Removed:** exclusion for patients receiving hospice services. **The numerator is revised to read:** Patients who were tested for each of the following at least once during the performance period: syphilis, gonorrhea, and chlamydia. **Updated denominator exception: Removed:** Chlamydia, gonorrhea, and syphilis screening results not documented (Patient refusal is the only allowed exception).
Measure Steward:	Health Resources and Services Administration
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the collection types available for this measure to include the eCQM Specification collection type to allow choice in submission method. We propose to update the measure to reflect the clinical recommendations[446] [447] for annual sexually transmitted infections (STIs) screenings given the prevalence of sexually transmitted co-infections over the course of HIV disease. According to one literature review, the mean prevalence of STI co-infection was 16.3 percent with syphilis, gonorrhea, and chlamydia showing median rates of 9.5 percent, 9.5 percent, and 5 percent respectively.[448] A key takeaway from this review, continued high rates of co-occurring STIs in this patient population will hinder efforts in HIV transmission prevention. We propose to update the instructions and denominator criteria to remove the requirement for at least two denominator eligible visits to ensure all patients who have been diagnosed with HIV receive appropriate testing. We propose to revise the age anchor to be at the start of the performance period to reduce burden in implementation and add coding for preventive medicine encounters, nonphysician, physician, and qualified health care professional (QHP) telephone assessments, and home or residence visits as it would be appropriate for patients at these encounters to be assessed for the quality action. We propose to remove the denominator exclusion for patients who use hospice services as it may still be appropriate to screen for and subsequently treat these infections. Additionally, we propose to remove the denominator exception for patient refusal as these sexually transmitted diseases can increase the risk for HIV infection through increases in the infectiousness and an individual's susceptibility.[449]

[446] US Preventive Services Task Force, Mangione, C. M., Barry, M. J., Nicholson, W. K., Cabana, M., Chelmow, D., Coker, T. R., Davis, E. M., Donahue, K. E., Jaén, C. R., Kubik, M., Li, L., Ogedegbe, G., Pbert, L., Ruiz, J. M., Stevermer, J., & Wong, J. B. (2022). Screening for Syphilis Infection in Nonpregnant Adolescents and Adults: US Preventive Services Task Force Reaffirmation Recommendation Statement. *JAMA, 328*(12), 1243–1249. *https://doi.org/10.1001/jama.2022.15322.*

[447] US Preventive Services Task Force, Davidson, K. W., Barry, M. J., Mangione, C. M., Cabana, M., Caughey, A. B., Davis, E. M., Donahue, K. E., Doubeni, C. A., Krist, A. H., Kubik, M., Li, L., Ogedegbe, G., Pbert, L., Silverstein, M., Simon, M. A., Stevermer, J., Tseng, C. W., & Wong, J. B. (2021). Screening for Chlamydia and Gonorrhea: US Preventive Services Task Force Recommendation Statement. *JAMA, 326*(10), 949–956. *https://doi.org/10.1001/jama.2021.14081.*

[448] Kalichman, S. C., Pellowski, J., & Turner, C. (2011). Prevalence of Sexually Transmitted Co-infections in People Living with HIV/AIDS: Systematic Review with Implications for Using HIV Treatments for Prevention. *Sexually Transmitted Infections, 87*(3), 183–190. *https://doi.org/10.1136/sti.2010.047514.*

[449] Hayes, R. J., Watson-Jones, D., Celum, C., van de Wijgert, J., & Wasserheit, J. (2010). Treatment of Sexually Transmitted Infections for HIV Prevention: End of the Road or New Beginning? *AIDS (London, England), 24*(0 4), S15–S26. *https://doi.org/10.1097/01.aids.0000390704.35642.47.*

D.22 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	226
CMS eCQM ID:	CMS138v12
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 who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.
Substantive Change:	**Updated measure description: For all collection types: Revised:** Patient age to 12 years and older. **Updated instructions: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Patient age to 12 years and older. 1) **Updated initial patient population: For the eCQM Specifications Collection type: Revised:** All patients aged 12 years and older seen for at least two visits or at least one preventive visit during the measurement period. **Updated denominator: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** For all submission criteria: Patient age to 12 years and older. **Updated denominator criteria: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** For all submission criteria: Patient age to 12 years and older. **Updated measure analytic: For all collection types: Revised:** data completeness will be determined utilizing performance rate one.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose revisions to this measure for all collection types to combine the patient population within Q402: Tobacco Use and Help with Quitting Among Adolescents with that of Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention resulting in a single, more robust measure, by lowering the denominator eligible age to 12 years and older to allow for the inclusion of adolescents into the measure's denominator. Measure Q402 has been proposed for removal under Table C.11 of this Appendix. We propose to update the analytic of the measure to utilize performance rate one for the determination of data completeness to ensure a complete data set is submitted and inclusive of all denominator eligible patients for this measure. As submission criteria two only includes those patients identified as tobacco users, the intent of the measure is to also ensure screening of all patients aged 12 years and older. Assessing data completeness utilizing submission criteria one will ensure that screening information was collected.

D.23 Controlling High Blood Pressure

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	236
CMS eCQM ID:	CMS165v12
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.
Substantive Change:	**Modified collection type:** Medicare CQMs Specifications, Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications collection type. **The measure guidance is revised to read: For the eCQM Specifications collection type:** In reference to the numerator element, only blood pressure readings performed by a clinician or an automated blood pressure monitor or device are acceptable for numerator compliance with this measure. This includes blood pressures taken in person by a clinician and blood pressures measured remotely by electronic monitoring devices capable of transmitting the blood pressure data to the clinician. Blood pressure readings taken by an automated blood pressure monitor or device and conveyed by the patient to the clinician are also acceptable. It is the clinician's responsibility and discretion to confirm the automated blood pressure monitor or device used to obtain the blood pressure is considered acceptable and reliable and whether the blood pressure reading is considered accurate before documenting it in the patient's medical record. **The measure instructions note and numerator note are revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** In reference to the numerator element, only blood pressure readings performed by a clinician or an automated blood pressure monitor or device are acceptable for numerator compliance with this measure. This includes blood pressures taken in person by a clinician and blood pressures measured remotely by electronic monitoring devices capable of transmitting the blood pressure data to the clinician. Blood pressure readings taken by an automated blood pressure monitor or device and conveyed by the patient to the clinician are also acceptable. It is the clinician's responsibility and discretion to confirm automated blood pressure monitor or device used to obtain the blood pressure is considered acceptable and reliable and whether the blood pressure reading is considered accurate before documenting it in the patient's medical record. **Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** Dementia combinations: Donepezil-memantine to list of dementia exclusion medications. **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** Patients 18-85 years of age by the end of the measurement period who had a visit during the measurement period and diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose to update the collection types available for this measure to include the Medicare CQMs Specifications collection type to allow choice in submission method for SSP ACOs reporting via the APP. See section IV.A.4.f.(1)(b) and section III.G.2. for further information on the Medicare CQMs Specifications collection type. We propose to revise the initial patient population for the eCQM Specifications collection type by specifying the patient visit must occur during the measurement period to clarify the encounter timing. We propose to revise the measure guidance for the eCQM Specifications collection type and the instructions note and numerator note for the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types around remote monitoring devices for capturing blood pressure readings. Currently, the measure allows patient reported data using most methods of digital collection/reporting and prohibits patient reported data taken with non-digital devices, such as with a manual blood pressure cuff and stethoscope. The measure is agnostic to how the reading gets in and the documentation practice of each office; therefore, whether patient is "conveying the reading to the clinician" by manually entering the BP reading (for example, patient portal) or having the device auto-transmit data directly, it is the clinician's responsibility and discretion to confirm that the automated blood pressure monitor used to obtain the blood pressure is considered acceptable and reliable. Additionally, we propose to update the denominator exclusion for the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types to include Donepezil-memantine in the list of dementia medication list, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with intent of the measure to exclude patients with this condition from the measure.

D.24 Use of High-Risk Medications in Older Adults

Category	Description
CBE # / eCQM CBE #:	0022 / N/A
Quality #:	238
CMS eCQM ID:	CMS156v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.
Substantive Change:	**Updated numerator definition: For the MIPS CQMs Specifications collection type: Revised:** For Numerator (Submission Criteria 1): Definitions: Table 1 - High-Risk Medications at any dose or duration:

Category	Description
	Revised: Antithrombotics – Dipyridamole (oral, excluding extended release) Cardiovascular, other – Nifedipine (excluding extended release) Table 2 - High-Risk Medications With Days Supply Criteria **Removed:** From Anti-Infectives, other - Nitrofurantoin macrocrystals Table 3 - High-Risk Medications With Average Daily Dose Criteria **Added:** Description: Alpha agonists, central Description: Cardiovascular, other Description: Tertiary tricyclic antidepressants (TCAs) (as single agent or as part of combination products) **Removed:** Doxepin hydrochloride For Numerator (Submission Criteria 2): Definitions: Table 4 - High-Risk Medications **Added:** To Antipsychotics, first (conventional) and second (atypical) generation - Aripiprazole lauroxil **The measure numerator is revised to read: For the eCQM Specifications collection type:** Submission Criteria/Rate 2: Patients with at least two orders of high-risk medications from the same drug class (i.e., antipsychotics and benzodiazepines) on different days except for appropriate diagnoses. a. Patients with two or more antipsychotic prescriptions ordered on different days, and who did not have a diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder on or between January 1 of the year prior to the measurement period and the IPSD for antipsychotics. b. Patients with two or more benzodiazepine prescriptions ordered on different days, and who did not have a diagnosis of seizure disorders, rapid eye movement sleep behavior disorder, benzodiazepine withdrawal, ethanol withdrawal, or severe generalized anxiety disorder on or between January 1 of the year prior to the measurement period and the IPSD for benzodiazepines. **Updated numerator exclusion: For the eCQM Specifications collection type: Removed:** Rate 2: For patients with two or more antipsychotic prescriptions ordered on different days, and who did not have a diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder on or between January 1 of the year prior to the measurement period and the IPSD for antipsychotics. For patients with two or more benzodiazepine prescriptions ordered on different days, and who did not have a diagnosis of seizure disorders, rapid eye movement sleep behavior disorder, benzodiazepine withdrawal, ethanol withdrawal, or severe generalized anxiety disorder on or between January 1 of the year prior to the measurement period and the IPSD for benzodiazepines. **Updated numerator logic: For the eCQM Specifications collection type: Revised:** for medications ordered on the same day intended to start on different dates.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the medication tables for the MIPS CQMs Specifications collection type to align with the current guidelines and ensure appropriate high-risk medications are identified. This would align with the intent of the measure and ensure the appropriate patient population is being assessed for the quality action. We propose to update the numerator for all collection types to clarify and ensure capture of the appropriate patient population. For the eCQM Specifications collection type, this was achieved by removing the standalone numerator exclusion and incorporating the exclusion language in the numerator criteria, to mitigate previous implementation concerns. Additionally, we propose to add logic for medications ordered on the same day but intended to start on different dates.

D.25 Childhood Immunization Status

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	240
CMS eCQM ID:	CMS117v12
Current Collection Type:	eCQM Specifications
Current Measure Description:	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.
Substantive Change:	**Updated numerator: Revised:** IPV, MMR, VZV, PCV, Hep A, and Flu: to allow for anaphylaxis due to the vaccine to count towards numerator compliance.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add language excluding patients with anaphylaxis due to vaccine administration to 6 of the 10 numerator criteria where applicable. A history of a severe allergic reaction to a vaccine should be considered a contraindication to additional doses of the same vaccine *(https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html).*

D.26 Cardiac Rehabilitation Patient Referral from an Outpatient Setting

Category	Description
CBE # / eCQM CBE #:	0643 / N/A
Quality #:	243
CMS eCQM ID:	N/A
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 criteria: Removed:** From 'Coronary Artery Bypass Graft Surgery' coding for endoscopic procedures on the heart and pericardium.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove coding for endoscopic procedures of the heart and pericardium as the coding is more related to the harvest of the artery and not the cardiac surgery itself and therefore, these patients may not be appropriate for the quality action.

D.27 Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	254
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	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.
Substantive Change:	**Updated denominator criteria:** **Revised:** Diagnosis of Other Current Condition in the Mother Classifiable Elsewhere but Complicating Pregnancy, Childbirth, or the Puerperium to Current Diagnosis of Pregnancy. **Added:** coding for other and unspecified abnormal uterine and vaginal bleeding and current diagnosis of pregnancy. **Updated denominator exception: Removed:** patient has visited the ED multiple times within 72 hours. **Updated measure instructions and numerator instructions: Revised: submission** frequency **from each time to each visit.**
Measure Steward:	American College of Emergency Physicians
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator criteria to include other and unspecified abnormal uterine and vaginal bleeding coding and revised the criteria for pregnancy to ensure all applicable patients are being included in the denominator eligible population and are being appropriately assessed. Additionally, we propose to remove the exception for those patients that have visited the ED multiple times within 72 hours and revise the measure submission to each denominator eligible visit as it would be clinically appropriate for them to receive an ultrasound with pregnancy location determination at each visit.

D.28 Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	275
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	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.
Substantive Change:	**The measure denominator is revised to read:** All patients, regardless of age, with a diagnosis of inflammatory bowel disease who initiated an anti-TNF agent during the performance period. **Updated denominator definition: Revised:** initiated an anti-TNF agent. **Updated denominator criteria: Revised:** initiated an anti-TNF agent.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add initiated an anti-TNF agent during the performance period in order to capture the intended patient population accurately. As the measure is currently written, it would allow patients who initiated treatment prior to the performance period and could inflate the intended population and possibly impact performance negatively with no clinician recourse.

D.29 Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	279
CMS eCQM ID:	N/A
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:	**The measure title is revised from 'Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy' to:** Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy. **The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available). **The measure denominator is revised to read:** All patients aged 18 years and older with obstructive sleep apnea who were prescribed an evidence-based therapy. **Updated denominator definition: Added:** Evidence-based Therapy – includes positive airway pressure, oral appliances, positional therapies, hypoglossal nerve stimulation, or other devices with monitoring capabilities. **Updated denominator criteria: Revised:** coding to reflect a diagnosis of obstructive sleep apnea. **Revised:** Evidence-based therapy was prescribed. **Updated numerator: Revised:** Patients with documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available). **Updated numerator definition: Added:** Documentation of adherence to therapy – includes a note documented in the patient's medical record that patient is adherent to the prescribed therapy for obstructive sleep apnea. Objective Informatics – a telemonitoring system that shows data demonstrating patient adherence to the prescribed therapy for obstructive sleep apnea (i.e., CPAP machines with SD cards that store data). Self-Reporting – patient and/or parent/caregiver attests to compliance with prescribed therapy for obstructive sleep apnea, which is documented in the medical record. Objective Reporting – data that are reported from an objective informatics or other data source and is not reported by the patient or parent/caregiver. **Removed:** Objectively Measured definition. **Updated numerator options: Revised:** Performance Met: Adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available, documented) Denominator Exception: Documentation of reason(s) for not objectively reporting adherence to evidence-based therapy (e.g., patients who have been diagnosed with a terminal or advanced disease with an expected life span of less than 6 months, patients who decline therapy, patients who do not return for follow-up at least annually, patients unable to access/afford therapy, patient's insurance will not cover therapy) Performance Not Met: Adherence to therapy was not assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available), reason not given.
Measure Steward:	American Academy of Sleep Medicine
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update multiple components of this measure to reflect on the assessment of patients with obstructive sleep apnea (OSA) who were prescribed an evidence-based therapy by revising the denominator criteria to reflect this patient population. We propose revisions to this measure to add flexibility in how the numerator is evaluated by allowing self-reporting for patients who don't have access to objective informatics systems or where resources may not be available. Additionally, we propose to add definitions that would clarify the intended denominator eligible patient population and appropriate clinical action for numerator compliance.

D.30 Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	291
CMS eCQM ID:	N/A
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 once during the measurement period.
Substantive Change:	**Updated denominator criteria: Added:** coding for speech language pathology and occupational therapy clinician types.
Measure Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add additional coding for speech language pathology and occupational therapy encounters. This would ensure a more complete denominator patient population is captured as it would be clinically appropriate for these clinician types to complete the quality action.

D.31 Chlamydia Screening for Women

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	310
CMS eCQM ID:	CMS153v12
Current Collection Type:	eCQM Specifications
Current Measure Description:	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.
Substantive Change:	**Updated denominator exclusion: Revised:** Women who are only eligible for the initial population due to a pregnancy test during the measurement period, and who had an order for an x-ray or for a specified medication on the date of the pregnancy test or the six days after the pregnancy test.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the denominator exclusion language to clarify the timing. The original measure language "within 7 days" is ambiguous as it can be interpreted as either "7 days after pregnancy test" or "on the day of pregnancy test and 6 days after". Therefore, clarifying the timeframe within the measure to evaluate a 7-day period better aligns with the measure intent of to include the day of the pregnancy test.

D.32 Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	317
CMS eCQM ID:	CMS22v12
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	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 elevated or hypertensive.
Substantive Change:	**Updated denominator: For all collection types: Added:** coding for audiology.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator criteria for all collection types to include audiology codes within the denominator eligible encounter criteria as this measure is applicable to their scope of care. Patients with high blood pressure are at an increased risk of hearing loss as compared to those without hypertension, making this concept important for audiologists to assess.[450]

[450] Agarwal, S., Mishra, A., Jagade, M., Kasbekar, V., & Nagle, S. K. (2013). Effects of Hypertension on Hearing. Indian Journal of Otolaryngology and Head and Neck Surgery: Official Publication of the Association of Otolaryngologists of India, 65(Suppl 3), 614–618. *https://doi.org/10.1007/s12070-013-0630-1.*

D.33 Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	326
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.
Substantive Change:	**Updated denominator exception: Revised:** Documentation of medical reason(s) for not prescribing an FDA-approved anticoagulant (e.g., present or planned atrial appendage occlusion or ligation or patient being currently enrolled in a clinical trial related to AF/atrial flutter treatment) **Removed:** documentation of system reasons exception.
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator exception to include patients currently being enrolled in a clinical trial related to AF/atrial flutter treatment as a medical reason for exception. Patients that are enrolled into a clinical trial related to AF/atrial flutter treatment may have contraindications for receiving FDA-approved oral anticoagulant drug therapy. Additionally, we propose to remove the denominator exception for documentation of system reason(s) as this option is not recommended for this measure due to wide-spread availability of these medications. This would also create alignment within the denominator exceptions across all American Heart Association (AHA) measures.

D.34 Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	331
CMS eCQM ID:	N/A
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 instructions: Added:** Each unique occurrence is defined as a 90-day period from onset of acute viral sinusitis symptoms. If multiple occurrences are documented within a 90-day period, Merit-based Incentive Payment System (MIPS) eligible clinicians should submit the most recent instance.
Measure Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the measure instructions to include additional clarifying language to remove ambiguity related to the definition of an occurrence of acute viral sinusitis. The revisions define a unique occurrence of acute viral sinusitis as a 90-day period from onset of acute viral sinusitis and include guidance in instances where multiple occurrences are documented.

D.35 HIV Viral Load Suppression

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	338
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	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.
Substantive Change:	**Modified collection type:** eCQM Specifications, MIPS CQMs Specifications collection type. **Updated instructions: Revised:** timing for patient encounter to the first 240 days of the performance period. **The measure description is revised to read:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period. **The measure denominator is revised to read:** All patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period with at least one eligible encounter in the first 240 days of the performance period. **Updated denominator criteria: Added:** coding for nonphysician, physician, and qualified health care professional (QHP) telephone assessments, residence services, and preventive medicine. Revised: timing for HIV diagnosis to be prior to or during the first 90 days of the performance period. Revised: timing for the denominator eligible encounter to occur during the first 240 days of the performance period.
Measure Steward:	Health Resources and Services Administration
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to update the collection types available for this measure to include the eCQM Specification collection type to allow choice in submission method. We propose to revise the measure description and denominator to update the timing of the patient's HIV diagnosis and eligible encounter. Requiring the HIV diagnosis before or with the first 3 months of the performance period in conjunction with limiting the eligible encounter timeframe allows the MIPS eligible clinician time to treat the patient in an effort to achieve numerator compliance. A viral load less than 200 copies/mL is optimal for patients with HIV to stay healthy and reduce transmission to others (*https://www.cdc.gov/hiv/risk/art/index.html*). According to the Panel on Antiretroviral Guidelines for Adults and Adolescents, antiretroviral therapy (ART) should be initiated as soon as possible after HIV diagnosis (*https://www.ncbi.nlm.nih.gov/books/NBK586306/*). Furthermore, the Panel on Antiretroviral Guidelines for Adults and Adolescents states indicates that individuals who are adherent to their ARV regimen and do not harbor resistance mutations to the component drugs can generally achieve suppression 8 to 24 weeks after ART initiation; rarely, in some patients it may take longer. Additionally, we propose to update the measure to include coding for telephone assessments with nonphysician/QHPs, residence services, and preventive medicine visits within the denominator eligible encounter criteria as this measure is applicable to the scope of care given by these clinicians.

D.36 Follow-Up Care for Children Prescribed ADHD Medication (ADD)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	366
CMS eCQM ID:	CMS136v13
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children 6-12 years of age and newly prescribed 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.
Substantive Change:	**Updated definition: Added:** Treatment days (covered days): The actual number of calendar days covered with prescriptions during the 301-day period. Use the following steps to identify and calculate covered days. Step 1: For same medications that are prescribed on the same day or on different days with overlapping days' supply, the days' supply is summed. The start and end dates are then identified. The start date is the date of service of the earliest prescription event and the first covered day. The end date is the calendar day when the days' supply runs out. The start date through the end date are considered covered days. This rule assumes that the patient will take one prescription at a time (and start taking the next prescription after exhausting the previous prescription). For example: - If there are three 7-days' supply prescription events for the same medication on January 1, the start date is January 1 and the end date is January 21. Covered days include January 1–21. - If there are two 7-days' supply prescription events for the same medication on January 1 and January 5, the start date is January 1 and the end date is January 14. Covered days include January 1–14. - If there are three 7-days' supply prescription events for the same medication on January 1, a 7-days' supply prescription event on January 20 and a 7-days' supply prescription event on January 28, the start date is January 1 and the end date is February 4. Covered days include January 1–February 4. Step 2: For all other events (multiple prescriptions for the same medication on different days without overlap, multiple prescriptions for different medications on the same or different days, with or without overlap), the covered days are identified by the start and end dates for each prescription event individually. The start date through the end date are considered covered days. This rule assumes the member will take the different medications concurrently. Step 3: Each calendar day covered by one or more medications is considered one covered day. **The initial patient population is revised to read:** Initial Population 1: Children 6-12 years of age as of the Intake Period who had an IPSD and who had a visit within 6 months prior to the IPSD including the IPSD. Children are removed if they had an acute inpatient stay with a principal diagnosis of mental, behavioral or neurodevelopmental disorder during the Initiation Phase. Initial Population 2: Children 6-12 years of age as of the Intake Period who had an IPSD and remained on the medication for at least 210 treatment days during the 301-day period, beginning on the IPSD through 300 days after the IPSD, and who had a visit within 6 months prior to the IPSD including the IPSD. Children are removed if they had an acute inpatient stay with a principal diagnosis of mental, behavioral or neurodevelopmental disorder during the Continuation and Maintenance Phase. **The measure numerator is revised to read:** Numerator 2: Patients who had at least one visit with a practitioner with prescribing authority during the Initiation Phase, and at least two follow-up visits on different dates of service during the 31-300 days after the IPSD.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing revisions to this measure that would simplify the logic and create definitions to align with the HEDIS measure by identifying the index prescription start date (IPSD) with negative medication history. We also propose to change the denominator qualifying encounter timeframe from during the measurement year to 6 months prior to the IPSD, which would enable the measure to attribute patients to clinicians who have a greater chance of interacting with the patient and/or prescribing the medication. Additionally, we propose to revise the numerator to align with the measure intent by clarifying that the two follow-up visits must occur on different dates.

D.37 Depression Remission at Twelve Months

Category	Description
CBE # / eCQM CBE #:	0710 / 0710e
Quality #:	370
CMS eCQM ID:	CMS159v12
Current Collection Type:	eCQM 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:	**Updated denominator exclusion: For all collection types: Removed:** Exclusion for patients who were permanent nursing home residents during the denominator identification period or the measure assessment period.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to update all collection types to remove the denominator exclusion related to patients who were permanent nursing home residents. This component has an extremely low rate of use, demonstrating that it's not a meaningful exclusion for the measure.

D.38 Functional Status Assessment for Total Hip Replacement

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	376
CMS eCQM ID:	CMS56v12
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 19 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.
Substantive Change:	**The measure description is revised to read:** Percentage of patients 19 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 300 – 425 days after the surgery. **The measure denominator exclusions are revised to read:** 1. Exclude patients who are in hospice care for any part of the measurement period. Exclude patients with severe cognitive impairment that starts before or in any part of the measurement period. 1. Exclude patients with one or more specific lower body fractures indicating trauma in the 24 hours before or at the start of the total hip arthroplasty. 2. Exclude patients with a partial hip arthroplasty procedure on the day of the total hip arthroplasty. 3. Exclude patients with a revision hip arthroplasty procedure, an implanted device/prosthesis removal procedure or a resurfacing/supplement procedure on the day of the total hip arthroplasty. 4. Exclude patients with a malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm on the day of the total hip arthroplasty. 5. Exclude patients with a mechanical complication on the day of the total hip arthroplasty. 6. Exclude patients with a second total hip arthroplasty procedure 1 year before or after the original total hip arthroplasty procedure. 7. Exclude patients who die on the day of the total hip arthroplasty procedure or in the 300 days after. **The initial patient population is revised to read:** Patients 19 years of age and older who had a primary THA between November two years prior to the measurement period and October of the year prior to measurement period; and who had an outpatient encounter between November of the year prior to the measurement period and the end of the measurement period. **Updated numerator: Revised:** timeframe for follow-up assessment to 300 – 425 days after the THA procedure.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to change the fracture exclusion from two fractures at the time of the procedure to one lower body fracture that would more accurately indicate a non-elective THA. We propose to add denominator exclusions to remove patients who do not receive elective THA and would not be appropriate for quality action assessment. We also propose to revise the initial patient population to push back the procedure timing and revise the numerator to extend the follow-up functional status assessment timing. This change harmonizes procedure and follow-up timing with other similar measures within the program reducing clinician burden when submitting similar measures across programs. This revision would also be reflected in the measure description.

D.39 Children Who Have Dental Decay or Cavities

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	378
CMS eCQM ID:	CMS75v12
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, 6 months to 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period as determined by a dentist.
Substantive Change:	**The measure description is revised to read:** Percentage of children, 1 – 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period as determined by a dentist. **The measure initial patient population is revised to read:** Children, 1 - 20 years of age at the start of the measurement period, with a clinical oral evaluation by a dentist during the measurement period.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to revise the age range in the description and the initial patient population, as dental visits before age one aren't significantly related to first dental examinations (*https://pubmed.ncbi.nlm.nih.gov/25422016/*). This change creates alignment with measures across programs such as the Medicaid Child Core set dental measures and the Dental Quality Alliance measures.

D.40 Primary Caries Prevention Intervention as Offered by Dentists

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	379
CMS eCQM ID:	CMS74v13
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, 6 months to 20 years of age, who received a fluoride varnish application during the measurement period as determined by a dentist.
Substantive Change:	**The measure description is revised to read:** Percentage of children, 1 – 20 years of age, who received two fluoride varnish applications during the measurement period as determined by a dentist. **Updated stratification: Revised:** Population 1 to reflect patient 1 – 5 years of age. **The measure initial patient population is revised to read:** Children, 1 – 20 years of age at the start of the measurement period, with a clinical oral evaluation by a dentist during the measurement period. **Updated numerator: Revised:** to require two fluoride varnishes on different days during the measurement period.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the age range for this measure as dental visits before age one are not significantly related to first dental examinations *(https://pubmed.ncbi.nlm.nih.gov/25422016/)*. This change creates alignment with measures across programs such as the Medicaid Child Core set dental measures and the Dental Quality Alliance measures. We also propose to update the numerator to require two fluoride applications within the measurement period as opposed to one fluoride application. This change would also align the measure with current evidence, clinical recommendations, and with the Topical Fluoride for Children measure used in the Medicaid Child Core Set as well as the Topical Fluoride for Children measure stewarded by the Dental Quality Alliance (*https://doi.org/10.14219/jada.archive.2013.0057*).

D.41 Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	382
CMS eCQM ID:	CMS177v12
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 (MDD) with an assessment for suicide risk.
Substantive Change:	**The measure description is revised to read:** Percentage of patient visits for those patients aged 6 through 16 years at the start of the measurement period with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk. **The initial patient population is revised to read:** All patient visits for those patients aged 6 through 16 at the start of the measurement period with a diagnosis of major depressive disorder.
Measure Steward:	Mathematica
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the measure description and initial patient population for the upper age limit to specify patients should be 16 years of age at the start of the measurement period. This would align with the current measure logic, which doesn't include patients who are 17 years of age.

D.42 Adherence to Antipsychotic Medications For Individuals with Schizophrenia

Category	Description
CBE # / eCQM CBE #:	1879 / N/A
Quality #:	383
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	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.
Substantive Change:	**Updated denominator criteria: Added:** additional outpatient place of service coding. **Updated denominator exclusions: Revised:** to exclude patients who have ever had a diagnosis of dementia.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose to add additional outpatient place of service coding for use with encounter coding for the outpatient, emergency department, and non-acute inpatient setting as schizophrenia may be diagnosed at encounters within these settings. This would ensure a complete denominator patient population is captured for quality action assessment. We also propose to expand the denominator exclusion so that it applies to patients who have ever had dementia as it is a chronic condition that can't be resolved and use of antipsychotics should be reserved for severe symptoms that have failed to respond adequately to nonpharmacological management strategies (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4994396/*).

D.43 Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	386
CMS eCQM ID:	N/A
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:	**The description is revised to read:** 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, lawful physician-hastened death, or hospice) or whose existing end of life plan was reviewed or updated at least once annually or more frequently as clinically indicated (i.e., rapid progression). **The numerator is revised to read:** Patients who were offered assistance in planning for end of life issues or whose existing end of life plan was reviewed or updated at least once annually or more frequently as clinically indicated (i.e., rapid progression). **Updated numerator options: Revised:** to include the concept of reviewing and updating an existing end of life plan.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the description, numerator, and numerator options to reflect numerator compliance for reviewing or updating an existing end of life plan. These revisions work to clarify the intent of the measure in regard to end of life issues and frequency, as well as the quality actions that would meet the intent of this measure, continuing to stress the importance of end of life planning.

D.44 Optimal Asthma Control

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	398
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	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.
Substantive Change:	**Updated denominator exclusion: Removed:** Patients who were permanent nursing home residents any time during the performance period.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to update the measure criteria to remove patients who were permanent nursing home residents any time during the performance period from the denominator exclusions and allow these patients to be included within the denominator of this measure. Patients within a nursing home should still be assessed for the quality action within this measure as it supports overall health and quality of life.

D.45 One-Time Screening for Hepatitis C Virus (HCV) for all Patients

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	400
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients age >= 18 years who received one-time screening for Hepatitis C Virus (HCV) infection.
Substantive Change:	**The measure title is revised from 'One-Time Screening for Hepatitis C Virus (HCV) for all patients' to:** One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation **The measure description is revised to read:** Percentage of patients age >= 18 years have never been tested for Hepatitis C Virus (HCV) infection who receive an HCV infection test AND who have treatment initiated within three months or who are referred to a clinician who treats HCV infection within one month if tested positive for HCV **The measure instructions are revised to read:** This measure is to be submitted a minimum of once per performance period for all patients > =18 years AND who are seen twice for any visits or who have at least one preventive visit through September 30 of the performance period AND who have never received an HCV antibody test. 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. **This measure will be calculated with 2 performance rates:** 1. Percentage of patients age >= 18 years who have never been tested for HCV antibodies and who receive an HCV antibody test. 2. Percentage of patients age >= 18 years who have a reactive HCV antibody test, who have a follow up HCV viral test, and if HCV viremia is detected, have treatment initiated within three months or are referred to a clinician who treats HCV infection within one month of the reactive HCV antibody test. 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 who have a reactive HCV antibody test, have a follow up HCV viral test, and if HCV viremia is detected, treatment is initiated within three months or they are referred to a clinician who treats HCV infection within one month of the reactive HCV antibody test. For all patients age >=18 years who have never been tested for HCV antibodies, submission criteria 1 is applicable, but submission criteria 2 will only be applicable for those patients who have a reactive HCV antibody test. A simple average, which is the sum of the performance rates divided by the number of the performance rates will be used to calculate performance. **NOTE:** Include only eligible encounters and HCV antibody test results documented through September 30 of the performance period. This will allow the evaluation of at least 90 days for treatment initiation or documentation of referral made within the performance period. **Updated denominator: Updated:** **THERE ARE TWO SUBMISSION CRITERIA FOR THIS MEASURE:** 1. All patients age >= 18 years age who have never been tested for HCV antibodies and who receive an HCV antibody test. AND 2. All patients age >= 18 years who have a reactive (positive) HCV antibody test and have a follow up HCV viral test, and if HCV viremia is detected, have treatment initiated within three months or are referred to a clinician who treats HCV infection within one month of the reactive HCV antibody test. This measure contains two submission criteria that aim to identify patients who are tested for HCV antibodies (submission criteria 1) and patients who have a reactive HCV antibody test and who have a follow up HCV viral test, and if HCV viremia is detected, have treatment initiated within three months or are referred to a clinician who treats HCV infection within one month of the reactive HCV antibody test (submission criteria 2). By separating this measure into various submission criteria, the MIPS eligible clinician will be able to better ascertain where gaps in performance exist and identify opportunities for improvement. For accountability reporting in the CMS MIPS program, the rate for submission criteria 2 is used for performance, however, both performance rates must be submitted. **Updated denominator/denominator criteria: Revised:** **SUBMISSION CRITERIA 1**: Patients who have never been tested for HCV antibodies and who receive an HCV antibody test. DENOMINATOR (Submission Criteria 1): All patients >= 18 years of age who are seen twice for any visits or who have at least one preventive visit January 1 and September 30 of the performance period. Denominator Criteria (Eligible Cases): Patients aged ≥ 18 years of age **AND** At least one preventive encounter **OR** At least two patient encounters **AND NOT** **DENOMINATOR EXCLUSION:** Diagnosis for Chronic Hepatitis C OR

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	Documentation or patient report of HCV antibody test or HCV RNA test which occurred prior to the performance period. **Added:** **SUBMISSION CRITERIA 2:** Patients with a reactive (positive) HCV antibody test with a follow up HCV viral test, and if HCV viremia is detected, treatment is initiated within three months or receives a referral to a clinician who treats HCV infection within one month of the reactive HCV antibody test **DENOMINATOR (Submission Criteria 2):** Patients >= 18 years of age who are seen twice for any visits OR who have at least one preventive visit AND have documentation of a reactive HCV antibody test between January 1 and September 30 of the performance period. Denominator Criteria (Eligible Cases): Patients aged ≥ 18 years of age **AND** All eligible instances when GXXXX is submitted for Performance Met (patient receives HCV antibody test and the test is reactive) in the numerator of Submission Criteria 1 **AND** At least one preventive encounter **OR** At least two patient encounters **Updated denominator note: Added:** For submission criteria 1: Either documentation of the prior HCV antibody test or HCV RNA test in the medical record or patient self-report of prior HCV antibody test or HCV RNA test is acceptable for this exclusion. **Updated numerator: Revised:** For submission criteria 1: Patients who receive an HCV antibody test between January 1 and September 30 of the performance period. **Added:** For submission criteria 2: Patients who have an HCV viral test conducted that (a) does not detect HCV viremia, or (b) detects HCV viremia and treatment is initiated within three months or they are referred to a clinician who treats HCV infection within one month of the reactive HCV antibody test. **Updated definitions:** **Removed:** For submission criteria 1: definition for screening for HCV Infection includes current or prior receipt of **Added:** For submission criteria 2: **Definition:** Examples of clinicians who treat HCV infection include but are not limited to: • Gastroenterologist • Hepatologist • Infectious disease clinicians Initiation of treatment definition for clinicians who do not refer patients to specialists for care: • Initiation of antiviral treatment, as appropriate, based on clinical guideline recommendations and patient characteristics. HCV viral test is defined as a test measuring an established marker of active HCV infection, including: • HCV RNA test • HCV core antigen test **Updated numerator options:** **Revised:** For submission criteria 1: **Performance Met:** Patient receives an HCV antibody test with nonreactive result **Performance Met:** Patient receives an HCV antibody test with reactive result **Denominator Exception:** Documentation of medical reason(s) for not receiving HCV antibody test due to limited life expectancy **Performance Not Met:** Patient does not receive HCV antibody test OR patient does receive HCV antibody test but results not documented, reason not given **Added:** For submission criteria 2: **Performance Met:** Patient, who has a reactive HCV antibody test, and has a follow up HCV viral test that detected HCV viremia, is referred within 1 month of the reactive HCV antibody test to a clinician who treats HCV infection **Performance Met:** Patient, who has a reactive HCV antibody test, and has a follow up HCV viral test that detected HCV viremia, has HCV treatment initiated within 3 months of the reactive HCV antibody test **Performance Met:** Patient has a reactive HCV antibody test, and has a follow up HCV viral test that does not detect HCV viremia **Performance Not Met:** Patient has a reactive HCV antibody test and does not have a follow-up HCV viral test, OR Patient has a reactive HCV antibody test and has a follow up HCV viral test that detects HCV viremia and is not referred to a clinician who treats HCV infection within 1 month and does not have HCV treatment initiated within 3 months of the reactive HCV antibody test, reason not given
Measure Steward:	American Gastroenterological Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise this measure to include follow up testing for HCV and, if viremia is detected, that treatment is initiated, or patients are referred to a clinician who treats HCV infection. This will be accomplished by stratifying the measure to create submission criteria (with corresponding performance rate) for patients who have never been tested for HCV antibodies and who receive an HCV test, and a submission criterion (with corresponding performance rate) for patients who have a reactive HCV

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	antibody test and, if HCV viremia detected, have treatment initiated or referral for treatment. This revision would be reflected within multiple components within the specification. These revisions take the measure one step further to ensure actions are being taken once the screening is completed so patients receive the appropriate care resulting in positive health outcomes. We would continue to monitor this measure throughout the rulemaking process for testing being performed by the measure steward regarding these proposed changes to the measure. Finalization of these revisions are contingent on completion of this testing. In the event the proposed substantive change(s) are 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. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark would be used for scoring.

D.46 Clinical Outcome Post Endovascular Stroke Treatment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	409
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.
Substantive Change:	**Updated denominator exclusion: Added:** For Submission Criteria 1: Exclude patients with a baseline mRS > 2
Measure Steward:	Society of Interventional Radiology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to add a denominator exclusion for Submission Criteria 1 to account for patients who have a baseline mRS of greater than 2 as endovascular stroke intervention would not be clinically indicated for this patient population.[451]

[451] American Heart Association, American Stroke Association. Acute Ischemic Stroke: Current Treatment Approaches for Acute Ischemic Stroke [PowerPoint slides]. *https://www.stroke.org/-/media/Stroke-Files/Ischemic-Stroke-Professional-Materials/AIS-Toolkit/AIS-Professional-Education-Presentation-ucm_485538.*

D.47 Osteoporosis Management in Women Who Had a Fracture

Category	Description
CBE # / eCQM CBE #:	0053 / N/A
Quality #:	418
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.
Substantive Change:	**Updated denominator criteria: Added: For all** submission criteria: coding for nonphysician, physician, and qualified health care professional (QHP) telephone assessments, and federally qualified health center (FQHC) visit.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	Additionally, we propose to update the measure to include coding for telephone assessments with nonphysician/QHPs, and federally qualified health center (FQHC) visits within the denominator eligible encounter criteria as this measure is applicable to the scope of care given by these clinicians.

D.48 Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling

Category	Description
CBE # / eCQM CBE #:	2152 / N/A
Quality #:	431
CMS eCQM ID:	N/A
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 12 months AND who received brief counseling if identified as an unhealthy alcohol user.
Substantive Change:	**Updated measure analytic: Revised:** data completeness will be determined utilizing submission criteria one.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the analytic of the measure to utilize submission criteria one for the determination of data completeness to ensure a complete data submission for all denominator eligible patients for this measure. As submission criteria two only includes those patients identified as unhealthy alcohol users, the intent of the measure is to also ensure screening of all patients aged 18 years and older. Assessing data completeness utilizing submission criteria one will ensure that screening information was collected.

D.49 Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	438
CMS eCQM ID:	CMS347v7
Current Collection Type:	eCQM 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: *All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes
Substantive Change:	**The measure description is revised to read: For all collection types:** 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: • All patients who were previously diagnosed with or currently have a diagnosis clinical atherosclerotic cardiovascular disease (ASCVD) including an ASCVD procedure; OR • Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40-75 years with a diagnosis of diabetes; OR • Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent. **Updated rate aggregation: For the eCQM Specifications collection type:** **Revised:** Population 2: Patients aged 20 to 75 years at the beginning of the measurement period **Added:** Population 4: Patients aged 40 to 75 at the beginning of the measurement period with a 10-year ASCVD risk score of > = 20 percent during the measurement period. **Revised:** Performance Rate to aggregate all 4 populations into a single performance rate. **Updated guidance: For the eCQM Specifications collection type: Revised:** the process to prevent counting patients more than once. **Updated denominator: For all collection types: Revised**: DENOMINATOR (SUBMISSION CRITERIA 2): Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia. **Added:** DENOMINATOR (SUBMISSION CRITERIA 4): Patients aged 40 to 75 years at the beginning of the measurement period with a 10-year ASCVD risk score of ≥ 20 percent during the measurement period. **Updated instructions: For the MIPS CQMs Specification collection type: Revised:** THERE ARE FOUR SUBMISSION CRITERIA FOR THIS MEASURE**: 1) All patients who were previously diagnosed with or currently have a diagnosis of clinical ASCVD, including an ASCVD procedure. OR 2) Patients aged 20 to 75 years at the beginning of the measurement period who have ever had a laboratory result of LDL-C ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia. OR 3) Patients aged 40 to 75 years at the beginning of the measurement period with Type 1 or Type 2 diabetes. OR 4) Patients aged 40 to 75 years at the beginning of the measurement period with a 10-year ASCVD risk score of > 20 percent. **Revised:** There is only one performance rate calculated for this measure. Patients can only be counted once and cannot be in more than one **submission criteria**. When submitting this measure, determine if the patient meets denominator eligibility in order of each risk category defined in the denominator submission criteria. For example, first evaluate if the patient meets denominator Submission Criteria 1. If no, then evaluate if the patient meets denominator Submission Criteria 2. If yes, then the patient will be in Submission Criteria 2 and is not eligible for denominator Submission Criteria 3 and 4. **Updated initial patient population: For the eCQM Specifications collection type:** Population 1: All patients who were previously diagnosed with or currently have a diagnosis of clinical ASCVD or ever had, including an ASCVD procedure. Population 2: Patients aged >= 20 to 75 years at the beginning of the measurement period who have ever had a laboratory result of LDL-C >=190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia. Population 3: Patients aged 40 to 75 years at the beginning of the measurement period with Type 1 or Type 2 diabetes. Population 4: Patients aged 40 to 75 at the beginning of the measurement period with 10-year ASCVD risk score (i.e., 2013 ACC/AHA ASCVD Risk Estimator or the ACC Risk Estimator Plus) of >= 20 percent during the measurement period. **Updated denominator criteria: For the MIPS CQM Specifications collection type:** **Revised:** For submission criteria 2: Patient aged 20 to 75 years at the beginning of the measurement period.

Category	Description
	Added: For submission criteria 4: Patients aged 40 through 75 years at the beginning of the measurement period AND Calculated 10-year ASCVD risk score of ≥ 20 percent during the measurement period AND Patient encounter during the performance period AND NOT DENOMINATOR EXCLUSIONS: Patients who are breastfeeding at any time during the measurement period OR Patients who have a diagnosis of rhabdomyolysis at any time during the measurement period **Updated numerator: For the MIPS CQM Specifications collection type: Added:** (SUBMISSION CRITERIA 4): Patients who are actively using or who receive an order (prescription) for statin therapy at any time during the measurement period. **Updated denominator exception: For the MIPS CQMs Specifications collection type: Added:** For submission **criteria** 4: Denominator Exceptions 1. Active Liver or Hepatic Disease or Insufficiency 2. End Stage Renal Disease 3. Statin-Associated Muscle Symptoms (SAMS) **Updated numerator definition: For the MIPS CQM Specification collection type: Added:** For submission criteria 4: 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. **Updated numerator note: For the MIPS CQM Specification collection type: Added:** For submission criteria 4: In order to meet the measure, current statin therapy use must be documented in the patient's current medication list or ordered during the measurement period. Only statin therapy meets the measure Numerator criteria (NOT other cholesterol lowering medications). Prescription or order does NOT need to be linked to an encounter or visit; it may be called to the pharmacy. Statin medication "samples" provided to patients can be documented as "current statin therapy" if documented in the medication list in health/medical record. Patients who meet the denominator criteria for inclusion but are not prescribed or using statin therapy will NOT meet performance for this measure. Adherence to statin therapy is not calculated in this measure. It may not be appropriate to prescribe statin therapy for some patients (see exceptions and exclusions for the complete list). Intensity of statin therapy in primary and secondary prevention: The expert panel of the 2018 ACC/AHA/MS Guidelines [1] defines recommended intensity of statin therapy on the basis of the average expected LDL-C response to specific statin and dose. Although intensity of statin therapy is important in managing cholesterol, this measure assesses prescription of ANY statin therapy, irrespective of intensity. Assessment of appropriate intensity and dosage documentation added too much complexity to allow inclusion of statin therapy intensity in the measure at this time. Denominator Exceptions should be active during the measurement period. **Updated numerator options: For the MIPS CQM Specification collection type: Added:** For **submission criteria** 4: **Performance Met:** Patients who are currently statin therapy users or received an order (prescription) for statin therapy **Denominator Exception:** Documentation of medical reason(s) for not currently being a statin therapy user or receiving an order (prescription) for statin therapy (e.g., patient with statin-associated muscle symptoms or an allergy to statin medication therapy, patients who are receiving palliative or hospice care, patients with active liver disease or hepatic disease or insufficiency, patients with end stage renal disease [ESRD] or other medical reasons) **Performance Not Met:** Patients who are not currently statin therapy users or did not receive an order (prescription) for statin therapy
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose revisions to this measure that would allow it to align more closely with the 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines.[452] Submission criteria one was updated to reflect a cap in the age denominator criteria to 75. The ACC/AHA 2018 cholesterol guidelines state that in adults older than 75 years with diabetes mellitus, it may be reasonable to initiate statin therapy after a clinician–patient discussion of potential benefits and risks for prevention of ASCVD events.[453] Additionally we proposed to add submission criteria 4, which specifically assesses statin use for patients that have a 10-

[452] Arnett, D. K., Blumenthal, R. S., Albert, M. A., Buroker, A. B., Goldberger, Z. D., Hahn, E. J., & Ziaeian, B. (2019). 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation, 140(11), e596-e646. *https://doi.org/10.1161/CIR.0000000000000678*.

[453] Saeed, A. & Mehta, L. (2020, October 1). Statin Therapy in Older Adults for Primary Prevention of Atherosclerotic Cardiovascular Disease: The Balancing Act. *https://www.acc.org/latest-in-cardiology/articles/2020/10/01/11/39/statin-therapy-in-older-adults-for-primary-prevention-of-atherosclerotic-cv-disease*.

Category	Description
	year ASCVD risk score of > 20 percent. Patients that meet this denominator criteria would be considered high risk and based on the guidelines, should be strongly recommended statin therapy solely based on risk alone and after a clinician patient risk discussion.[454] Furthermore, we propose to update the description and measure instructions to clearly communicate the changes within submission criteria one and the inclusion of a submission criteria 4. Due to the proposal of submission criteria 4, we propose to revise the measure instructions to explain to interested parties how this measure would be calculated for the purpose of MIPS. In the event the proposed substantive change(s) are 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. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark would be used for scoring.

D.50 Non-Recommended Cervical Cancer Screening in Adolescent Females

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	443
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.
Substantive Change:	**Updated denominator exclusion: Added:** coding for Cytokine Release Syndrome.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the denominator exclusions criteria by adding ICD-10-CM codes for Cytokine Release Syndrome, which would allow clinicians to capture and exclude patients with Cytokine Release Syndrome, as it may be appropriate for these patients to receive cervical cancer screening. It would also create alignment with the HEDIS measure.

D.51 Appropriate Workup Prior to Endometrial Ablation

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	448
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	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.
Substantive Change:	**Updated denominator criteria: Removed:** coding for extraction of endometrium.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to remove ICD-10 codes 0UDB7ZZ and 0UDB8ZZ from the denominator criteria as these codes do not represent endometrial ablation, but rather endometrial extraction. This change would ensure that the patients included within the denominator would truly meet the intent of the measure. Additionally, it would ensure all patients undergoing this procedure are included within the denominator to be assessed for the quality action described in the numerator.

D.52 Functional Status After Primary Total Knee Replacement

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	470
CMS eCQM ID:	N/A
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) or a 71 or greater on the KOOS, JR tool at one year (9 to 15 months) postoperatively.
Substantive Change:	**Updated numerator definition: Revised:** Postoperative Assessment Oxford Knee Score (OKS) or KOOS, JR - A postoperative Oxford Knee Score (OKS) or KOOS, JR functional assessment score can be obtained from the patient one year (9 to 15 months) after the date of procedure. Assessment scores obtained prior to 9 months and after 15 months postoperatively will not be used for measure calculation.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to revise the numerator definition to add 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 seven 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 in 2017 (*https://www.hss.edu/hoos-jr-koos-jr-outcomes-surveys.asp*). Additionally, the language has been revised and would allow for assessments completed via telephone.

D.53 HIV Screening

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	475
CMS eCQM ID:	CMS349v6
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).
Substantive Change:	**Updated denominator exception: Added:** Patients who die on or before the end of the measurement period.
Measure Steward:	Centers for Disease Control and Prevention
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add a denominator exception for patients who die before receiving an HIV screening. Since it is possible that a clinician could advance schedule an HIV test for a patient who potentially may die prior to the test, allowing this denominator exception would preserve performance of reporting clinicians while maintaining the intent of the measure.

D.54 Psoriasis – Improvement in Patient-Reported Itch Severity

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	485
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of patients, aged 18 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit
Substantive Change:	**The description is revised to read:** The percentage of patients, aged 8 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 3 or more points at a follow up visit. **The measure denominator is revised to read:** All patients aged 8 years and older, with a diagnosis of psoriasis with an initial (index visit) Numeric Rating Scale (NRS), Visual Rating Scale (VRS), or ItchyQuant assessment score of greater than or equal to 4 who are returning for a follow-up visit. **Updated denominator definition:** **Revised:** patient age to 8 years and older on date of service **Added:** Visual Rating Scale (VRS) for Pruritis – Note: (**This scale is intended for patients 18 years and older**) **Updated numerator: Revised:** required assessment score change from 2 or more points to 3 or more points. **Updated numerator options: Revised:** required assessment score change from 2 or more points to 3 or more points.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to revise the denominator and the denominator criteria to change the age from 18 years and older to 8 years and older. We also propose to add a note to the Visual Rating Scale (VRS) for Pruritis definition as this tool is only validated for patients 18 years and older. We propose a reduction in assessment score from 2 or more points to 3 or more points to align with current clinical guidelines. This skin condition has an annual prevalence of up to 0.71 percent within the pediatric patient population. Therefore, inclusion of the pediatric patient population would provide support for this frequently seen chronic inflammatory skin disorder and have significant impact on their overall quality of life (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5683294/*).

D.55 Dermatitis – Improvement in Patient-Reported Itch Severity

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	486
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of patients, aged 18 years and older, with a diagnosis of dermatitis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit.
Substantive Change:	**The description is revised to read:** The percentage of patients, aged 8 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 3 or more points at a follow up visit. **The measure denominator is revised to read:** All patients aged 8 years and older, with a diagnosis of psoriasis with an initial (index visit) Numeric Rating Scale (NRS), Visual Rating Scale (VRS), or ItchyQuant assessment score of greater than or equal to 4 who are returning for a follow-up visit. **Updated denominator definition: Removed:** Visual Rating Scale (VRS) for Pruritis. **Updated denominator criteria:** **Revised:** patient age to 8 years and older on date of service **Added:** Visual Rating Scale (VRS) for Pruritis – Note: (**This scale is intended for patients 18 years and older**) **Updated numerator: Revised:** required assessment score change from 2 or more points to 3 or more points. **Updated numerator options: Revised:** required assessment score change from 2 or more points to 3 or more points.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to revise the denominator and the denominator criteria to change the age from 18 years and older to 8 years and older. We also propose to add a note to the VRS for Pruritis definition as this tool is only validated for patients 18 years and older. We propose a reduction in assessment score from 2 or more points to 3 or more points to align with current clinical guidelines. Optimizing management of dermatitis in pediatric patients is critical to reduce signs of inflammation, alleviate pruritus and sleep disturbance, minimize the development and/or impact of comorbidities, and improve the patient and caregiver's quality of life (*https://pubmed.ncbi.nlm.nih.gov/33838839/*).

D.56 Screening for Social Drivers of Health

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	487
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
Substantive Change:	**Updated denominator criteria: Added:** coding for occupational therapy. **Updated denominator exception:** **Added:** **Denominator Exception:** Patient reason for not screening for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety (e.g., patient declined or other patient reasons)
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add encounter codes for MIPS eligible occupational therapists based upon interested parties' feedback: "Occupational therapy practitioners across practice settings should consider how current housing status and social determinants of health may impact their clients' occupational performance and ability to manage health conditions" (*https://pubmed.ncbi.nlm.nih.gov/32007967/*). We also propose to include a denominator exception as some patients may prefer not to discuss this information, however, attempting to screen every patient is important.

D.57 Adult Immunization Status

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	493
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.
Substantive Change:	**Updated denominator:** **Removed:** For all submission criteria: Active chemotherapy during the measurement period OR Bone marrow transplant during the measurement period OR History of immunocompromising conditions, cochlear implants, anatomic or functional asplenia, sickle cell anemia & Hemoglobin (HB)-S disease or cerebrospinal fluid leaks any time during the patient's history prior to or during the measurement period: • Anatomic or Functional Asplenia • Cerebrospinal Fluid Leak • Cochlear Implant • Cochlear Implant Device • Cochlear Implant Diagnosis • Immunocompromising Conditions • Sickle Cell Anemia and HB-S Disease **Updated denominator exception:** **Added:** For submission criteria 3: Documentation that administration of second recombinant zoster vaccine could not occur during the performance period due to the recommended 2-6 month interval between doses (i.e., first dose received after October 31)
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove denominator exclusions for all submission criteria for patients receiving active chemotherapy, who have a bone marrow transplant, or history of immunocompromising conditions as these are not contraindicators for receiving these vaccines and is in alignment with ACIP recommendations (*https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html*). We propose to add a denominator exception if there is a system reason that the second dose of recombinant zoster vaccine could not be administered within the prescribed interval during the performance period, as there is a minimum interval requirement between doses.

Table Group DD: Previously Finalized Quality Measures with Substantive Changes Proposed for Partial Removal as Component Measures in Traditional MIPS and Proposed for Retention for Use in Relevant MVPs for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

As noted under Table Group CC of this Appendix, beginning with the CY 2024 performance period/2026 MIPS payment year and future years, we propose to maintain measures Q112: Breast Cancer Screening, Q113: Colorectal Cancer Screening, and Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan for MIPS Value Pathways (MVP) development, and maintain measures Q112 and Q113 for purposes of Shared Savings Program ACOs reporting through the APP as discussed in section III.G.2.c.(2) of this proposed rule. These measures have proposed substantive changes under Table Group DD and Table Group E of this Appendix.

Note: Electronic clinical quality measures (eCQMs) that are endorsed by a CBE are shown in Table DD of this Appendix as follows: CBE # / eCQM CBE #.

The DD Tables within this proposed rule provide the substantive changes proposed for the quality measures in CY 2024. 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 2024 may not be identified within this proposed rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2024 CPT and ICD-10 updates and assessment of these codes inclusion by the Measure Steward, these changes may be postponed until CY 2025. The 2023 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 website at *https://qpp.cms.gov*.

In addition to the proposed substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but they are important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes would expand or contract the measure's current eligible patient population. Therefore, please refer to the current year measure specification and the 2024 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation. Language has also been added, to all applicable 2024 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, would the DD table corresponding to that measure reflect an update to the denominator allowing for telehealth encounters in the 'Substantive Change' cell.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the proposed substantive changes, there may be revisions within the logic that are not considered substantive in nature, however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow.

Note: For the CY 2024 performance period/2026 MIPS payment year (and prior CY 2023 performance period/2025 MIPS payment year), the CMS Web Interface measures as a collection type is only available for APM Entities, specifically Shared Savings Program ACOs reporting through the APP (the CMS Web Interface measures as a collection type is no longer available under traditional MIPS). Thus, the CMS Web Interface collection type collection type is not listed in any table under Table Group DD of this Appendix. For further information regarding the Shared Savings Program requirements under the APP and the CMS Web Interface collection type available under the APP, see section III.G.2.c.(2) of this proposed rule. For information regarding proposed changes to the CMS Web Interface measures for the CY 2024 performance period/2026 MIPS payment year, see Table Group E of this Appendix.

We request comments on these substantive changes.

DD.1 Breast Cancer Screening

Category	Description
CBE # / eCQM CBE #:	2372 / N/A
Quality #:	112
CMS eCQM ID:	CMS125v12
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM 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:	**Updated measure description: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Patient age to 40 – 74. **Updated denominator: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Patient age to 41 – 74. **Updated denominator criteria: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Patient age to 41 – 74. **Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** Dementia combinations: Donepezil-memantine to list of dementia exclusion medications.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator exclusion to include Donepezil-memantine in the list of dementia exclusion medications, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore would align with intent of the measure to exclude patients with this condition from the measure. Additionally, we propose to update the denominator eligible age criteria for this measure to align with the May 2023 draft recommendation statement issued by the USPSTF.[455]

DD.2 Colorectal Cancer Screening

Category	Description
CBE # / eCQM CBE #:	0034 / N/A
Quality #:	113
CMS eCQM ID:	CMS130v12
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** Dementia combinations: Donepezil-memantine to list of dementia exclusion medications.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator exclusion to include Donepezil-memantine in the list of dementia exclusion medications, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore would align with intent of the measure to exclude patients with this condition from the measure.

Table Group E: Previously Finalized CMS Web Interface Quality Measures with Substantive Changes Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

The E Tables within this proposed rule provide the substantive changes proposed for the CMS Web Interface quality measures in CY 2024. It should be noted that for the CY 2024 performance period/2026 MIPS payment year (and prior CY 2023 performance period/2025 MIPS payment year), the CMS Web Interface as a collection type is only available for APM Entities, specifically Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs), reporting through the APM Performance Pathway (APP) (the CMS Web Interface measures as a collection type is no longer available under traditional MIPS).

The changes that are made to the code 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 2024 may not be identified within the proposed rule due to the availability of these changes to the public. The 2024 CMS Web Interface Measure Coding Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures.

In addition to the proposed substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but they 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 2024 CMS Web Interface Measure Coding Release Notes once posted to review all coding changes.

The 2024 eCQM collection type measures had substantive changes that could prove burdensome to collect, therefore, the CMS Web Interface specifications will align with the 2024 MIPS CQMs specifications changes for these measures.

The tables below contain proposed **changes for performance year** 2024 CMS **Web Interface measure specifications to be used in the Shared Savings Program** for **quality reporting.** Note: there are substantive changes proposed for 9 of the 10 CMS Web Interface measures.

E.1 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
CBE #	0059
Quality #:	001 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	DM-2
Current Collection Type:	CMS Web Interface
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:	**Updated denominator exclusion: Added:** Dementia combinations: Donepezil-memantine to the list of dementia medication exclusion medications.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose to update the denominator exclusion to include Donepezil-memantine in the list of dementia exclusion medications, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with intent of the measure to exclude patients with this condition from the measure.

E.2 Preventive Care and Screening: Influenza Immunization

Category	Description
CBE #	0041
Quality #:	110 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	PREV-7
Current Collection Type:	CMS Web Interface
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:	**Updated denominator exclusion criteria: Added:** Anaphylaxis due to the vaccine on or before the measurement period.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator exclusion by adding an exclusion for patients who experienced anaphylaxis due to the vaccine. While anaphylaxis due to the flu vaccine is rare, patients who have previously experienced a severe allergic reaction due to the influenza vaccine, regardless of the component suspected of being responsible for the reaction, shouldn't receive additional doses of the vaccine (*https://www.cdc.gov/flu/prevent/egg-allergies.htm#:~:text=A%20person%20who%20has%20previously,get%20a%20flu%20vaccine%20again*).

E.3 Breast Cancer Screening

Category	Description
CBE #	2372
Quality #:	112 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	PREV-5
Current Collection Type:	CMS Web Interface
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:	**Updated measure description: Revised:** Patient age to 40 – 74. **Updated denominator: Revised:** Patient age to 41 – 74. **Updated initial population: Revised:** Patient age to 41 – 74. **Updated denominator exclusion: Added:** Dementia combinations: Donepezil-memantine to list of dementia exclusion medications.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator exclusion to include Donepezil-memantine in the list of dementia exclusion medications, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with intent of the measure to exclude patients with this condition from the measure. Additionally, we propose to update the denominator eligible age criteria for this measure to align with the May 2023 draft recommendation statement issued by the USPSTF for breast cancer screening.[456]

[456] USPSTF (2023). Task Force Issues Draft Recommendation Statement on Screening for Breast Cancer. *https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/file/supporting_documents/breast-cancer-screening-draft-rec-bulletin.pdf*.

E.4 Colorectal Cancer Screening

Category	Description
CBE #	0034
Quality #:	113 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface:	PREV-6
Current Collection Type:	CMS Web Interface
Current Measure Description:	Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Updated denominator exclusion: Added:** Dementia combinations: Donepezil-memantine to list of dementia exclusion medications.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator exclusion to include Donepezil-memantine in the list of dementia exclusion medications, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with intent of the measure to exclude patients with this condition from the measure.

E.5 Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
CBE #	N/A
Quality #:	134 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	PREV-12
Current Collection Type:	CMS Web Interface
Current Measure Description:	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.
Substantive Change:	**Updated guidance: Revised:** The intent of the measure is to screen for new cases of depression in patients who have never had a diagnosis of bipolar disorder prior to the qualifying encounter used to evaluate the numerator. Patients who have ever been diagnosed with bipolar disorder will be excluded from the measure. **Updated denominator exclusion: Removed:** Diagnosis of depression from the denominator exclusion. **Updated denominator criteria: Added:** coding for qualifying encounters for nutritionists/dieticians and home-based health care.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the denominator exclusion and applicable measure guidance to remove a previous diagnosis of depression as an exclusion, as patients with a history of depression clinically may require more frequent monitoring and ongoing treatment for reoccurrence of symptoms. We propose to update the denominator to include encounter codes for nutritionists and dieticians, as well as home-based encounter codes, as it is clinically appropriate to conduct depression screenings during these encounters.

E.6 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
CBE #	0028
Quality #:	226 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	PREV-10
Current Collection Type:	CMS Web Interface
Current Measure Description:	Percentage of patients aged 18 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 or up to two days after the date of the qualifying encounter.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 12 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 12 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months. **The initial population is revised to read:** All patients aged 12 years and older seen for at least two visits or at least one preventive visit during the measurement period
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose revisions to this measure to lower the denominator eligible age to 12 years and older to allow for the inclusion of adolescents into the measure's denominator. Lowering the denominator eligible age aligns with proposed changes for all other collection types, which combine the patient population within measure Q402: Tobacco Use and Help with Quitting Among Adolescents with that of measure Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention resulting in a single, more robust measure.

E.7 Controlling High Blood Pressure

Category	Description
CBE #	N/A
Quality #:	236 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	HTN-2
Current Collection Type:	CMS Web Interface
Current Measure Description:	Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.
Substantive Change:	**The measure initial patient population is revised to read:** Patients 18-85 years of age who had a visit during the measurement period and diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period. **Updated denominator exclusion: Added:** Dementia combinations: Donepezil-memantine to list of dementia exclusion medications. **Updated guidance: Revised:** In reference to the numerator element, only blood pressure readings performed by a clinician or an automated blood pressure monitor or device are acceptable for numerator compliance with this measure. This includes blood pressures taken in person by a clinician and blood pressures measured remotely by electronic monitoring devices capable of transmitting the blood pressure data to the clinician. Blood pressure readings taken by an automated blood pressure monitor or device and conveyed by the patient to the clinician are also acceptable. It is the clinician's responsibility and discretion to confirm the automated blood pressure monitor or device used to obtain the blood pressure is considered acceptable and reliable and whether the blood pressure reading is considered accurate before documenting it in the patient's medical record. **Updated numerator note: Revised:** In reference to the numerator element, only blood pressure readings performed by a clinician or an automated blood pressure monitor or device are acceptable for numerator compliance with this measure. This includes blood pressures taken in person by a clinician and blood pressures measured remotely by electronic monitoring devices capable of transmitting the blood pressure data to the clinician. Blood pressure readings taken by an automated blood pressure monitor or device and conveyed by the patient to the clinician are also acceptable. It is the clinician's responsibility and discretion to confirm automated blood pressure monitor or device used to obtain the blood pressure is considered acceptable and reliable and whether the blood pressure reading is considered accurate before documenting it in the patient's medical record.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose to revise the initial patient population to specify the patient visit must occur during the measurement period. This revision provides clarification of the encounter timing. Additionally, we propose to update the denominator exclusion to include Donepezil-memantine in the list of dementia medication list, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with intent of the measure to exclude patients with this condition from the measure. We propose to revise the measure guidance and the numerator note around remote monitoring devices for capturing blood pressure readings. Currently, the measure allows patient reported data using most methods of digital collection/reporting and prohibits patient reported data taken with non-digital devices, such as with a manual blood pressure cuff and stethoscope. The measure is agnostic to how the reading gets in and the documentation practice of each office; therefore, whether patient is "conveying the reading to the clinician" by manually entering the BP reading (for example, patient portal) or having the device auto-transmit data directly, it is the clinician's responsibility and discretion to confirm that the automated blood pressure monitor used to obtain the blood pressure is considered acceptable and reliable.

E.8 Depression Remission at Twelve Months

Category	Description
CBE #	0710
Quality #:	370 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	MII-1
Current Collection Type:	CMS Web Interface
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.
Substantive Change:	**Updated denominator exclusion: Removed:** Exclusion for patients who were permanent nursing home residents during the denominator identification period or the measure assessment period.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to remove the denominator exclusion related to patients who were permanent nursing home residents. This component has an extremely low rate of use, demonstrating that it's not a meaningful exclusion for the measure.

E.9 Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
CBE #	N/A
Quality #:	438 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	PREV-13
Current Collection Type:	CMS Web Interface
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: *All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes
Substantive Change:	**The measure description is revised to read:** 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: • All patients who were previously diagnosed with or currently have a diagnosis clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR • Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40 to 75 years with a diagnosis of diabetes; OR • Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent. **Updated denominator guidance:** **Revised:** Denominator Population Guidance: The denominator population covers four distinct populations. There is only one performance rate calculated for this measure. Use the following process to prevent counting patients more than once. Denominator Population 1: All patients who were previously diagnosed with or currently have a diagnosis of clinical ASCVD, including an ASCVD procedure before the end of the measurement period If YES, patient meets Denominator Population 1 risk category If NO, screen for next risk category Denominator Population 2: Patients aged 20 to 75 years at the beginning of the measurement period who have ever had a laboratory result of LDL-C ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia If YES, patient meets Denominator Population 2 risk category If NO, screen for next risk category Denominator Population 3: Patients aged 40 to 75 years at the beginning of the measurement period with a diagnosis of Type 1 or Type 2 diabetes at any time during the measurement period If YES, patient meets Denominator Population 3 risk category If NO, screen for next risk category Denominator Population 4: Patients aged 40 to 75 years at the beginning of the measurement period with a 10-year ASCVD risk score of ≥ 20 percent during the measurement period If YES, patient meets Denominator Population 4 risk category If NO, patient does NOT meet denominator criteria and is NOT eligible for measure inclusion.

Category	Description
	Added: For Denominator Population Guidance for Encounter: To meet Denominator Population 4: There is no LDL-C result required. **Removed:** For Denominator Population Guidance for Encounter: Lifestyle modification coaching: A healthy lifestyle is important for the prevention of cardiovascular disease. However, lifestyle modification monitoring and documentation added too much complexity to allow its inclusion in the measure at this time. **The initial population is revised to read:** Population 1: All patients who were previously diagnosed with or currently have an active diagnosis of clinical ASCVD or ever had, including an ASCVD procedure. Population 2: Patients aged 20 to 75 years at the beginning of the measurement period who have ever had a laboratory result of LDL-C ≥190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia. Population 3: Patients aged 40 to 75 years at the beginning of the measurement period with Type 1 or Type 2 diabetes. Population 4: Patients aged 40 to 75 at the beginning of the measurement period with a 10-year ASCVD risk score of ≥ 20 percent **Updated denominator:** **Revised:** Population 2: Patients aged 20 to 75 years at the beginning of the measurement period who have ever had laboratory result of LDL-C ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia **Added:** Population 4: Patients aged 40 to 75 at the beginning of the performance period with a 10-year ASCVD risk score of ≥ 20 percent during the performance period. **Updated numerator definition: Added:** 10 Year Risk Assessment - The 10-year ASCVD risk score is calculated using the Pooled Cohort Equations: 1) the 2013 ACC/AHA ASCVD Risk Estimator OR 2) the ACC Risk Estimator Plus. If your EHR does not have either of these risk calculators, we recommend that you use the on-line versions. The 10-year ASCVD risk assessment must be performed during the measurement period **Updated submission guidance: Revised:** DENOMINATOR CONFIRMATION, POPULATION 2 ○ Determine if the patient is aged 20 to 75 years at the beginning of the measurement period AND has ever had a laboratory result of LDL-C ≥ 190 mg/dL OR were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia ○ If the patient is 20 to 75 years at the beginning of the measurement period AND has ever had a laboratory result of LDL-C ≥ 190 mg/dL documented OR were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia select "Yes" **OR** ○ If the patient is not 20 to 75 years at the beginning of the measurement period OR has never had a laboratory result of LDL-C ≥ 190 mg/dL AND has never been previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia documented select "No Diagnosis" **Added:** DENOMINATOR CONFIRMATION, POPULATION 4 ○ Determine if the patient is aged 40 to 75 years at the beginning of the measurement period with a 10-year ASCVD risk score of ≥ 20 percent during the measurement period ○ If the patient is aged 40-75 years at the beginning of the measurement period with a 10-year ASCVD risk score of ≥ 20 percent during the measurement period select "Yes" **OR** ○ If the patient is not aged 40 to 75 years at the beginning of the measurement period or does not have a 10-year ASCVD risk score of ≥ 20 percent during the measurement period select "No – Risk Assessment" **OR** ○ If there is a denominator exclusion for patient disqualification from the measure select "Denominator Exclusion" **OR** ○ If there is an "other" CMS approved reason for patient disqualification from the measure select "No- Other CMS Approved Reason"
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose revisions to this measure that would allow it to align more closely with the 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on

Category	Description
	Clinical Practice Guidelines.[457] We propose to update submission criteria 2 to reflect a cap in the age denominator criteria to 75. The ACC/AHA 2018 cholesterol guidelines state that in adults older than 75 years with diabetes mellitus, it may be reasonable to initiate statin therapy after a clinician–patient discussion of potential benefits and risks for prevention of ASCVD events.[458] Additionally we propose to add submission criteria 4, which specifically assesses statin use for patients that have a 10-year ASCVD risk score of > 20 percent. Patients that meet this denominator criteria would be considered high risk and based on the guidelines, should be strongly recommended statin therapy solely based on risk alone and after a clinician patient risk discussion.[459] Furthermore, we propose to update the description and measure instructions to clearly communicate the changes within submission criteria one and the inclusion of a submission criteria 4.

APPENDIX 2: IMPROVEMENT ACTIVITIES

In this proposed rule, for the CY 2024 performance period/2026 MIPS payment year and future years, we are proposing to add five new improvement activities, modify one previously adopted improvement activity, and remove three previously adopted improvement activities. These proposals are discussed in section IV.A.4.f. of this proposed rule and in more detail below. We request comment on our proposals.

Table A: New Improvement Activities for the CY 2024 Performance Period/2026 MIPS Payment Year and for Future Years

New Improvement Activity	
Proposed Activity ID:	**IA_PM_XX**
Proposed Subcategory:	Population Management
Proposed Activity Title:	Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services
Proposed Activity Description:	Establish policies and procedures to improve practice capacity to increase HIV prevention screening, improve HIV prevention education and awareness, and reduce disparities in pre-exposure prophylaxis (PrEP) uptake. Use one or more of the following activities: • Implement electronic health record (EHR) prompts or clinical decision support tools to increase appropriate HIV prevention screening; • Require that providers and designated clinical staff take part in at least one educational opportunity that includes components on the importance and application of HIV prevention screening and PrEP initiation in clinical practice; and/or • Assess and refine current policies for HIV prevention screening, including integrated sexually transmitted infection (STI)/HIV testing processes, universal HIV screening, and PrEP initiation.
Proposed Weighting:	Medium
Rationale:	The Centers for Disease Control and Prevention (CDC) estimates that nearly 1.2 million Americans are living with HIV and that nearly one in eight are not aware that they are infected.[10,11] Social determinants of health (SDOH) factors, including low socioeconomic status, living in poverty, lack of transportation to care services, low health literacy levels

[457] Arnett, D. K., Blumenthal, R. S., Albert, M. A., Buroker, A. B., Goldberger, Z. D., Hahn, E. J., Himmelfarb, C. D., Khera, A., Lloyd-Jones, D., McEvoy, J. W., Michos, E. D., Miedema, M. D., Muñoz, D., Smith, S. C., Jr, Virani, S. S., Williams, K. A., Sr, Yeboah, J., & Ziaeian, B. (2019). 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation, 140(11), e596–e646. *https://doi.org/10.1161/CIR.0000000000000678*.

[458] Saeed, A. & Mehta, L. (2020, October 1). Statin Therapy in Older Adults for Primary Prevention of Atherosclerotic Cardiovascular Disease: The Balancing Act. *https://www.acc.org/latest-in-cardiology/articles/2020/10/01/11/39/statin-therapy-in-older-adults-for-primary-prevention-of-atherosclerotic-cv-disease*.

[459] Arps, K., Blumenthal, R., & Martin, S. (2018, November 15). New Aspects of the Risk Assessment Guidelines, Scientific Evidence and Future Goals. *https://www.acc.org/latest-in-cardiology/articles/2018/11/14/07/10/new-aspects-of-the-risk-assessment-guidelines*.

	to complete medical forms, homelessness, and intimate partner violence can lead to limitations in seeking preventive measures, including accessing healthcare providers or HIV testing sites.[40] The CDC recommends that all individuals between the ages of 13 and 64 get tested for HIV at least once as part of routine healthcare.[13] Individuals at greater risk, including gay, bisexual, and other men who have sex with men (MSM), and persons who inject drugs, are recommended for more frequent, annual HIV screening.[12,13] The CDC also recommends that all sexually active adult and adolescent patients should receive information about HIV pre-exposure prophylaxis (PrEP), and recommends PrEP as an effective HIV prevention strategy.[14] Taking PrEP as prescribed reduces the risk of transmitting HIV through sexual contact by about 99 percent, and limits the risk of acquiring HIV by at least 74 percent among people who inject drugs.[14] Lack of HIV preventive care and referrals among vulnerable populations in the U.S. leads to inequities in access to HIV prevention treatment.[30,36] One study reported that fewer Black, Hispanic, or Latino people who tested negative for HIV and were eligible for PrEP received a referral for treatment as compared with other racial and ethnic groups.[36] Among both males and females, Black and Hispanic people have far lower PrEP uptake rates relative to their risk than do White males, a disparity that is starkest among Black males.[29] Despite MSM representing the highest proportion of Americans diagnosed with HIV, lack of awareness and understanding of PrEP has led to low rates of PrEP use among this group; in one study conducted among Black/African American and white PrEP-eligible MSM, 61 percent were aware of PrEP, but only 9 percent used it.[36] In another study conducted among Black/African American MSM, PrEP awareness was 39 percent, but actual use was less than 5 percent.[36] Barriers to PrEP uptake have contributed to low rates of use, with more than one-half of PrEP-eligible MSM being reported as failing to reach the contemplation stage (for example, willing and self-identified as appropriate candidates) of PrEP adoption.[34] Implementation of an electronic HIV screening alert almost doubled the rates of universal HIV screening in one study of primary care providers in a Midwestern practice and this implementation also reduced racial disparities in care.[38] Provider knowledge about PrEP was associated with both past and potential future initiation of PrEP, and an observed greater willingness to prescribe PrEP was associated with higher PrEP knowledge.[7] HIV diagnoses in MSM in New South Wales, Australia, declined from 295 (cases) in the 12 months before PrEP roll-out to 221 (cases) in the 12 months after roll-out. Grulich and colleagues (2018) also observed a decline both in recent HIV infections (from 149 cases to 102) and in other HIV-related diagnoses.[27] This HIV prevention-focused activity, including clinician education, will help to narrow gaps and inequities in care related to HIV prevention in clinical practice, and that it will highlight HIV prevention guidelines, including recommendations to enhance prevention screening and PrEP awareness and use. We propose weighting this activity medium, because this activity may be accomplished by establishing or refining policies and procedures to improve practice capacity to increase HIV prevention screening and linkage to appropriate prevention resources. See the definition of medium weighting in the CY 2019 PFS final rule (83 FR 59780 and 59781).
New Improvement Activity	
Proposed Activity ID:	**IA__MVP**
Proposed Subcategory:	N/A
Proposed Activity Title:	Practice-Wide Quality Improvement in MIPS Value Pathways
Proposed Activity Description:	Create a quality improvement initiative within your practice and create a culture in which all staff actively participates. Clinicians must be participating in MIPS Value Pathways (MVPs) to attest to this activity.

	Create a quality improvement plan that involves a minimum of three of the measures within a specific MVP and that is characterized by the following: • Train all staff in quality improvement methods, particularly as related to other quality initiatives currently underway in the practice; • Promote transparency and accelerate improvement by sharing practice-level and panel-level quality of care and patient experience and utilization data with staff; • Integrate practice change/quality improvement into all staff duties, including communication and education regarding all current quality initiatives; • Designate regular team meetings to review data and plan improvement cycles with defined, iterative goals as appropriate; or • Promote transparency and engage patients and families by sharing practice-level quality of care and patient experience and utilization data with patients and families, including activities in which clinicians act upon patient experience data. In addition, clinicians may consider: • Creation of specific plans for recognition of individual or groups of clinicians and staff when they meet certain practice-defined quality goals. Examples include recognition for achieving success in measure reporting and/or a high level of effort directed to quality improvement and practice standardization; and • Participation in the American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program.
Proposed Weighting:	High
Rationale:	Clinical practice quality improvement (QI) activities are commonly limited to staff members directly involved in the performance of the specific activity. Creating a culture of QI among all staff working as a team drives outcomes more effectively than when the work is done in isolation. This collaborative approach allows for a more comprehensive view of QI goals and, in turn, the development of most efficient and effective initiatives. Additionally, the positive and unpredictable ideas that come from a high-functioning collaborative team can be crucial to achieving QI that is most meaningful to both patients and providers. Creating coordination between the goals of this activity and the goals of the measures within an MVP will create an intuitive focus within a specific clinical area, which will allow clinicians and other staff members to be most productive in their QI efforts. This coordinated clinical focus is likely to lessen the perceived burden of MIPS and MVP while the effort required will still be sufficiently high. Team-based quality improvement approaches have been found to be highly effective in healthcare.[18,32] In addition, this activity will incentivize voluntary MVP adoption, which will drive clinician accountability and quality improvement on factors that are more relevant to their practice. For a discussion of the benefits of MVPs, please see the 2021 PFS final rule (85 FR 84844 through 84846). We propose making this activity high-weighted because MIPS eligible clinicians will need considerable time and resources to implement practice-wide quality improvement via MVPs. See the definition for high weighting in the CY 2019 PFS final rule (83 FR 59780 and 59781). While this MVP-only activity could appear duplicative on the surface, this MVP activity specifically defines the nature of the QI project that clinicians must complete, and it is particular to the measures they are reporting on in the MVP they have chosen. We are requiring clinicians complete the project focused on three separate measures. In contrast, IA_PSPA_19 requires only a focused single improvement. This is consistent with the work that clinicians will need to complete to be successful with MVPs.
New Improvement Activity	
Proposed Activity ID:	**IA_PM_XX**

Proposed Subcategory:	Population Management
Proposed Activity Title:	Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines
Proposed Activity Description:	Incorporate the Cervical Cancer Screening and Management (CCSM) Clinical Decision Support (CDS) tool within the electronic health record (EHR) system to provide clinicians with ready access to and assisted interpretation of the most up-to-date clinical practice guidelines in CCSM to ensure adequate screening, timely follow-up, and optimal patient care. The CCSM CDS helps ensure that patient populations receive adequate screening and management, according to evidence-based recommendations in the United States Preventive Services Task Force (USPSTF) screening and American Society for Colposcopy and Cervical Pathology (ASCCP) management guidelines for cervical cancer. The CDS integrates into the clinical workflow a clinician-facing dashboard to support the clinician's awareness and adoption of and preventive care for cervical cancer, including screening and any necessary follow-up treatment. The CCSM CDS is fully conformant with the HL7 Fast Healthcare Interoperability Resources (FHIR) standard, so it can be used with any certified EHR platform. The CDS Hooks and SMART-on-FHIR interoperability interface standards provide two ways to integrate with the clinical workflow in a way that complements existing displays and information pre-visit, during visit, and for post-visit follow-up. CCSM CDS helps the clinician evaluate the patient's clinical data against existing guidance and displays patient-specific recommendations.
Proposed Weighting:	High
Rationale:	Cervical cancer is largely a disease of health inequity, with higher rates among lower socio-economic groups, immigrant populations, and women in rural settings.[22] Cervical cancer is highly preventable when precancerous lesions are detected early and appropriately managed.[53] However, the complexity of and frequent updates to existing evidence-based clinical guidelines make it challenging for clinicians to stay abreast of the latest recommendations.[53] In addition, limited availability of and accessibility to CDS make it difficult for groups who are medically underserved to receive screening and/or appropriate follow-up care. The CCSM CDS is one solution to help improve cervical cancer outcomes. The CCSM CDS provides clinical guidelines in a shareable, structured, and computer-interpretable format to facilitate meaningful improvements in the number of patients screened and treated for cervical precancer. This includes addressing current gaps in screening uptake and timely follow-up care among populations that are often medically underserved.[22] Analysis of data collected from 1,037 Federally Qualified Health Centers from 2016 to 2021 by the Health Resources and Services Administration (HRSA) Uniform Data System (UDS) found that only about 50 percent of women received recommended cervical cancer screening.[16] Additionally, National Quality Assurance Committee (NCQA) Healthcare Effectiveness and Data Information Set (HEDIS) measures of cervical cancer screening rates show that Medicaid HMOs have rates at least 10% lower than Commercial HMOs.[42] The CDC-developed CCSM CDS tool has been developed in a standards-based, EHR-agnostic way.[21,44] The CDS tools are designed to help clinicians more efficiently evaluate patient clinical data against CCSM guidance and display patient-specific recommendations. This reduces the manual workload of monitoring patients who need screening and potential follow-up. Evidence suggests that clinician adherence to the CCSM guidelines can assist clinicians in improving screening and management outcomes and address existing disparities in guideline concordant care.[46] This activity will leverage the convenience and efficiency of more sophisticated, standards-based decision support tooling to assist clinicians in applying complex data-driven guidelines.[21] This CCDS CDS can help provide optimal care and better

	engagement with diverse patient populations, including historically underserved populations.[22,53,16,42] We propose weighting this activity high, because this activity will require integrating the CCSM CDS tool into clinicians'/practices' EHR dashboards, learning how to use it, and then using it. See the definition of high weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
New Improvement Activity	
Proposed Activity ID:	**IA_BMH_XX**
Proposed Subcategory:	Behavioral and Mental Health
Proposed Activity Title:	Behavioral/Mental Health and Substance Use Screening & Referral for Pregnant and Postpartum Women
Proposed Activity Description:	Screen for perinatal mood and anxiety disorders (PMADs) and substance use disorder (SUD) in pregnant and postpartum women, and screen and refer to treatment and/or refer to appropriate social services, and document this in-patient care plans.
Proposed Weighting:	High
Rationale:	As many as one in five women are affected by perinatal mood and anxiety disorders (PMADs) in their lifetimes [23,24]yet studies estimate that between 50-80 percent of women are not screened during the prenatal or postpartum periods.[6] This highlights barriers to receiving behavioral healthcare in the perinatal period, such as stigma in receiving mental health care, lack of awareness about the prevalence of PMADs, and limited access to affordable behavioral health services.[51] Though all women can experience PMADs, those that are particularly vulnerable include historically underserved racial and ethnic populations, those with lower socioeconomic status, and younger mothers.[51] Research has demonstrated a link between untreated PMADs and maternal SUD[3,33,39,43] While there are limited data estimating the prevalence of maternal SUD, opioid use among perinatal women quadrupled between 1998 and 2014, leading to an increase in infants born with Neonatal Abstinence Syndrome (NAS)[2,3]. Methamphetamine and marijuana use among pregnant and postpartum women has also increased.[1,62] The largest disparity in maternal SUD, particularly opioid use disorder, is seen among mothers living in rural areas[61] Increased costs associated with maternal SUD, particularly for infants born with NAS was estimated at approximately $93,400 per infant in 2012.[43] While the effects of untreated PMADs and maternal SUD can lead to increased severity of PMADs (including risk of maternal suicide), initiation or increased substance use behaviors, and pregnancy complications,[5,19] the implications extend beyond mothers. Infants and children can also be impacted by lower rates of mother/infant bonding, breastfeeding, safe sleep and other infant safety practices, and other activities impacting neurodevelopment.[8,51] Infants, children, and partners of mothers who experience PMADs are also more likely to experience a depressive disorder.[35,51] Furthermore, prevalence of maternal substance use disorders is associated with increased number of children entering the foster system and increased risk of substance use among these children.[51,54] Rates of screening for PMADs and maternal SUD greatly vary during pregnancy and postpartum.[6] The American College of Obstetricians and Gynecologists (ACOG) recommends that all perinatal women be screened for PMADs, and referred for services upon positive screen.[2] The American Academy of Pediatrics recommends that pediatricians routinely screen mothers of patients for postpartum depression at the one-, two-, four- and six-month well child visits.[17] The U.S. Preventive Services Task Force also recommends that clinicians provide or refer pregnant and postpartum persons who are at increased risk of perinatal depression to counseling interventions and has determined that doing so provides improved outcomes for those at increased risk.[4,7]

	There are several prominent guidelines for screening and treating substance use disorder in pregnant women, including the Substance Abuse and Mental Health Services Administration Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and their Infants.[45] The Biden-Harris Administration has also released the National Drug Control Strategy and Substance Use in Pregnancy: Improving Outcomes for Families plan that outlines key steps to "explore, identify barriers, and establish policy to help pregnant women with substance use disorder (SUD) obtain prenatal care and addiction treatment without fear of child removal."[56,57,58,59] Many of these guidelines describe the need for routine verbal screenings to reduce bias and discrimination in those who are screened using specimens.[25] We propose making this activity high-weighted, because MIPS-eligible clinicians will need considerable time and resources to implement the requirements for this activity to train providers on appropriate screening practices, integrate screenings into clinical workflow, and establish a mechanism for referring, linking, and following up with patients upon positive screen. See the definition for high weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
New Improvement Activity	
Proposed Activity ID:	**IA_BMH_XX**
Proposed Subcategory:	Behavioral and Mental Health
Proposed Activity Title:	Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults
Proposed Activity Description:	Complete age-appropriate screening for mental health and substance use in older adults, as well as screening and referral to treatment and/or referral to appropriate social services, and document this in-patient care plans.
Proposed Weighting:	High
Rationale:	Social isolation in the elderly is associated with depression; anxiety; cognitive decline; physical disabilities; lower self-ratings of health; and premature mortality from all causes.[19,26,41,54] Nearly one-quarter (24 percent) of Americans aged 65 and older living in the community are considered to be socially isolated, and a sizable proportion of adults in the US report feeling lonely (35 percent of adults aged 45 and older and 43 percent of adults aged 60 and older).[34] Also, unhealthy alcohol use and use of other drugs has been increasing rapidly among older adults.[37,63] The Substance Abuse and Mental Health Services Administration (SAMHSA), the American Society of Addiction Medicine (ASAM), and the American Psychiatric Association (APA) all recommend routine screening for mental health and substance use issues in elders to identify ongoing concerns or patients at risk for future issues.[39] Many mental health screening tools available for the general adult population, such as the Patient Health Questionnaire (PHQ-9) depression screener and the Generalized Anxiety Disorder 7-item scale (GAD-7), are appropriate for older adults.[38] The APA recommends that "older individuals be referred to treatment settings that offer age-appropriate group therapy and non-confrontational individual therapy focusing on late-life issues of loss and sources of social support. Older adults also deserve to receive full consideration for the potential benefits of medication management for substance use disorders."[4] We propose making this activity high-weighted, because MIPS eligible clinicians will need considerable time and resources to implement the requirements for this activity. See the definition for high weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).

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Table B: Changes to Previously Adopted Improvement Activities for the CY 2024 Performance Period/2026 MIPS Payment Year and for Future Years

In this rule, we propose to modify one previously finalized improvement activity for the CY 2024 performance period/2026 MIPS payment year and future years.

Current Improvement Activity	
Current Activity ID:	**IA_PSPA_16**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Use of Decision Support and Standardized Treatment Protocols
Current Activity Description:	Use decision support and standardized treatment protocols to manage workflow in the team to meet patient needs.
Current Weighting:	Medium
Proposed Change and Rationale:	We are proposing to modify this activity's description, "Use decision support and standardized treatment protocols to manage workflow in the team to meet patient needs," and its validation criteria to explicitly promote the use of clinical decision support (CDS), particularly open-source, freely available, interoperable CDS. "Moving the needle" to make progress toward interoperability continues to be an essential Federal goal, as demonstrated by new rules that the Office of the National Coordinator for Health Information Technology (ONC) announced on April 11, 2023, that it will be proposing for Cures Act implementation.[1] The urgent importance of interoperability is noted on the HealthIT.gov website: "Interoperability helps clinicians deliver safe, effective, patient-centered care. It also provides new ways for individuals and caregivers to access electronic health information to manage and coordinate care. Advancing interoperability is now an essential part of most health care activities ranging from health equity to public health emergency response."[2]
Proposed Revised Activity Title:	Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs.
Proposed Revised Activity Description:	Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools—and standardized treatment protocols to manage workflow on the care team to meet patient needs. Clinicians should focus on utilizing open-source, freely available, interoperable CDS in completing the requirements of this activity.

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TABLE C: Improvement Activities Proposed for Removal for the CY 2024 Performance Period/2026 MIPS Payment Year and for Future Years

In this rule, we propose to remove three previously finalized improvement activities from the CY 2024 performance period/2026 MIPS payment year and future years. These improvement activities are discussed in detail below. Improvement activity removal factors are discussed in the CY 2020 PFS final rule (84 FR 62568 through 63563).

Current Improvement Activity	
Current Activity ID:	**IA_BMH_6**
Current Subcategory:	Behavioral and Mental Health
Current Activity Title:	Implementation of co-location PCP and MH services
Current Activity Description:	Integration facilitation and promotion of the colocation of mental health and substance use disorder services in primary and/or non-primary clinical care settings.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under removal factor two, there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice, and factor three, activity does not align with current clinical guidelines or practice. We have received interested-party feedback expressing concern that this activity is out-of-date, and that IA_BMH_6 substantially overlaps with IA_BMH_7 (Implementation of Integrated Patient Centered Behavioral Health Model). IA_BMH_7 better aligns with evidence supporting improved patient outcomes.[1] Furthermore, IA_BMH_6 focuses on co-location of mental health and substance use disorder services in primary and/or non-primary clinical care settings, which has not been found to consistently improve patient outcomes.[2] In the current rulemaking cycle, we are proposing two new activities in the Behavioral and Mental Health subcategory. We note that the removal of IA_BMH_6 is being proposed in order to ensure that the improvement activities Inventory best reflects current clinical practice, and in no way reflects a de-emphasis of the ongoing priority CMS is placing on behavioral and mental health in general, and on substance use disorder in particular.
Current Improvement Activity	
Current Activity ID:	**IA_BMH_13**
Current Subcategory:	Behavioral and Mental Health
Current Activity Title:	Obtain or Renew an Approved Waiver for Provision of Buprenorphine as Medication-Assisted Treatment for Opioid Use Disorder
Current Activity Description:	Complete any required training and obtain or renew an approved waiver for provision of medication-assisted treatment of opioid use disorders using buprenorphine. Note: This activity may be selected once for low-capacity waivers, as these do not expire, and once every 3 years for the expanded waiver, in keeping with renewal requirements.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under removal factor three, activity does not align with current clinical guidelines or practice. In late December 2022, the end of the "X-waiver" was announced, so doctors/nurse practitioners no longer need to complete training and obtain a waiver from the Drug Enforcement Administration (DEA) to be able to prescribe buprenorphine (medication-assisted treatment; MAT). Section 1262 of the Consolidated Appropriations Act of 2023 (also referred to as the "Omnibus Bill") was passed in December 2022.[3] We note that the removal of IA_BMH_13 is being proposed in order to ensure that the improvement activities Inventory best reflects current clinical practice, and in no way reflects a de-emphasis of the ongoing priority CMS is placing on behavioral and mental health in general, and on substance use disorder in particular. This removal is necessary as the X-waiver is no longer a requirement of MAT prescribing.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_29**

Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Consulting Appropriate Use Criteria (AUC) Using Clinical Decision Support when Ordering Advanced Diagnostic Imaging
Current Activity Description:	Clinicians attest that they are consulting specified applicable AUC through a qualified clinical decision support mechanism for all applicable imaging services furnished in an applicable setting, paid for under an applicable payment system, and ordered on or after January 1, 2018. This activity is for clinicians that are early adopters of the Medicare AUC program (2018 performance year) and for clinicians that begin the Medicare AUC program in future years as specified in our regulation at §414.94. The AUC program is required under section 218 of the Protecting Access to Medicare Act of 2014. Qualified mechanisms will be able to provide a report to the ordering clinician that can be used to assess patterns of image-ordering and improve upon those patterns to ensure that patients are receiving the most appropriate imaging for their individual condition.
Current Weighting:	High
Removal Rationale:	We propose to remove this activity under removal factor seven, improvement activity is "obsolete." The AUC CDS program has ended, so it will no longer be possible to attest to this activity.

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APPENDIX 3: MVP INVENTORY

MVP Development: Background

In the CY 2021 PFS final rule (85 FR 84849 through 84854), the CY 2022 PFS final rule (86 FR 65998 through 66031), and the CY 2023 PFS final rule (87 FR 70210 through 70211) we finalized a set of criteria to use in the development of MVPs, including MVP reporting requirements, MVP maintenance, and the selection of measures and activities within an MVP.

This appendix contains two groups of proposed MVP tables: Group A: proposed new MVPs and Group B: proposed modifications to previously finalized MVPs. Group A includes five new proposed MVPs. Group B includes 12 previously finalized MVPs with proposed modifications.

Each MVP includes measures and activities from the quality performance category, improvement activities performance category, and the cost performance category that are relevant to the clinical theme of the MVP. In addition, each MVP includes a foundational layer that is comprised of population health measures and Promoting Interoperability performance category measures.

MVP Development: Performance Category Sources

The MVP tables below contain a set of MIPS quality measures, QCDR measures (as applicable), improvement activities, cost measures, and foundational measures based on clinical topics. For further reference, the sources of the measures and activities in the MVP tables are as follows:

- Existing MIPS quality measures are located in the 2023 MIPS Quality Measures List on the Quality Payment Program website.[460] In addition, see Appendix 1: MIPS Quality Measures of this proposed rule for proposed modifications to existing quality measures.
- Existing QCDR measures are based on the most recent publication of the 2023 QCDR Measure Specification file, located on the Quality Payment Program website.[461] We plan to modify the list of 2024 QCDR measures around December 2023.
- Improvement activities are located in the 2023 Improvement Activities Inventory, and the 2023 MIPS Data Validation Criteria are located in the Quality Payment Program website.[462] In addition, see Appendix 2: Improvement Activities of this proposed rule for any proposed removals, additions, or modifications to existing improvement activities.
- Existing cost measures are located in the 2023 Cost Measures Inventory.[463] In addition, see section IV.A.4.f.(2) of this proposed rule for proposals regarding the cost performance category.
- For further details on the population health measures (attributed to the Quality Performance Category) included in the foundational layer, see the CY 2022 PFS final rule (86 FR 65408 through 65409).
- Existing Promoting Interoperability measures adopted in prior rulemaking and included in the foundational layer are located on the Quality Payment Program website.[464] In addition, see section IV.A.4.f.(4) of this proposed rule for proposals regarding the existing Promoting Interoperability performance category measures.

MVP Development: Global Inclusion of a Quality Measure and an Improvement Activity

- Consistent with the priority to advance health equity throughout various CMS programs, including the Quality Payment Program, we are proposing to include Q487: Screening for Social Drivers of Health in both new and previously finalized MVPs. Health equity supports health for all the people served by our programs by designing, implementing, and operationalizing policies and programs that eliminate avoidable differences in health outcomes experienced by people who are disadvantaged or underserved and providing the care and support that beneficiaries need to thrive (*https://www.cms.gov/pillar/health-equity*). The measure supports the process of collecting drivers of health (DOH) data, which is a foundational step towards defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians who choose to submit this measure though it is not required. For further details regarding the basis on which CMS determined Q487: Screening for Social Drivers of Health is appropriate to measure clinician performance as well as how it does so, see 87 FR 69872 through 69784.
- We are proposing to add a newly proposed improvement activity, IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways, a high weighted activity, to each of the new and previously finalized MVPs. This activity would expand the opportunity for quality improvement (QI) activities across and among practices, ultimately leading to improvements in quality of care and fostering a culture of participation by all staff. In addition, we believe this activity would incentivize voluntary MVP adoption, which is important to the transformation of clinical practice by encouraging practice to participate payment options such as MVPs and APMs that measure performance in ways that are more relevant practice members. See Appendix 2, Improvement Activities: Table A of this proposed rule for detailed information regarding the proposed IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways activity.

MVP Table Symbol Information and Definitions

Please note the following symbols and definitions used within the MVP tables in the Group A and Group B tables below:

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[460] See the 2023 MIPS Quality Measures List: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2217/2023%20MIPS%20Quality%20Measures%20List.xlsx.*

[461] See *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2174/2023_QCDR_Measure_Specifications.xlsx* for QCDR measures.

[462] See the 2023 Improvement Activities Inventory: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2237/2023%20Improvement%20Activities%20Inventory.zip* and 2023 MIPS Data Validation Criteria: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2313/2023%20MIPS%20Data%20Validation%20Criteria.zip* for improvement activity details.

[463] See the 2023 Cost Measures Inventory: *https://qpp.cms.gov/mips/explore-measures?tab=costMeasures&py=2023.*

[464] See the 2023 Promoting Interoperability Measure Specifications: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2223/2023%20MIPS%20Promoting%20Interoperability%20Measure%20Specifications.zip* for Promoting Interoperability measure details.

● New quality measures, improvement activities, and cost measures proposed for inclusion in MIPS beginning with the CY 2024 performance period/2026 MIPS payment year and future years are identified with a caret symbol (^). See Appendix 1, MIPS Quality Measures: Table Group A of this proposed rule for further information regarding new MIPS measures. See Appendix 2, Improvement Activities: Table A of this proposed rule for further information regarding new improvement activities. See section IV.A.4.f.(2) of this proposed rule for further information regarding new cost measures.

● Quality measures, improvement activities, and cost measures that we are proposing to add to a previously finalized MVP are identified with a plus sign (+) within the Group B MVP tables in this appendix.

● Existing quality measures and improvement activities with proposed revisions are identified with an asterisk (*).

● Quality measures identified with a double asterisk (**) are individual measures duplicating a component of the TBD: Preventive Care and Wellness (composite) measure. The quality measures that include the (**) can only be submitted when included in an MVP. Please see Appendix 1: MIPS Quality Measures Table A.6 of this proposed rule for any additional information regarding the Preventive Care and Wellness (composite) measure.

● Quality measures that are considered high priority (as defined in § 414.1305) are illustrated with an exclamation point (!) and outcome measures (as defined in § 414.1305) are illustrated with a double exclamation point (!!). Further details of these types of measures are located in the CMS Measures Management System Hub.[465]

● QCDR measures proposed in the MVP tables below that are illustrated with a pound sign (#) indicate that testing data is still pending and due on or before September 1, 2023. We refer readers to the CY 2022 PFS final rule for additional details regarding requirements for QCDR measures considered for an MVP (86 FR 65407 through 65408).

● Improvement activities that include a health equity component are illustrated with a tilde (~) within the MVP table.

● IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation is illustrated with a percent (%) to indicate that attestation to this improvement activity provides full credit for the improvement activity performance category within an MVP.

In addition, quality measure collection types are identified in parentheses after each quality measure title within each MVP table and improvement activity medium/high weight designations are identified in parentheses after each improvement activity.

Group A: New MVPs Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

A.1 Focusing on Women's Health MVP

The proposed Focusing on Women's Health MVP focuses on the clinical theme of providing treatment and management of women's health. This MVP would be most applicable to clinicians who treat patients within the practice of gynecology, obstetrics, and urogynecology, including nonphysician practitioners (NPPs) such as certified nurse-midwives, nurse practitioners, and physician assistants.

Quality Measures

We propose to include 18 MIPS quality measures and one QCDR measure within the quality performance category of this MVP, which are specific to the clinical topic of women's health by assessing three critical areas of care: obstetrics, preventive women's health, and urogynecology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in women's health:

- Q048: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older: This MIPS quality measure ensures annual assessment for the presence or absence of urinary incontinence for women.
- Q112: Breast Cancer Screening: This MIPS quality measure ensures women have a mammogram to screen for breast cancer in accordance with clinical guidelines.
    - Q309: Cervical Cancer Screening: This MIPS quality measure assesses for the performance of cervical cancer screening in women in accordance with clinical guidelines.
    - Q310: Chlamydia Screening for Women: This MIPS quality measure identifies women that are sexually active to ensure that they have had at least one test for chlamydia.
    - Q335: Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse): This inverse MIPS quality measure identifies patients who have delivered a live singleton at < 39 weeks of gestation and assesses for elective deliveries (without medical indication) by cesarean birth or induction of labor.
    - Q336: Maternity Care: Postpartum Follow-up and Care Coordination: This MIPS quality measure ensures the following postpartum care is completed: 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 assurance immunization are reviewed and updated.
    - Q400: One-Time Screening for Hepatitis C Virus (HCV) for all Patients: This MIPS quality measure currently requires that patients have received a one-time screening for hepatitis C virus (HCV) infection. However, this measure has proposed substantive changes that would require treatment initiation or referral within a set timeframe in addition to screening. Please reference Appendix 1: MIPS Quality Measures: Table D.45 for further information.
    - Q422: Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury: This MIPS quality measure evaluates patients that undergo cystoscopy at the time of hysterectomy for pelvic organ prolapse to evaluate for lower urinary tract injury.
    - Q432: Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair: This MIPS quality measure evaluates for injury, during or within 30 days, to the bladder after surgery for patients that undergoing pelvic organ prolapse repair.
    - Q448: Appropriate Workup Prior to Endometrial Ablation: This MIPS quality measure ensures endometrial sampling or hysteroscopy with biopsy with results documented prior to an endometrial ablation.
    - Q472: Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Facto Profile for Osteoporotic Fracture: This MIPS quality measure ensures women receive an order for a dual-energy x-ray absorptiometry (DXA) scan if they exhibit select risk factors for osteoporotic fracture.
    - Q475: HIV Screening: This MIPS quality measure ensures patients receive a one-time test for HIV.
    - TBD: CVD Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument: This proposed MIPS quality measure evaluates pregnant or postpartum patients for a completed cardiovascular disease (CVD) risk assessment utilizing a standard instrument.
    - UREQA8: Vitamin D level: Effective Control of Low Bone Mass/Osteopenia and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level Achieved: This MIPS quality measure ensures patients diagnosed with osteopenia or osteoporosis achieve a serum 25 Hydroxy-Vitamin D result greater than or equal to 30.0 ng/dL.

In addition, we are proposing to include the following broadly applicable MIPS quality measures that are relevant to clinicians that specialize in women's health. The quality measures below assess for age-specific screenings, and follow-up actions for select measures, in addition to recommended vaccinations:

- Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan: This MIPS quality measure ensures all patients are screened for depression with a follow-up plan documented for those patients who screen positive.
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure screens patients for tobacco use. Any patients that are found to be tobacco users should receive tobacco cessation intervention.
- Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: This MIPS quality measure screens patients, aged 18 years and older, for unhealthy alcohol use using a systematic screening method at least once within the last 12 months. If the patient is screened positive for unhealthy alcohol use, then they should receive brief counseling.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
- Q493: Adult Immunization Status: This MIPS quality measure ensures that adults are up-to-date with the recommended routine vaccines: influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.

Improvement Activities

We reviewed the improvement activity inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We propose to include 14 improvement activities that reflect actions and processes undertaken by clinicians who specialize in women's health, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients being seen for women's health care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_1: Enhance Engagement of Medicaid and Other Underserved Populations
- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_16: Promote Self-management in Usual Care
- IA_BMH_11: Implementation of a Trauma-Informed Care (TIC) Approach to Clinical Practice
- IA_BMH_XX: Behavioral/Mental Health and Substance Use Screening and Referral for Pregnant and Postpartum Women
- IA_CC_9: Implementation of practices/processes for developing regular individual care plans
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_6: Use of toolsets or other resources to close healthcare disparities across communities
- IA_PM_XX: Use of Decision Support to Improve Adherence to Cervical Cancer Screening and Management Guidelines

Cost Measures

We propose to include two MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of women's health. We reviewed the MIPS cost measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in women's health and align with other measures and activities within this MVP:

- Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care in inpatient hospitals, including those providing obstetric and gynecological care.
- Total Per Capita Cost (TPCC): This MIPS cost measure captures the overall costs of care after establishing a primary care-type relationship. Obstetricians and gynecologists are included in attribution for the TPCC measure.

Currently, there are no applicable episode-based cost measures available but one could be considered for development in the future.

TABLE A.1: Focusing on Women's Health MVP

As stated in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the proposed Focusing on Women's Health MVP. We request comment on the measures and activities included in this MVP.

Symbol Key:
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Double asterisk (**): quality measures that are proposed for submission only when included in an MVP
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures proposed in this MVP table pending testing data

Quality	Improvement Activities	Cost
(*) Q048: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQMs Specifications) **(*)(**) Q112:** Breast Cancer Screening (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!) Q309:** Cervical Cancer Screening (Collection Type: eCQM Specifications) **(*) Q310:** Chlamydia Screening for Women (Collection Type: eCQM Specifications) **(!!) Q335:** Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse) (Collection Type: MIPS CQMs Specifications) **(!) Q336:** Maternity Care: Postpartum Follow-up and Care Coordination (Collection Type: MIPS CQMs Specifications) **(*) Q400:** One-Time Screening for Hepatitis C Virus (HCV) for all Patients (Collection Type: MIPS CQMs Specifications) **Q422:** Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury	**(~) IA_AHE_1:** Enhance Engagement of Medicaid and Other Underserved Populations (High) **(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_BMH_11:** Implementation of a Trauma-Informed Care (TIC) Approach to Clinical Practice (Medium) **(^) IA_BMH_XX:** Behavioral/Mental Health and Substance Use Screening and Referral for Pregnant and Postpartum Women (High) **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **(~) IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(^)(%) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation	**Medicare Spending Per Beneficiary (MSPB) Clinician** **Total Per Capita Cost (TPCC)**

(Collection Type: MIPS CQMs Specifications, Medicare Part B Claims Measure Specifications) **(*)(!) Q431:** Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling (Collection Type: MIPS CQMs Specifications) **(!!) Q432:** Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair (Collection Type: MIPS CQMs Specifications) **(*)(!) Q448:** Appropriate Workup Prior to Endometrial Ablation (Collection Type: MIPS CQMs Specifications) **(!) Q472:** Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture (Collection Type: eCQM Specifications) **(*) Q475:** HIV Screening (Collection Type: eCQM Specifications) **(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(*)Q493:** Adult Immunization Status (Collection Type: MIPS CQMs Specifications) **(^) TBD:** CVD Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument (Collection Type: MIPS CQMs Specifications) **(#)(!!) UREQA8:** Vitamin D level: Effective Control of Low Bone Mass/Osteopenia and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level Achieved (Collection Type: QCDR)	**(~) IA_PM_6:** Use of toolsets or other resources to close healthcare disparities across communities (Medium) **(^) IA_PM_XX:** Use of Decision Support to Improve Adherence to Cervical Cancer Screening and Management Guidelines (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis IIigh Priority Practices Safety Assurance Factors for EIIR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA)

	Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

A.2 Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP

The proposed Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP focuses on the clinical theme of providing care for patients experiencing some of the most common otolaryngology conditions such as, but not limited to: otologic conditions, chronic rhinosinusitis (CRS), age-related hearing loss (ARHL) and otitis media. This proposed MVP would be most applicable to clinicians who treat patients within the practice of otolaryngology, including NPPs such as audiologists, nurse practitioners, and physician assistants.

Quality Measures

We propose to include eight MIPS quality measures and four QCDR measures within the quality performance category of this MVP, which promote the management and care associated with otolaryngology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in treating patients with otolaryngology conditions:

- Q277: Sleep Apnea: Severity Assessment at Initial Diagnosis: This MIPS quality measure ensures adults diagnosed with obstructive sleep apnea have an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.
- Q331: Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse): This overuse MIPS quality measure assesses for prescribed antibiotics within 10 days after the onset of symptoms for those patients diagnosed with acute viral sinusitis.
- Q332: Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use): This appropriate use MIPS quality measure ensures patients diagnosed with acute bacterial sinusitis are prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.
- Q355: Unplanned Reoperation within the 30 Day Postoperative Period: This MIPS quality measure evaluates for an unplanned reoperation within 30 days of a denominator eligible procedure.
- Q357: Surgical Site Infection (SSI): This MIPS quality measure evaluates for SSI within 30 days of a denominator eligible procedure.
- AAO16: Age-Related Hearing Loss: Comprehensive Audiometric Evaluation: This MIPS quality measure ensures patients aged 60 years and older who have failed a hearing screening and/or who report suspected hearing loss receive, are ordered, or referred for comprehensive audiometric evaluation.
- AAO20: Tympanostomy Tubes: Comprehensive Audiometric Evaluation: This MIPS quality measure ensures pediatric patients diagnosed with otitis media with effusion (OME) receive tympanostomy tube insertion and a comprehensive audiometric evaluation within 6 months prior to tympanostomy tube insertion.
- AAO21: Otitis Media with Effusion (OME): Comprehensive Audiometric Evaluation for Chronic OME > or = 3 months: This MIPS quality measure ensures pediatric patients diagnosed with otitis media with effusion (OME) including chronic serous, mucoid, or nonsuppurative OME of > or = 3 months duration receive an order or referral for comprehensive audiometric evaluation.
- AAO23: Allergic Rhinitis: Intranasal Corticosteroids or Oral Antihistamines: This MIPS quality measure ensures patients 2 years and older with a diagnosis of allergic rhinitis are prescribed or recommended intranasal corticosteroids (INS) or non-sedating oral antihistamines.

In addition, we are proposing to include the following broadly applicable MIPS quality measures that are relevant to otolaryngology. The quality measures below assess for age specific screenings, and follow-up actions for select measures:

- Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: This MIPS quality measure assesses patients, aged 18 years and older, for a BMI documented with a follow-up plan documented if their most recent documented BMI was outside of normal parameters.
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure screens patients for tobacco use. Any patients that are found to be tobacco users should receive tobacco cessation intervention.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

Improvement Activities

We reviewed the improvement activity inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We propose to include 11 improvement activities that reflect actions and processes undertaken by clinicians who specialize in treating patients with otolaryngology conditions, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes

and improve quality of care patients with otolaryngology conditions. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_5: MIPS Eligible Clinician Leadership in Clinical Trials or CBPR
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_15: Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
- IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop
- IA_CC_13: Practice Improvements to Align with OpenNotes Principles
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_16: Implementation of medication management practice improvements
- IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements

Cost Measures

We propose to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of otolaryngology. We reviewed the MIPS cost measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the cost measure to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in otolaryngology care and aligns with the other measures and activities within this MVP:

- Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care in inpatient hospitals, including otolaryngologic care. This aligns with the surgical measures within this MVP, including Q355: Unplanned Reoperation within the 30 Day Postoperative Period and Q357: Surgical Site Infection (SSI).

Currently, there are no applicable episode-based cost measures available, but one could be considered for development in the future.

TABLE A.2: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP

As stated in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the proposed Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP. We request comment on the measures and activities included in this MVP.

Symbol Key:
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Double asterisk (**): quality measures that are proposed for submission only when included in an MVP
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures proposed in this MVP table pending testing data

Quality	Improvement Activities	Cost
(**) **Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (*) **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **Q277:** Sleep Apnea: Severity Assessment at Initial Diagnosis (Collection Type: MIPS CQMs Specifications)	(~) **IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) (~) **IA_AHE_5:** MIPS Eligible Clinician Leadership in Clinical Trials or CBPR (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**

(*)(!) Q331: Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQMs Specifications) **(!) Q332:** Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use) (Collection Type: MIPS CQMs Specifications) **(!!) Q355:** Unplanned Reoperation within the 30 Day Postoperative Period (Collection Type: MIPS CQMs Specifications) **(!!) Q357:** Surgical Site Infection (SSI) (Collection Type: MIPS CQMs Specifications) **(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(#)(!) AAO16:** Age-Related Hearing Loss: Comprehensive Audiometric Evaluation (Collection Type: QCDR) **(#) AAO20:** Tympanostomy Tubes: Comprehensive Audiometric Evaluation (Collection Type: QCDR) **(#) AAO21:** Otitis Media with Effusion (OME): Comprehensive Audiometric Evaluation for Chronic OME > or = 3 months (Collection Type: QCDR) **(#) AAO23:** Allergic Rhinitis: Intranasal Corticosteroids or Oral Antihistamines (Collection Type: QCDR)	**IA_CC_1:** Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop (Medium) **IA_CC_13:** Practice Improvements to Align with OpenNotes Principles (Medium) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(^)(%) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_16:** Implementation of medication management practice improvements (Medium) **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional)

	Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

A.3 Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP

The proposed Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP focuses on the clinical theme of promoting quality care for patients suffering from infectious disorders. This proposed MVP would be most applicable to clinicians who treat patients within the practices of infectious disease and immunology, including NPPs such as nurse practitioners and physician assistants.

Quality Measures

We propose to include 14 MIPS quality measures within the quality performance category of this MVP, which focus on a variety of infectious disease conditions that may impact patient health. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine which quality measures to include in this MVP.

The following quality measures would provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in the prevention and treatment of infectious disorders within their patient population:

- Q205: HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis: This MIPS quality measure ensures patients aged 13 years and older with a diagnosis of HIV/AIDS are screened for chlamydia, gonorrhea, and syphilis at least once since the diagnosis of HIV infection.
- Q310: Chlamydia Screening for Women: This MIPS quality measure identifies women that are sexually active to ensure that they have had at least one test for chlamydia.
- Q338: HIV Viral Load Suppression: This MIPS quality measure ensures all patients with a diagnosis of HIV annually achieve a HIV viral load less than 200 copies/mL at last HIV viral load test.
- Q340: HIV Medical Visit Frequency: This MIPS quality measure ensures all patients with a diagnosis of HIV had at least one medical visit in each 6 month period within a 24 month measurement period.
- Q387: Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users: This MIPS quality measure ensures all patients that are identified as active injection drug users receive screening for HCV each year.
- Q400: One-Time Screening for Hepatitis C Virus (HCV) for all Patients: This MIPS quality measure currently requires that patients have received a one-time screening for hepatitis C virus (HCV) infection. However, this measure has proposed substantive changes that would require treatment initiation or referral within a set timeframe in addition to screening. Please reference Appendix 1: MIPS Quality Measures: Table D.45 for further information.
- Q401: Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis: This MIPS quality measure ensures adult patients with a diagnosis of chronic hepatitis C cirrhosis receive imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once each year.
- Q475: HIV Screening: This MIPS quality measure ensures patients receive a one-time test for HIV.

In addition, we are proposing to include the following broadly applicable MIPS quality measures that are relevant to infectious disorders. The quality measures below encourage antimicrobial stewardship, medication reconciliation, appropriate immunization receipt and preventive screenings:

- Q065: Appropriate Treatment for Upper Respiratory Infection (URI): This appropriate use MIPS quality measure evaluates that patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) did not receive an antibiotic order.
- Q130: Documentation of Current Medications in the Medical Record: This MIPS quality measure This MIPS quality measure bases performance on clinicians documenting the list of current medications using all immediate resources for capture of this important clinical topic.
- Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan: This MIPS quality measure ensures all patients are screened for depression with a follow-up plan documented for those patients who screen positive.
- Q240: Childhood Immunization Status: This MIPS quality measure ensures children 2 years of age receive 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.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
- Q493: Adult Immunization Status: This MIPS quality measure ensures that adults are up-to-date with the recommended routine vaccines: influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.

Improvement Activities

We reviewed the improvement activity inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We propose to include 14 improvement activities that reflect actions and processes undertaken by clinicians who provide prevention and treatment for infectious disorders to patients, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients needing infectious disorder care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_1: Enhance Engagement of Medicaid and Other Underserved Populations
- IA_AHE_5: MIPS Eligible Clinician Leadership in Clinical Trials or CBPR
- IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_15: Engagement of patients, family and caregivers in developing a plan of care
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_6: Use of Toolsets or Other Resources to Close Health and Health Care Inequities Across Communities
- IA_PM_11: Regular review practices in place on targeted patient population needs
- IA_PM_14: Implementation of methodologies for improvements in longitudinal care management for high risk patients
- IA_PM_XX: Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services
- IA_PSPA_23: Completion of CDC Training on Antibiotic Stewardship
- IA_PSPA_32: Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support

Cost Measures

We propose to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of infectious disorders. We reviewed the MIPS cost measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the cost measure to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in treating infectious disorders and aligns with the other measures and activities within this MVP:

- Total Per Capita Cost (TPCC): This MIPS cost measure captures the overall costs of care after establishing a primary care-type relationship. Infectious Disease specialists are included in attribution for the TPCC measure.

Currently, there are no applicable episode-based cost measures applicable to the clinical topics assessed within other components of this MVP, but one could be considered for development in the future.

TABLE A.3: Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP

As stated in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the proposed Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP. We request comment on the measures and activities included in this MVP.

Symbol Key:
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(*) Q065: Appropriate Treatment for Upper Respiratory Infection (URI) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications)	**(~) IA_AHE_1:** Enhance Engagement of Medicaid and Other Underserved Populations (High) **(~) IA_AHE_5:** MIPS Eligible Clinician Leadership in Clinical Trials or CBPR (Medium) **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High)	**Total Per Capita Cost (TPCC)**

(*) Q205: HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis (Collection Type: MIPS CQMs Specifications) **(*) Q240:** Childhood Immunization Status (Collection Type: eCQM Specifications) **(*) Q310:** Chlamydia Screening for Women (Collection Type: eCQM Specifications) **(*)(!!) Q338:** HIV Viral Load Suppression (Collection Type: MIPS CQMs Specifications) **(!) Q340:** HIV Medical Visit Frequency (Collection Type: MIPS CQMs Specifications) **Q387:** Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users (Collection Type: MIPS CQMs Specifications) **(*) Q400:** One-Time Screening for Hepatitis C Virus (HCV) for all Patients (Collection Type: MIPS CQMs Specifications) **Q401:** Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis (Collection Type: MIPS CQMs Specifications) **(*) Q475:** HIV Screening (Collection Type: eCQM Specifications) **(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(*)Q493:** Adult Immunization Status (Collection Type: MIPS CQMs Specifications)	**IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(^)(%) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_6:** Use of Toolsets or Other Resources to Close Health and Health Care Inequities Across Communities (Medium) **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **(~) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients (Medium) **(^) IA_PM_XX:** Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services (Medium) **IA_PSPA_23:** Completion of CDC Training on Antibiotic Stewardship (High) **IA_PSPA_32:** Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support (High)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA)

	Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

A.4 Quality Care in Mental Health and Substance Use Disorders MVP

The proposed Quality Care in Mental Health and Substance Use Disorders MVP focuses on the clinical theme of promoting prevention of and quality care in behavioral health, including mental health and substance use disorders (SUD). This proposed MVP would be most applicable to clinicians who treat patients with mental health and substance use disorders within the practices of mental/behavioral health and psychiatry, including NPPs such as clinical social workers, nurse practitioners, and physician assistants.

Quality Measures

We propose to include 12 MIPS quality measures and 3 QCDR measures within the quality performance category of this MVP, which focus on a variety of behavioral health, including mental health and SUDs that may impact patient health. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP would provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in treating patients with behavioral health, including mental health and SUDs:

- Q009: Anti-Depressant Medication Management: This MIPS quality measure ensures adult patients diagnosed with major depression treated with antidepressant medication remained on an antidepressant medication treatment. There are two performance rates for this measure that evaluate compliance for at least 84 days or 180 days.
- Q305: Initiation and Engagement of Substance Use Disorder Treatment: This MIPS quality measure ensures patients 13 years of age and older with a new SUD episode have the initiation of intervention or medication within 14 days of the new SUD episode or engage in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication within 34 days of the initiation.
- Q366: Follow-Up Care for Children Prescribed ADHD Medication (ADD): This MIPS quality measure ensures children 6-12 years of age with a newly prescribed a medication for attention-deficit/hyperactivity disorder (ADHD) receive appropriate follow-up care.
- Q370: Depression Remission at Twelve Months: This MIPS quality measure assesses adolescent and adult patients diagnosed with major depression or dysthymia for achieved remission in 12 months (+/- 60 days).
- Q382: Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment: This MIPS quality measure ensures pediatric patients with a diagnosis of major depressive disorder (MDD) receive an assessment for suicide risk.
- Q383: Adherence to Antipsychotic Medications For Individuals with Schizophrenia: This MIPS quality measure assesses an adult patient diagnosed with schizophrenia or schizoaffective disorder prescribed an antipsychotic medication had a Proportion of Days Covered (PDC) of at least 0.8 for their antipsychotic medications.
- Q468: Continuity of Pharmacotherapy for Opioid Use Disorder (OUD): This MIPS quality measure assesses for the continuous treatment (180 days) of pharmacotherapy treatment for adult patients diagnosed with opioid use disorder.
- TBD: Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder: This proposed MIPS quality measure assesses patients diagnosed with mental and/or substance use disorder for maintenance or improvement in functioning at 30 to 180 days after index assessment.
- TBD: Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk: This proposed MIPS quality measure ensures adult patients with suicidal ideation, behavior symptoms or increased suicide risk have a suicide safety plan initiated, reviewed, and/or updated in collaboration between the patient and their clinician.
- TBD: Reduction in Suicidal Ideation or Behavior Symptoms: This proposed MIPS quality measure assesses patients diagnosed with mental and/or substance use disorder with suicidal thoughts, behaviors, or risk symptoms for a reduction in suicidal ideation and/or behavior symptoms within 120 days of index assessment of the Columbia-Suicide Severity Rating Scale (C-SSRS).
- MBHR2: Anxiety Response at 6-months: This MIPS quality measure ensures adult patients with an anxiety disorder demonstrate a response to treatment at 6-months (+/- 60 days).
- MBHR7: Posttraumatic Stress Disorder (PTSD) Outcome Assessment for Adults and Children: This MIPS quality measure ensures patients with a history of a traumatic event and report symptoms consistent with PTSD for at least one month following the traumatic event have a symptom improvement based on a standardized symptom monitor in response to treatment in at least six months.
- MBHR15: Consideration of Cultural-Linguistic and Demographic Factors in Cognitive Assessment: This MIPS quality measure ensures patients are referred for evaluation due to concerns for cognitive changes or difficulties receive a standardized valid assessment of cognition with results documented, including documentation of provider's consideration of relevant cultural-linguistic and demographic factors that may have affected assessment and resulting assessment.

In addition, we are proposing to include the following broadly applicable MIPS quality measures that are relevant to behavioral health, including mental health and SUDs. The quality measures below address preventive screenings, which support the capture of the patient's voice and safety for patients that are experiencing behavioral health, including mental health and SUD disorders:

- Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan: This MIPS quality measure ensures all patients are screened for depression with a follow-up plan documented for patients who screen positive.

- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

Improvement Activities

We reviewed the improvement activity inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We propose to include 18 improvement activities that reflect actions and processes undertaken by clinicians who provide neurological care to patients, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients needing neurological care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_1: Enhance Engagement of Medicaid and Other Underserved Populations
- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_5: MIPS Eligible Clinician Leadership in Clinical Trials or CBPR
- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health
- IA_BE_12: Use evidence-based decision aids to support shared decision-making.
- IA_BE_16: Promote Self-management in Usual Care
- IA_BE_23: Integration of patient coaching practices between visits
- IA_BMH_2: Tobacco use
- IA_BMH_5: MDD prevention and treatment interventions
- IA_BMH_7: Implementation of Integrated Patient Centered Behavioral Health Model
- IA_BMH_XX: Behavioral/mental health and substance use screening & referral for pregnant and postpartum women
- IA_BMH_XX: Behavioral/mental health and substance use screening & referral for older adults
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_6: Use of toolsets or other resources to close healthcare disparities across communities
- IA_PSPA_32: Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support

Cost Measures

We propose to include three MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic behavioral health, including mental health and SUDs. We reviewed the MIPS cost measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in mental health and SUDs and align with the other measures and activities within this MVP:

- Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care in inpatient hospitals, including hospitalizations for mental health conditions and SUDs.
- Depression: This episode-based cost measures evaluates a clinician's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat depression. While interested parties expressed concerns with the inclusion of this measure within this MVP during the 2024 MVP candidate feedback period, this measure is appropriate for use in MIPS for the reasons described in section IV.A.4.f.(2) of this proposed rule.
- Psychoses and Related Conditions: This episode-based cost measure evaluates a clinician's risk-adjusted cost to Medicare for patients who receive inpatient treatment for psychoses or related conditions during the performance period. This acute inpatient medical condition measure includes costs of services that are clinically related to the attributed clinician's role in managing care during each episode, from the clinical event that opens, or "triggers," the episode through 45 days after the trigger. While interested parties expressed concerns with the inclusion of this measure within this MVP during the 2024 MVP candidate feedback period, this measure is appropriate for use in MIPS for the reasons described in section IV.A.4.f.(2) of this proposed rule.

TABLE A.4: Quality Care in Mental Health and Substance Use Disorders MVP

As stated in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the Quality Care in Mental Health and Substance Use Disorders MVP. We request comment on the measures and activities included in this MVP.

Symbol Key:
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Double asterisk (**): quality measures that are proposed for submission only when included in an MVP
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures

Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures proposed in this MVP table pending testing data

Quality	Improvement Activities	Cost
Q009: Anti-Depressant Medication Management (Collection Type: eCQM Specifications) (*) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (!) **Q305:** Initiation and Engagement of Substance Use Disorder Treatment (Collection Type: eCQM Specifications) (*) **Q366:** Follow-Up Care for Children Prescribed ADHD Medication (ADD) (Collection Type: eCQM Specifications) (*)(!!) **Q370:** Depression Remission at Twelve Months (Collection Type: eCQM Specifications, MIPS CQMs Specifications) (*)(!) **Q382:** Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment (Collection Type: eCQM Specifications) (*)(!!) **Q383:** Adherence to Antipsychotic Medications For Individuals with Schizophrenia (Collection Type: MIPS CQMs Specifications) (!) **Q468:** Continuity of Pharmacotherapy for Opioid Use Disorder (OUD) (Collection Type: MIPS CQMs Specifications) (*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) (^)(!!) **TBD:** Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder (Collection Type: MIPS CQMs Specifications) (^) **TBD:** Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk (Collection Type: MIPS CQMs Specifications) (^)(!!) **TBD:** Reduction in Suicidal Ideation or Behavior Symptoms (Collection Type: MIPS CQMs Specifications) (#)(!!) **MBHR2:** Anxiety Response at 6-months (Collection Type: QCDR)	(~) **IA_AHE_1:** Enhance Engagement of Medicaid and Other Underserved Populations (High) (~) **IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) (~) **IA_AHE_5:** MIPS Eligible Clinician Leadership in Clinical Trials or CBPR (Medium) (~) **IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) (~) **IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_12:** Use evidence-based decision aids to support shared decision-making. (Medium) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_BE_23:** Integration of patient coaching practices between visits (Medium) **IA_BMH_2:** Tobacco use (Medium) **IA_BMH_5:** MDD prevention and treatment interventions (Medium) (~) **IA_BMH_7:** Implementation of Integrated Patient Centered Behavioral Health Model (High) (^) **IA_BMH_XX:** Behavioral/mental health and substance use screening & referral for pregnant and postpartum women (High) (^) **IA_BMH_XX:** Behavioral/mental health and substance use screening & referral for older adults (High) (~) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium) (^)(%) **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High)	**Medicare Spending Per Beneficiary (MSPB) Clinician** (^) **Depression** (^) **Psychoses and Related Conditions**

(#)(!!) **MBHR7:** Posttraumatic Stress Disorder (PTSD) Outcome Assessment for Adults and Children (Collection Type: QCDR) (#)(!) **MBHR15:** Consideration of Cultural-Linguistic and Demographic Factors in Cognitive Assessment (Collection Type: QCDR)	(%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation (~) **IA_PM_6:** Use of toolsets or other resources to close healthcare disparities across communities (Medium) **IA_PSPA_32:** Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support (High)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) (!!) **Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation	

A.5 Rehabilitative Support for Musculoskeletal Care MVP

The proposed Rehabilitative Support for Musculoskeletal Care MVP focuses on the clinical theme of promoting quality care for patients. This proposed MVP would be most applicable to clinicians and NPPs who specialize in providing rehabilitative support for musculoskeletal care such as chiropractic, physiatry, physical therapy and occupational therapy, as well as nurse practitioners and physician assistants.

Quality Measures

We propose to include 10 MIPS quality measures within the quality performance category of this MVP, which promote rehabilitative support for patients. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in providing rehabilitative support for musculoskeletal care:

- Q217: Functional Status Change for Patients with Knee Impairments: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the knee. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM

for reporting of this quality measure.

- Q218: Functional Status Change for Patients with Hip Impairments: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the hip. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure.
- Q219: Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the lower leg, foot or ankle. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure.
- Q220: Functional Status Change for Patients with Low Back Impairments: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the low back. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure.
- Q221: Functional Status Change for Patients with Shoulder Impairments: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the shoulder. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure.
- Q222: Functional Status Change for Patients with Elbow, Wrist or Hand Impairments: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the elbow, wrist or hand. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure.
- Q478: Functional Status Change: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the neck. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure.

In addition, we are proposing to include the following broadly applicable MIPS quality measures that are relevant to rehabilitative support for musculoskeletal care. The quality measures below address preventive screenings and care plan for falls:

- Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: This MIPS quality measure assesses patients, aged 18 years and older, for a BMI documented with a follow-up plan documented if their most recent documented BMI was outside of normal parameters.
- Q155: Falls: Plan of Care: This MIPS quality measure ensures adult patients, with a history of falls, have a plan of care for falls.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

Improvement Activities

We reviewed the improvement activity inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We propose to include 17 improvement activities that reflect actions and processes undertaken by clinicians who provide rehabilitative support for musculoskeletal care to patients, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients needing rehabilitative support for musculoskeletal care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_6: Provide Education Opportunities for New Clinicians
- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BMH_12: Promoting Clinician Well-Being
- IA_BMH_XX: Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults
- IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop
- IA_CC_8: Implementation of documentation improvements for practice/process improvements
- IA_CC_12: Care coordination agreements that promote improvements in patient tracking across settings
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_EPA_3: Collection and use of patient experience and satisfaction data on access
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways

- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PSPA_16: Use of decision support and standardized treatment protocols
- IA_PSPA_21: Implementation of fall screening and assessment programs

Cost Measures

We propose to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of rehabilitative support for musculoskeletal care. We reviewed the MIPS cost measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the cost measure to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in rehabilitative support for musculoskeletal care and aligns with the other measures and activities included within this MVP:

- Low Back Pain: This episode-based cost measure evaluates a clinician's or clinician group's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat low back pain. This aligns with Q220: Functional Status Change for Patients with Low Back Impairments.

TABLE A.5: Rehabilitative Support for Musculoskeletal Care MVP

As stated in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the proposed Rehabilitative Support for Musculoskeletal Care MVP. We request comment on the measures and activities included in this MVP.

Symbol Key:
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Double asterisk (**): quality measures that are proposed for submission only when included in an MVP
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(**) **Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (!) **Q155:** Falls: Plan of Care (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) (!!) **Q217**: Functional Status Change for Patients with Knee Impairments (Collection Type: MIPS CQMs Specifications) (!!) **Q218:** Functional Status Change for Patients with Hip Impairments (Collection Type: MIPS CQMs Specifications) (!!) **Q219:** Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments (Collection Type: MIPS CQMs Specifications) (!!) **Q220:** Functional Status Change for Patients with Low Back Impairments (Collection Type: MIPS CQMs Specifications) (!!) **Q221:** Functional Status Change for Patients with Shoulder Impairments (Collection Type: MIPS CQMs Specifications) (!!) **Q222:** Functional Status Change for Patients with Elbow, Wrist or Hand Impairments (Collection Type: MIPS CQMs Specifications) (!!) **Q478:** Functional Status Change for Patients with Neck Impairments (Collection Type: MIPS CQMs Specifications) (*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications)	(~) **IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) (~) **IA_AHE_6:** Provide Education Opportunities for New Clinicians (High) (~) **IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) (~) **IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (IIigh) **IA_BMH_12:** Promoting Clinician Well-Being (High) (^) **IA_BMH_XX:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults (High) **IA_CC_1:** Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop (Medium) **IA_CC_8:** Implementation of documentation improvements for practice/process improvements (Medium) **IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings (Medium) (~) **IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) (~) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium) (~) **IA_EPA_3:** Collection and use of patient experience and satisfaction data on access (Medium) (^)(%) **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) (%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PSPA_16:** Use of decision support and standardized treatment protocols (Medium) **IA_PSPA_21:** Implementation of fall screening and assessment programs (Medium)	(^) **Low Back Pain**
Foundational Layer		

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

Group B: Modifications to Previously Finalized MVPs for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

TABLE B.1: Advancing Cancer Care MVP

Table B.1 represents the measures and activities that were finalized within the Advancing Cancer Care MVP in (87 FR 70653 through 70659) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Advancing Cancer Care MVP within the quality performance category of this MVP to include three additional MIPS quality measures and one additional QCDR measure that address appropriate cancer care treatment. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP provide a meaningful and comprehensive assessment of the clinical care for clinicians providing cancer care to patients:

- Q490: Appropriate Intervention of Immune-related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors: This MIPS quality measure identifies patients diagnosed with cancer who are on immune checkpoint inhibitor therapy and develop grade 2 or above diarrhea and/or colitis to assess for appropriate intervention of managing immune-related diarrhea and colitis.
- PIMSH13: Oncology: Mutation testing for stage IV lung cancer completed prior to start of targeted therapy: This QCDR measure assesses the use of mutation testing for all actionable biomarkers with appropriate mutation-directed therapy, in accordance with current National Comprehensive Cancer Network (NCCN) guidelines for stage IV non-small cell lung cancer.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity. In addition, we are proposing to add the following broadly applicable MIPS quality measure, which is relevant to patients receiving cancer care and their understanding of their health care treatment journey:

- TBD: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This proposed MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in their ability to manage their health and be an active partner in their health care journey.

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we are proposing to add six additional improvement activities that address maintenance requests from the public, and that address priority areas including clinician well-being, interoperability, patient safety, and expanding use of telehealth:

- IA_BMH_12: Promoting Clinician Well-Being
- IA_CC_13: Practice Improvements to Align with OpenNotes Principles
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_ERP_4: Implementation of a Personal Protective Equipment (PPE) Plan
- IA_PSPA_13: Participation in Joint Commission Evaluation Initiative
- IA_PSPA_28: Completion of an Accredited Safety or Quality Improvement Program

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures proposed in this MVP table pending testing data

Quality	Improvement Activities	Cost
(!) **Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications)	**IA_BE_4:** Engagement of patients through implementation of improvements in patient portal	**Total Per Capita Cost (TPCC)**

(*) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (!) **Q143**: Oncology: Medical and Radiation – Pain Intensity Quantified (Collection Type: eCQM Specifications, MIPS CQMs Specifications) (!) **Q144:** Oncology: Medical and Radiation – Plan of Care for Pain (Collection Type: MIPS CQMs Specifications) (!) **Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) (!) **Q450:** Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer (Collection Type: MIPS CQMs Specifications) **Q451:** 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 (Collection Type: MIPS CQMs Specifications) (!) **Q452:** Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies (Collection Type: MIPS CQMs Specifications) (!) **Q453:** Percentage of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better) (Collection Type: MIPS CQMs Specifications) (!!) **Q457:** Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better) (Collection Type: MIPS CQMs Specifications) **Q462:** Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy (Collection Type: eCQM Specifications) (+)(*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) (+) **Q490:** Appropriate Intervention of Immune-related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors (Collection Type: MIPS CQMs Specifications) (^)(+)(!!) **TBD:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications) (!) **PIMSH2:** Oncology: Utilization of GCSF in Metastatic Colorectal Cancer (Collection Type: QCDR) (+)(#)(!) **PIMSH13:** Oncology: Mutation testing for stage IV lung cancer completed prior to start of targeted therapy (Collection Type: QCDR)	(Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) (+) **IA_BMH_12:** Promoting Clinician Well-Being (High) **IA_CC_1**: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop (Medium) (+) **IA_CC_13:** Practice Improvements to Align with OpenNotes Principles (Medium) **IA_CC_17:** Patient Navigator Program (High) (~) **IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) (+)(~) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium) (+) **IA_ERP_4:** Implementation of a Personal Protective Equipment (PPE) Plan (Medium) (^)(+)(%) **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) (%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation (~) **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients (Medium) **IA_PM_15:** Implementation of episodic care management practice improvements (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PM_21:** Advance Care Planning (Medium) (+) **IA_PSPA_13:** Participation in Joint Commission Evaluation Initiative (Medium) **IA_PSPA_16:** Use of decision support and standardized treatment protocols (Medium)	

	(+) IA_PSPA_28: Completion of an Accredited Safety or Quality Improvement Program (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

TABLE B.2: Optimal Care for Kidney Health MVP

Table B.2 represents the measures and activities that were finalized within the Optimal Care for Kidney Health MVP in (87 FR 70660 through 70664) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Optimal Care for Kidney Health MVP within the quality performance category of this MVP to include to include six additional MIPS quality measures that encompass the appropriate care for kidney health and assess appropriate inclusion on the transplant waitlist. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP encompass appropriate care for kidney health and assess appropriate inclusion on the transplant waitlist:

- Q488: Kidney Health Evaluation: This MIPS quality measure ensures patients with diabetes receive a kidney health evaluation including both an estimated glomerular filtration rate (eGFR) and a urine albumin-creatinine ratio (uACR).
- TBD: First Year Standardized Waitlist Ratio (FYSWR): This proposed MIPS quality measure ensures patients with end-stage renal disease (ESRD) are placed on the kidney or kidney-pancreas transplant list or that the patient received a living donor transplant in the first year after initiation of dialysis.
- TBD: Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW): This proposed MIPS quality measure captures the adjusted count of patient months for dialysis patients on the kidney and kidney-pancreas transplant waitlist and patients on the kidney or kidney -pancreas transplant waitlist in active status.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity. In addition, we are proposing to add the following two broadly applicable MIPS quality measures which address patient's understanding of their health care journey:

- Q493: Adult Immunization Status: This MIPS quality measure ensures that adults are up-to-date with the recommended routine vaccines: influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.
- TBD: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This proposed MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the ability to manage their health and be an active partner in their health care journey.

We are also proposing to modify the previously finalized Optimal Care for Kidney Health MVP to remove two MIPS quality measures that would be replaced by MIPS quality measure Q493 Adult Immunization Status, which is a more robust measure supporting the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for this at-risk patient population. The quality actions represented in the below measures would be captured in the composite measure:

- Q110: Preventive Care and Screening: Influenza Immunization
- Q111: Pneumococcal Vaccination Status for Older Adults

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we are proposing to add two additional improvement activities that address maintenance requests from the public, and that address priority areas including food insecurity and population health:

- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_PM_13: Chronic Care and Preventative Care Management for Empaneled Patients

We are also proposing to remove the following improvement activity in response to maintenance requested from the public and interested-party feedback and agree with the recommendation that IA_PM_13: Chronic Care and Preventative Care Management for Empaneled Patients better targets the MVP population while still advancing care coordination:

- IA_PM_14: Implementation of methodologies for improvements in longitudinal care management for high risk patients

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component

Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(*)(!!) **Q001:** Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (!) **Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) (!) **Q130:** Documentation of Current Medications in the Medical Record (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (*)(!!) **Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (!!) **Q482:** Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate (Collection Type: MIPS CQMs Specifications) (+)(*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) (+)(*) **Q488:** Kidney Health Evaluation (Collection Type: MIPS CQMs Specifications) **Q489:** Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy (Collection Type: MIPS CQMs Specifications) (*)(+) **Q493:** Adult Immunization Status (Collection Type: MIPS CQMs Specifications) (^)(+) **TBD:** First Year Standardized Waitlist Ratio (FYSWR) (Collection Type: MIPS CQMs Specifications) (^)(+) **TBD:** Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) (Collection Type: MIPS CQMs Specifications) (^)(+)(!!) **TBD:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications)	(~) **IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) (+)(~) **IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_14:** Engage Patients and Families to Guide Improvement in the System of Care (High) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_CC_2**: Implementation of improvements that contribute to more timely communication of test results (Medium) **IA_CC_13:** Practice Improvements to Align with OpenNotes Principles (Medium) (^)(+)(%) **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) (%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation (~) **IA_PM_11:** Regular Review Practices in Place on Targeted Patient Population Needs (Medium) (+) **IA_PM_13:** Chronic Care and Preventative Care Management for Empaneled Patients (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PSPA_16:** Use of decision support and standardized treatment protocols (Medium)	**Acute Kidney Injury Requiring New Inpatient Dialysis (AKI)** **Total Per Capita Cost (TPCC)**

Foundational Layer	
Population Health Measures	**Promoting Interoperability**

(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

TABLE B.3: Optimal Care for Patients with Episodic Neurological Conditions MVP

Table B.3 represents the measures and activities that were finalized within the Optimal Care for Patients with Episodic Neurological Conditions MVP in (87 FR 70665 through 70668) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Optimal Care for Patients with Episodic Neurological Conditions MVP within the quality performance category of this MVP to include to include two additional MIPS quality measures that address health equity and the patient's understanding of their health care journey. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity. In addition, we are proposing to add the following broadly applicable MIPS quality measure, which is relevant to patients receiving care for episodic neurological conditions. The quality measure below addresses the patient's understanding of their health care journey:

- TBD: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This proposed MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the ability to manage their health and be an active partner in their health care journey.

We are also proposing to modify the previously finalized Optimal Care for Patients with Episodic Neurological Conditions MVP to remove one QCDR measure as it is a process measure with no follow-up or link to a health outcome as doesn't ensure preventive therapies were successful.

- AAN30: Migraine Preventive Therapy Management

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we are proposing to add one additional improvement activity that addresses a maintenance request from the public and that addresses the priority area of including the patient voice in their health care decision making:

- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **Q268:** Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy (Collection Type: MIPS CQMs Specifications) **(!) Q419:** Overuse of Imaging for the Evaluation of Primary Headache (Collection Type: MIPS CQMs	**(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **(+) IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_BE_24:** Financial Navigation Program (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**

Specifications) (+)(*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) (^)(+)(!!) **TBD:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications) **AAN5:** Medication Prescribed for Acute Migraine Attack (Collection Type: QCDR) (!!) **AAN22:** Quality of Life Outcome for Patients with Neurologic Conditions (Collection Type: QCDR) **AAN29:** Comprehensive Epilepsy Care Center Referral or Discussion for Patients with Epilepsy (Collection Type: QCDR) **AAN31**: Acute Treatment Prescribed for Cluster Headache (Collection Type: QCDR) **AAN32:** Preventive Treatment Prescribed for Cluster Headache (Collection Type: QCDR)	**IA_BMH_4:** Depression screening (Medium) **IA_BMH_8:** Electronic Health Record Enhancements for BH data capture (Medium) **IA_CC_1:** Implementation of use of specialist reports back to referring clinician or group to close referral loop (Medium) (~) **IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) (~) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium) (^)(+)(%) **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation (~) **IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PM_21:** Advance Care Planning (Medium) **IA_PSPA_21:** Implementation of fall screening and assessment programs (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) (!!) **Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting

	Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

TABLE B.4: Supportive Care for Neurodegenerative Conditions MVP

Table B.4 represents the measures and activities that were finalized within the Supportive Care for Neurodegenerative Conditions MVP in (87 FR 70669 through 70672) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Supportive Care for Neurodegenerative Conditions MVP within the quality performance category of this MVP to include to include one additional MIPS quality measure that addresses health equity. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity.

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we are proposing to add one additional improvement activity that addresses a maintenance request from the public, and that addresses the priority area of including patient voices in their health care decision making:

- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*)(!) Q238:** Use of High-Risk Medications in Older Adults (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **Q281:** Dementia: Cognitive Assessment (Collection Type: eCQM Specifications) **Q282:** Dementia: Functional Status Assessment (Collection Type: MIPS CQMs Specifications) **(!) Q286:** Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia (Collection Type: MIPS CQMs Specifications) **(!) Q288:** Dementia: Education and Support of Caregivers for Patients with Dementia (Collection Type: MIPS CQMs Specifications) **Q290:** Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease (Collection Type: MIPS CQMs	**(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **(+) IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_BMH_4:** Depression screening (Medium) **IA_BMH_8:** Electronic Health Record Enhancements for BH data capture (Medium) **IA_CC_1:** Implementation of use of specialist reports back to referring clinician or group to close referral loop (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**

Specifications) **(*) Q291:** Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease (Collection Type: MIPS CQMs Specifications) **(!) Q293:** Rehabilitative Therapy Referral for Patients with Parkinson's Disease (Collection Type: MIPS CQMs Specifications) **(*)(!) Q386:** Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences (Collection Type: MIPS CQMs Specifications) **(+)(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **AAN9:** Querying and Follow-Up About Symptoms of Autonomic Dysfunction for Patients with Parkinson's Disease (Collection Type: QCDR) **(!!) AAN22:** Quality of Life Outcome for Patients with Neurologic Conditions (Collection Type: QCDR) **(!!) AAN34:** Patient reported falls and plan of care (Collection Type: QCDR)	**(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(~) IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(^)(+)(%) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PM_21:** Advance Care Planning (Medium) **IA_PSPA_21:** Implementation of fall screening and assessment programs (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

Table B.5: Advancing Care for Heart Disease MVP

Table B.5 represents the measures and activities that were finalized within the Advancing Care for Heart Disease MVP in (87 FR 70679 through 70683) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Advancing Care for Heart Disease MVP within the quality performance category of this MVP to include four additional MIPS quality that are relevant to patients receiving care for heart disease. We reviewed the quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP are relevant to patients receiving care for heart disease. The quality measures below address appropriate medications for patients with coronary artery disease (CAD):

- Q006: Coronary Artery Disease (CAD): Antiplatelet Therapy: This MIPS quality measure assesses that patients diagnosed with CAD are prescribed aspirin or clopidogrel.
- Q118: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker–(ARB)–Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%): This MIPS quality measure assesses that patients diagnosed with CAD, in addition to a prior myocardial infarction or current or prior LVEF ≤ 40%, are prescribed a beta-blocker therapy.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity. In addition, we are proposing to add one additional broadly applicable MIPS quality measure that is relevant to patients receiving care for heart disease. The quality measure below addresses the patient's understanding of their health care journey:

- TBD: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This proposed MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the ability to manage their health and be an active partner in their health care journey.

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we are proposing to add two additional improvement activities that address maintenance requests from the public, and that address priority areas including food insecurity and the incorporation of patient voices into health care decision making:

- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings

Cost Measures

We are also proposing to add two MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of cardiac care. We reviewed the MIPS cost measure inventory and considered feedback received from interested parties through the MVP maintenance process to determine the cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in cardiac care and align with the other measures and activities included within this MVP:

- Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care in inpatient hospitals, including cardiac care. An interested party recommended that the MSPB Clinician measure replace the TPCC measure. We agree that it is appropriate to include MSPB Clinician within this MVP. However, TPCC is appropriate to include in this MVP for the reasons stated when the measure was initially finalized for use in this MVP (86 FR 66012 through 66103).
- Heart Failure: This episode-based cost measure evaluates a clinician's or clinician group's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat heart failure. The addition of this measure aligns with included quality measures, such as Q005: 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) and Q008: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Double asterisk (**): quality measures that are proposed for submission only when included in an MVP
Single exclamation point (!): quality measures that are considered high priority

Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(*) Q005: 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) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(+)(*) Q006:** Coronary Artery Disease (CAD): Antiplatelet Therapy (Collection Type: MIPS CQMs Specifications) **(*) Q007:** Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*) Q008:** Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(!) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(+)(*) Q118:** Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker–(ARB)–Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) (Collection Type: MIPS CQMs Specifications) **(**) Q128:** Preventive care and screening: Body Mass Index (BMI) screening and follow-up plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q238:** Use of High-Risk Medications in Older Adults (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q243:** Cardiac Rehabilitation Patient Referral from an Outpatient Setting (Collection Type: MIPS CQMs Specifications) **(*) Q326:** Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy	**(+)(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **(+) IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_12:** Use of evidence-based tools to support shared decision making (Medium) **IA_BE_15:** Engagement of Patients, Families, and Caregivers in Developing a Plan of Care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_BE_25:** Drug Cost Transparency (High) **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **(^)(+)(%) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) **(~) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high-risk patients (Medium) **IA_PSPA_4:** Administration of the AHRQ Survey of Patient Safety Culture (Medium) **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium)	**Elective Outpatient Percutaneous Coronary Intervention (PCI)** **ST-Elevation Myocardial Infarction (STEMI) with Percutaneous Coronary Intervention (PCI)** **(^)(+) Heart Failure** **(+) Medicare Spending Per Beneficiary (MSPB) Clinician** **Total Per Capita Cost (TPCC)**

(Collection Type: MIPS CQMs Specifications) **(!) Q377:** Functional Status Assessments for Heart Failure (Collection Type: eCQM Specifications) **(!!) Q392:** Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation (Collection Type: MIPS CQMs Specifications) **(!!) Q393:** Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision (Collection Type: MIPS CQMs Specifications) **(!!) Q441:** Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQMs Specifications) (+)(*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(!!) Q492:** Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System (Collection Type: Administrative Claims) (^)(+)(!!) **TBD:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications)		

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional)

	Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

Table B.6: Advancing Rheumatology Patient Care MVP

Table B.6 represents the measures and activities that were finalized within the Advancing Rheumatology Patient Care MVP in (87 FR 70687 through 70689) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Advancing Rheumatology Patient Care MVP within the quality performance category of this MVP to include three additional MIPS quality measures and one QCDR measure that are relevant to patients receiving rheumatology care. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

The following QCDR measure proposed within this MVP addresses appropriate clinical care for patients with rheumatological conditions:

- UREQA10: Ankylosing Spondylitis: Controlled Disease Or Improved Disease Function: This QCDR outcome measure ensures assessment of disease control or improvement based on Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score in patients with ankylosing spondylitis.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity. In addition, we are proposing to include two additional broadly applicable MIPS quality measures that are relevant to patients receiving care for rheumatological conditions. The quality measures below address immunization status and the patient's understanding of their health care journey:

- Q493: Adult Immunization Status: This MIPS quality measure ensures that adults are up-to-date with the recommended routine vaccines: influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.
- TBD: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This proposed MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the ability to manage their health and be an active partner in their health care journey.

We are also proposing to modify the previously finalized Optimal Care for Kidney Health MVP to remove one MIPS quality measure that would be replaced by MIPS quality measure Q493: Adult Immunization Status, which is a more robust measure supporting the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for this at-risk patient population. The quality actions represented in the below measure would be captured in the composite measure:

- Q111: Pneumococcal Vaccination Status for Older Adults

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we are proposing to add three additional improvement activities that address maintenance requests from the public, and that address priority areas including incorporating the patient voice into health care decision making:

- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BE_24: Financial Navigation Program
- IA_BE_25: Drug Cost Transparency

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures proposed in this MVP table pending testing data

Quality	Improvement Activities	Cost
(!) Q130: Documentation of Current Medications in the Medical Record (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High)	**Total Per Capita Cost (TPCC)**

(*) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **Q176:** Tuberculosis Screening Prior to First Course Biologic Therapy (Collection Type: MIPS CQMs Specifications) **Q177:** Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity (Collection Type: MIPS CQMs Specifications) **Q178:** Rheumatoid Arthritis (RA): Functional Status Assessment (Collection Type: MIPS CQMs Specifications) **Q180:** Rheumatoid Arthritis (RA): Glucocorticoid Management (Collection Type: MIPS CQMs Specifications) (+)(*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) (*)(+) **Q493:** Adult Immunization Status (Collection Type: MIPS CQMs Specifications) (^)(+)(!!) **TBD:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications) **ACR12:** Disease Activity Measurements for Patients with PsA (Collection Type: QCDR) (!!) **ACR14:** Gout Serum Urate Target (Collection Type: QCDR) (!) **ACR15:** Safe Hydroxychloroquine Dosing (Collection Type: QCDR) (+)(#)(!!) **UREQA10:** Ankylosing Spondylitis: Controlled Disease Or Improved Disease Function (Collection Type: QCDR)	(~) **IA_BE_1:** Use of certified EHR to capture patient reported outcomes (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) (+) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) (+) **IA_BE_24:** Financial Navigation Program (Medium) (+) **IA_BE_25**: Drug Cost Transparency (High) **IA_BMH_2:** Tobacco use (Medium) (~) **IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) (~) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium) (^)(+)(%) **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) (%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) (!!) **Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information

	OR Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

TABLE B.7: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP

Table B.7 represents the measures and activities that were finalized within the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP in (87 FR 70690 through 70692) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP to include three additional MIPS quality measures and one QCDR measure that are relevant to patients receiving emergency medical care. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP address appropriate use of medication and diagnostic testing:

- Q065: Appropriate Treatment for Upper Respiratory Infection (URI): This appropriate use MIPS quality measure evaluates that patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) did not receive an antibiotic order.
- Q416: Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years: This appropriate use MIPS quality measure evaluates the appropriate use of head computed tomography (CT) in pediatric patients presenting with minor blunt head trauma.
- HCPR24: Appropriate Utilization of Vancomycin for Cellulitis: This appropriate use QCDR measure evaluates for appropriate antibiotic ordering for patients diagnosed with cellulitis.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity.

We are also proposing to modify the previously finalized Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP to remove one QCDR measure as it is a process measure that should be a standard of care as demonstrated by the measure's high performance in the PY2023 MIPS Historical Quality Benchmarks file.

- ACEP21: Coagulation Studies in Patients Presenting with Chest Pain with No Coagulopathy or Bleeding

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we are proposing to add one additional improvement activity that addresses a maintenance request from the public, and that addresses the priority area of clinician well-being:

- IA_BMH_12: Promoting Clinician Well-Being

We are also proposing to remove the following improvement activities after consideration of feedback received from the public through the MVP maintenance process:

- IA_PSPA_19: Implementation of formal quality improvement methods, practice changes, or other practice improvement processes

Cost Measures

In addition, we are proposing to add one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of emergency medicine. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in emergency medicine and aligns with the other measures and activities included within this MVP:

- Emergency Medicine: This episode-based cost measure evaluates a clinician's risk-adjusted cost to Medicare for patients who have an emergency department (ED) visit during the performance period. This measure includes costs of Part A and B services during each episode from the start of the ED visit that opens, or "triggers," the episode through 14 days after the trigger, excluding a defined list of services for each ED visit type that are unrelated to the ED care.

We are also proposing to remove the following cost measure because the Emergency Medicine episode-based cost measure more closely aligns with the measures and activities included in this MVP:

- Medicare Spending Per Beneficiary (MSPB) Clinician

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component

Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures proposed in this MVP table pending testing data

Quality	Improvement Activities	Cost
(+)(*) **Q065:** Appropriate Treatment for Upper Respiratory Infection (URI) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) (*)(!) **Q116:** Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis (Collection Type: MIPS CQMs Specifications) (*) **Q254:** Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain (Collection Type: MIPS CQMs Specifications) (!) **Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) (*)(!) **Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQMs Specifications) (!) **Q415:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older (Collection Type: MIPS CQMs Specifications) (+)(!) **Q416:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years (Collection Type: MIPS CQMs Specifications) (+)(*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) (!!) **ACEP50:** ED Median Time from ED arrival to ED departure for all Adult Patients (Collection Type: QCDR) (!) **ACEP52:** Appropriate Emergency Department Utilization of Lumbar Spine Imaging for Atraumatic Low Back Pain (Collection Type: QCDR) (!) **ECPR46:** Avoidance of Opiates for Low Back Pain or Migraines (Collection Type: QCDR) (+)(#)(!) **HCPR24:** Appropriate Utilization of Vancomycin for Cellulitis (Collection Type: QCDR)	(~) **IA_AIIE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) (+) **IA_BMH_12:** Promoting Clinician Well-Being (High) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) (^)(+)(%) **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) (%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization (Medium) (~) **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_15:** Implementation of Antimicrobial Stewardship Program (ASP) (Medium)	(^)(+) **Emergency Medicine**

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide)

(!!) Q484: Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

TABLE B.8: Improving Care for Lower Extremity Joint Repair MVP

Table B.8 represents the measures and activities that were finalized within the Improving Care for Lower Extremity Joint Repair MVP in (87 FR 70693 through 70695) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Improving Care for Lower Extremity Joint Repair MVP to include one additional MIPS quality measure that is relevant to patients receiving care for lower extremity joint repair. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity.

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Double asterisk (**): quality measures that are proposed for submission only when included in an MVP
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(*)(!) Q024: Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!) Q350:** Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy (Collection Type: MIPS CQMs Specifications) **(!) Q351:** Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation (Collection Type: MIPS CQMs Specifications) **(*)(!) Q376:** Functional Status Assessment for Total Hip Replacement (Collection Type: eCQM Specifications) **(*)(!!) Q470:** Functional Status After Primary Total Knee Replacement (Collection Type: MIPS CQMs Specifications) **(!!) Q480:** Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_12** Use evidence-based decision aids to support shared decision-making (Medium) **IA_CC_7:** Regular training in care coordination (Medium) **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **IA_CC_13:** Practice improvements for bilateral exchange of patient information (Medium) **IA_CC_15:** PSH Care Coordination (High) **(^)(+)(%) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High)	**Elective Primary Hip Arthroplasty** **Knee Arthroplasty**

(TKA) for Merit-based Incentive Payment System (MIPS) (Collection Type: Administrative Claims) **(+)(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications)	**(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_18:** Measurement and improvement at the practice and panel level (Medium) **IA_PSPA_27:** Invasive Procedure or Surgery Anticoagulation Medication Management (Medium)	
Foundational Layer		
Population Health Measures		**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation	

TABLE B.9: Patient Safety and Support of Positive Experiences with Anesthesia MVP

Table B.9 represents the measures and activities that were finalized within the Patient Safety and Support of Positive Experiences with Anesthesia MVP in (87 FR 70695 through 70697) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Patient Safety and Support of Positive Experiences with Anesthesia MVP to include one additional MIPS quality measure and two additional QCDR measures that are relevant to patients receiving anesthesia care. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

The following QCDR measures proposed within this MVP address appropriate utilization of general anesthesia and rates of intraoperative hypotension:

- ABG44: Low Flow Inhalational General Anesthesia: This QCDR measure identifies adult patients undergoing elective procedures, lasting at minimum 30 minutes, that require inhalational general anesthesia to assess for appropriate total fresh gas flow during the maintenance phase of the anesthetic.
- EPREOP31: Intraoperative Hypotension among Non-Emergent Noncardiac Surgical Cases: This outcome QCDR measure identifies adult patients undergoing noncardiac, non-emergency surgery requiring general, neuraxial, or regional anesthesia care to evaluate if the patient had a mean arterial pressure (MAP) below 65 mmHg exceeding a cumulative length of 15 minutes.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity.

We are also proposing to modify the previously finalized Patient Safety and Support of Positive Experiences with Anesthesia MVP to remove one QCDR measure as it is a process measure that should be a standard of care as demonstrated by the measure's high performance in the PY2023 MIPS Historical Quality Benchmarks file.

- AQI69: Intraoperative Antibiotic Redosing

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures proposed in this MVP table pending testing data

Quality	Improvement Activities	Cost
(!!) **Q404:** Anesthesiology Smoking Abstinence (Collection Type: MIPS CQMs Specifications) (!!) **Q424:** Perioperative Temperature Management (Collection Type: MIPS CQMs Specifications) (!) **Q430:** Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy (Collection Type: MIPS CQMs Specifications)	**IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_22:** Improved practices that engage patients pre-visit (Medium) **IA_BMH_2:** Tobacco use (Medium) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **IA_CC_15:** PSH Care Coordination (High)	**Medicare Spending Per Beneficiary (MSPB) Clinician**

(!) **Q463:** Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics) (Collection Type: MIPS CQMs Specifications) (!) **Q477:** Multimodal Pain Management (Collection Type: MIPS CQMs Specifications) (+)(*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) (+)(#)(!) **ABG44:** Low Flow Inhalational General Anesthesia (Collection Type: QCDR) (!!) **AQI48:** Patient-Reported Experience with Anesthesia (Collection Type: QCDR) (+)(#)(!) **EPREOP31:** Intraoperative Hypotension among Non-Emergent Noncardiac Surgical Cases (Collection Type: QCDR)	**IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes (High) (~) **IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Records (High) (^)(+)(%) **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) (%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization (Medium) (~) **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_16:** Use of decision support and standardized treatment protocols (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) (!!) **Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

TABLE B.10: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP

Table B.10 represents the measures and activities that were finalized within the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP in (87 FR 70698 through 70700) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP within the quality performance category of this MVP to include to include one additional MIPS quality measure that addresses health equity. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity.

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we are proposing to add three additional improvement activities that address maintenance requests from the public, and that address priority areas including food insecurity, incorporating patient voices into health care decision making, and behavioral and mental health:

- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BMH_XX: Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures proposed in this MVP table pending testing data

Quality	Improvement Activities	Cost
(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*) Q187:** Stroke and Stroke Rehabilitation: Thrombolytic Therapy (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q326:** Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (Collection Type: MIPS CQMs Specifications) **(!!) Q344:** Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) (Collection Type: MIPS CQMs Specifications)	**(+)(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(~) IA_BE_1:** Use of certified EHR to capture patient reported outcomes (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **(+) IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_24:** Financial Navigation Program (Medium) **(^)(+) IA_BMH_XX:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults (High)	**Intracranial Hemorrhage or Cerebral Infarction**

(*)(!!) Q409: Clinical Outcome Post Endovascular Stroke Treatment (Collection Type: MIPS CQMs Specifications) **(!!) Q413:** Door to Puncture Time for Endovascular Stroke Treatment (Collection Type: MIPS CQMs Specifications) **(*) Q438**: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(!!) Q441**: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQMs Specifications) **(+)(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications)	**IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **IA_CC_13:** Practice improvements for bilateral exchange of patient information (Medium) **IA_CC_17:** Patient Navigator Program (High) **(^)(+)(%) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Implementation of Patient-Centered Medical Home model **IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) **IA_PM_15:** Implementation of episodic care management practice improvements (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

TABLE B.11: Value in Primary Care MVP

We are proposing to modify the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single consolidated primary care MVP titled Value in Primary Care MVP. Table B.11 represents the measures and activities that were finalized within the Promoting Wellness MVP (87 FR 70673 through 70678) and the Optimizing Chronic Disease Management MVP (87 FR 70684 through 70686) with modifications proposed for the CY 2024 performance

period/2026 MIPS payment year and future years. This MVP also aligns with the Adult Universal Core Set/Patient Care First CMMI Model primary care measures.

Quality Measures

We are proposing to modify the previously finalized Promoting Wellness MVP to include six additional MIPS quality measures that are relevant to patients receiving primary or preventive care. The quality measures below address appropriate clinical care for patients receiving primary or preventive care including well visits or condition specific visits in the auspices of primary care:

- Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%): This inverse outcome MIPS quality measure assesses diabetic patients for poor control of their HbA1c.
- Q236: Controlling High Blood Pressure: This outcome MIPS quality measure assesses patient diagnosed with hypertension for adequately controlled blood pressure.
- Q305: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: This MIPS quality measure ensures patients 13 years of age and older with a new substance use disorder (SUD) episode have the initiation of intervention or medication within 14 days of the new SUD episode or engage in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication within 34 days of the initiation.
- Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: This MIPS quality measure identifies patients at high risk of cardiovascular events and ensures they are prescribed or currently on a statin therapy.
- TBD: Preventive Care and Wellness (composite): This composite MIPS quality measure combines 7 current preventive care measures with age and sex appropriate preventive screenings and wellness services, creating a robust, broadly encompassing preventive care assessment. The measure would set a more stringent performance standard by requiring a comprehensive set of preventive care standards be completed for each patient, working to drive quality care, and ensuring more all-inclusive preventive care.
- TBD: Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk: This proposed MIPS quality measure ensures adult patients with suicidal ideation, behavior symptoms or increased suicide risk have a suicide safety plan initiated, reviewed, and/or updated in collaboration between the patient and their clinician.

We are proposing to modify the previously finalized Promoting Wellness MVP to include two additional broadly applicable MIPS quality measures that are relevant to patients receiving primary or preventive care. The quality measures below address health equity, immunization status, and the patient's wishes:

- Q047: Advance Care Plan: This MIPS quality measure assesses for medical record documentation of an advance care plan or surrogate decisions maker for patients aged 65 years and older.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

We are also proposing to modify the previously finalized Promoting Wellness MVP to remove four MIPS quality measures that would be replaced by MIPS quality measure TBD: Preventive Care and Wellness (composite), which is a more robust measure supporting the comprehensive evaluation of compliance with recommended adult preventive care, improving quality care and preventing/controlling disease for the general patient population. The quality actions represented in the measures below would be captured in the composite measure:

- Q112: Breast Cancer Screening
- Q113: Colorectal Cancer Screening
- Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Additionally, the following five measures are being proposed for removal to streamline the clinical concepts within the Value in Primary Care MVP to align with the clinical concepts of preventive care, quality chronic disease management, and alignment with the Adult Universal Foundation measures.[466] The below MIPS quality measures represent important preventive screening and patient voice measures clinical concepts and as such, the measure or concept can be found in other MVPs:

- Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age
- Q309: Cervical Cancer Screening
- Q310: Chlamydia Screening in Women
- Q400: One-Time Screening for Hepatitis C Virus (HCV) for all Patients
- Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we are proposing to add three additional improvement

[466] D.B. Jacobs, M. Schreiber, M. Seshamani, D. Tsai, E. Fowler, L.A. Fleisher. Aligning quality measures across CMS—The universal foundation: N Engl J Med (2023).

activities that address maintenance requests from the public, and that address priority areas including equity, food insecurity, and clinical decision support (CDS):

- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_PM_XX: Use of Decision Support to Improve Adherence to Cervical Cancer Screening and Management Guidelines
- IA_PM_XX: Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services

We are also proposing to remove the following two improvement activities in response to interested-party feedback:

- IA_BMH_9: Unhealthy Alcohol Use for Patients with Co-occurring Conditions of Mental Health and Substance Abuse and Ambulatory Care Patients
- IA_PSPA_19: Implementation of formal quality improvement methods, practice changes, or other practice improvement processes

Cost Measures

We propose to add four MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of cardiac care. The additional cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in cardiac care and align with the other measures and activities included within this MVP:

- Asthma/COPD: This episode-based cost measure evaluates a clinician's or clinician group's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat asthma or COPD.
- Diabetes: This episode-based cost measure evaluates a clinician's or clinician group's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat diabetes.
- Depression: This episode-based cost measures evaluates a clinician's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat depression.
- Heart Failure: This episode-based cost measure evaluates a clinician's or clinician group's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat heart failure.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(+)(*)(!!) **Q001:** Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (+) **Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) (*) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (+)(*)(!!) **Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (+)(!) **Q305:** Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (Collection Type: eCQM Specifications) (!) **Q321:** CAHPS for MIPS Clinician/Group	(~) **IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) (+)(~) **IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) (~) **IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_12:** Use evidence-based decision aids to support shared decision-making (Medium)	(+) **Asthma/COPD** (+) **Diabetes** (^)(+) **Depression** (^)(+) **Heart Failure** **Total Per Capita Cost (TPCC)**

Survey (Collection Type: CAHPS Survey Vendor) (+)(*) **Q438:** Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM Specifications, MIPS CQMs Specifications) (*) **Q475:** HIV Screening (Collection Type: eCQM Specifications) (!!) **Q483:** Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) (Collection Type: MIPS CQMs Specifications) (+)(*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) (*)**Q493**: Adult Immunization Status (Collection Type: MIPS CQMs Specifications) (^)(+) **TBD:** Preventive Care and Wellness (composite) (Collection Type: MIPS CQMs Specifications) (+)(!) **TBD:** Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk (Collection Type: MIPS CQMs Specifications)	**IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **IA_CC_13:** Practice improvements for bilateral exchange of patient information (Medium) (~) **IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) (^)(+)(%) **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) (%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation (~) **IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **IA_PM_13:** Chronic Care and Preventative Care Management for Empaneled Patients (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) (^)(+) **IA_PM_XX:** Use of Decision Support to Improve Adherence to Cervical Cancer Screening and Management Guidelines (Medium) (^)(+) **IA_PM_XX**: Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) (!!) **Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT	

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