DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 414, 424, and 425

[CMS–1676–F]

RIN 0938–AT02

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

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

ACTION: Final rule.

SUMMARY: This major final rule addresses changes to the Medicare physician fee schedule (PFS) and other Medicare Part B payment policies such as changes to the Medicare Shared Savings Program, 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. In addition, this final rule includes policies necessary to begin offering the expanded Medicare Diabetes Prevention Program model.

DATES: These regulations are effective on January 1, 2018.

FOR FURTHER INFORMATION CONTACT: Jessica Bruton, (410) 786–5991, for any physician payment issues not identified below.

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Roberta Epps, (410) 786–4503, for issues related to PAMA section 218(a) policy and transition from traditional X-ray imaging to digital radiography.

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Ann Marshall, (410) 786–3059, for issues related to primary care, chronic care management (CCM), and evaluation and management (E/M) services.

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Patrick Sartini, (410) 786–9252, for issues related to the valuation of imaging services and malpractice RVUs.

Michael Soracoe, (410) 786–6312, for issues related to the practice expense methodology, impacts, conversion factor, and valuation of pathology and surgical procedures.

Pamela West, (410) 786–2302, for issues related to therapy services.

Corinne Axelrod, (410) 786–5620, for issues related to rural health clinics or federally qualified health centers.

Felicia Eggleston, (410) 786–9287, for issues related to DME infusion drugs.

Rasheeda Johnson, (410) 786–3434, for issues related to initial data collection and reporting periods for the clinical laboratory fee schedule.

Edmund Kasaitis, (410) 786–0477, for issues related to biosimilars.

JoAnna Baldwin, (410) 786–7205, or Sarah Fulton, (410) 786–2749, for issues related to appropriate use criteria for advanced diagnostic imaging services.

Crystal Kellam, (410) 786–7970, for issues related to physician quality reporting system.

Alesia Hovatter, (410) 786–6861, for issues related to Physician Compare.

Alexandra Mugge, (410) 786–4457, for issues related to the EHR incentive program.

Kari Vandegrift, (410) 786–4008, or *ACO@cms.hhs.gov*, for issues related to the Medicare Shared Savings Program.

Kimberly Spalding Bush, (410) 786–3232, or Fiona Larbi, (410) 786–7224, for issues related to Value-based Payment Modifier and Physician Feedback Program.

Wilfred Agbenyikey, (410) 786–4399, for issues related to MACRA patient relationship categories and codes.

Carlye Burd, (410) 786–1972, or Albert Wesley, (410) 786–4204, for issues related to the Medicare Diabetes Prevention Program expanded model.

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Acronyms

In addition, because of the many organizations and terms to which we refer by acronym in this final rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

A1c Hemoglobin A1c
AAA Abdominal aortic aneurysms
ABLE Achieving a Better Life Experience Act of 2014 (Pub. L. 113–295)
ACI Advancing Care Information
ACO Accountable care organization
AMA American Medical Association
APM Alternative Payment Model
ASC Ambulatory surgical center
ATA American Telehealth Association
ATRA American Taxpayer Relief Act (Pub. L. 112–240)
AUC Appropriate Use Criteria

AWV Annual wellness visit
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
BHI Behavioral health integration
BLS Bureau of Labor Statistics
CAD Coronary artery disease
CAH Critical access hospital
CBSA Core-Based Statistical Area
CCM Chronic care management
CDSM Clinical Decision Support Mechanism
CEHRT Certified EHR technology
CF Conversion factor
CG–CAHPS Clinician and Group Consumer Assessment of Healthcare Providers and Systems
CLFS Clinical Laboratory Fee Schedule
CoA Certificate of Accreditation
CoC Certificate of Compliance
CoCM Collaborative care model
CoR Certificate of Registration
CNM Certified nurse-midwife
CP Clinical psychologist
CPC Comprehensive Primary Care
CPEP Clinical Practice Expert Panel
CPT [Physicians] Current Procedural Terminology (*CPT codes, descriptions and other data only are copyright 2015 American Medical Association. All rights reserved.*)
CQM Clinical quality measure
CSW Clinical social worker
CT Computed tomography
CW Certificate of Waiver
CY Calendar year
DFAR Defense Federal Acquisition Regulations
DHS Designated health services
DM Diabetes mellitus
DSMT Diabetes self-management training
eCQM Electronic clinical quality measures
ED Emergency Department
EHR Electronic health record
E/M Evaluation and management
EMT Emergency Medical Technician
EP Eligible professional
eRx Electronic prescribing
ESRD End-stage renal disease
FAR Federal Acquisition Regulations
FDA Food and Drug Administration
FFS Fee-for-service
FQHC Federally qualified health center
FR Federal Register
FSHCAA Federally Supported Health Centers Assistance Act
GAF Geographic adjustment factor
GAO Government Accountability Office
GPCI Geographic practice cost index
GPO Group purchasing organization
GPRO Group practice reporting option
GTR Genetic Testing Registry
HCPCS Healthcare Common Procedure Coding System
HHS [Department of] Health and Human Services
HOPD Hospital outpatient department
HPSA Health professional shortage area
IDTF Independent diagnostic testing facility
IPPE Initial preventive physical exam
IPPS Inpatient Prospective Payment System
IQR Inpatient Quality Reporting
ISO Insurance service office
IT Information technology
IWPUT Intensity of work per unit of time
LCD Local coverage determination
MA Medicare Advantage
MAC Medicare Administrative Contractor
MACRA Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10)
MAP Measure Applications Partnership
MAPCP Multi-payer Advanced Primary Care Practice
MAV Measure application validity [process]
MCP Monthly capitation payment
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
MFP Multi-Factor Productivity
MIPPA Medicare Improvements for Patients and Providers Act (Pub. L. 110–275)
MIPS Merit-based Incentive Payment System
MMA Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173, enacted on December 8, 2003)
MP Malpractice
MPPR Multiple procedure payment reduction
MRA Magnetic resonance angiography
MRI Magnetic resonance imaging
MSA Metropolitan Statistical Areas
MSPB Medicare Spending per Beneficiary
MU Meaningful use
NCD National coverage determination
NCQDIS National Coalition of Quality Diagnostic Imaging Services
NP Nurse practitioner
NPI National Provider Identifier
NPP Nonphysician practitioner
NQS National Quality Strategy
OACT CMS's Office of the Actuary
OBRA '89 Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239)
OBRA '90 Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508)
OES Occupational Employment Statistics
OMB Office of Management and Budget
OPPS Outpatient prospective payment system
OT Occupational therapy
PA Physician assistant
PAMA Protecting Access to Medicare Act of 2014 (Pub. L. 113–93)
PAMPA Patient Access and Medicare Protection Act (Pub. L. 114–115)
PC Professional component
PCIP Primary Care Incentive Payment
PE Practice expense
PE/HR Practice expense per hour
PEAC Practice Expense Advisory Committee
PECOS Provider Enrollment, Chain, and Ownership System
PFS Physician Fee Schedule
PLE Provider-led Entity
PLI Professional Liability Insurance
PMA Premarket approval
PMH–NP Psychiatric mental health nurse practitioner
PPM Provider-Performed Microscopy
PQRS Physician Quality Reporting System
PPIS Physician Practice Expense Information Survey
PPS Prospective Payment System
PT Physical therapy
PT Proficiency Testing
PT/INR Prothrombin Time/International Normalized Ratio
PY Performance year
QA Quality Assessment
QC Quality Control
QCDR Qualified clinical data registry
QRUR Quality and Resources Use Report
RBRVS Resource-based relative value scale
RFA Regulatory Flexibility Act
RHC Rural health clinic
RIA Regulatory impact analysis
RUC American Medical Association/Specialty Society Relative Value Scale Update Committee
RUCA Rural Urban Commuting Area
RVU Relative value unit
SBA Small Business Administration
SGR Sustainable growth rate
SIM State Innovation Model
SLP Speech-language pathology
SMS Socioeconomic Monitoring System
SNF Skilled nursing facility
TAP Technical Advisory Panel
TC Technical component
TIN Tax identification number
TCM Transitional Care Management
UAF Update adjustment factor
UPIN Unique Physician Identification Number
USPSTF United States Preventive Services Task Force
VBP Value-based purchasing
VM Value-Based Payment Modifier

Addenda Available Only Through the Internet on the CMS Web Site

The PFS Addenda along with other supporting documents and tables referenced in this final rule are available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2018 PFS Final Rule, refer to item CMS–1676–F. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this final rule and posted on the CMS Web site identified above should contact Jessica Bruton at (410) 786–5991.

CPT (Current Procedural Terminology) Copyright Notice

Throughout this final rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2016 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary

A. Purpose

This final rule makes payment and policy changes under the Medicare Physician Fee Schedule (PFS) and implements required statutory changes under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295), Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93), and the Consolidated Appropriations Act of 2016 (Pub. L. 114–113). This final rule also makes changes to payment policy and other related policies for Medicare Part B, Part D, and Medicare Advantage.

1. Summary of the Major Provisions

Section 1848 of the Social Security Act (the Act) 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; and, that we establish by regulation each year's payment amounts for all physicians' services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas. In this major final rule, we establish RVUs for CY 2018 for the PFS, and other Medicare Part B payment policies, to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. In addition, this final rule includes discussions and finalized policies regarding:

- Potentially Misvalued Codes.
- Telehealth Services.
- Establishing Values for New, Revised, and Misvalued Codes.
- Establishing Payment Rates under the PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital.
- Evaluation & Management (E/M) Guidelines and Care Management Services.
- Care Coordination Services and Payment for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).
- Part B Drug Payment: Infusion Drugs Furnished Through an Item of Durable Medical Equipment (DME).
- Solicitation of Public Comments on Initial Data Collection and Reporting Periods for Clinical Laboratory Fee Schedule.
- Payment for Biosimilar Biological Products under Section 1847A of the Act.
- Appropriate Use Criteria for Advanced Diagnostic Imaging Services.
- PQRS Criteria for Satisfactory Reporting for Individual EPs and Group Practices for the 2018 PQRS Payment Adjustment.
- Clinical Quality Measurement for Eligible Professionals Participating in the Electronic Health Record (EHR) Incentive Program for 2016.
- Medicare Shared Savings Program.
- Value-Based Payment Modifier and the Physician Feedback Program.
- MACRA Patient Relationship Categories and Codes.
- Changes to the Medicare Diabetes Prevention Program (MDPP) Expanded Model.
- Physician Self Referral Law: Annual Update to the List of CPT/HCPCS Codes.
- Therapy Caps.

2. Summary of Costs and Benefits

The statute requires that annual adjustments to PFS RVUs may not cause annual estimated expenditures to differ by more than $20 million from what they would have been had the adjustments not been made. If adjustments to RVUs would cause expenditures to change by more than $20 million, we must make adjustments to preserve budget neutrality. These adjustments can affect the distribution of Medicare expenditures across specialties. We have determined that this major final rule is economically significant. For a detailed discussion of the economic impacts, see section V. of this final rule.

II. Provisions of the Final Rule, and Analysis of and Responses to Public Comments for PFS

A. Background

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

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

1. Development of the Relative Values

a. Work RVUs

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

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

similar codes, and magnitude estimation. More information on these issues is available in that rule.

b. Practice Expense RVUs

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

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

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

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

Section 212 of the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113, enacted on November 29, 1999) (BBRA) directed the Secretary of Health and Human Services (the Secretary) to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept these supplemental data through March 1, 2005.

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

c. Malpractice RVUs

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

d. Refinements to the RVUs

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

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

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

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

e. Application of Budget Neutrality to Adjustments of RVUs

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

2. Calculation of Payments Based on RVUs

To calculate the payment for each service, the components of the fee schedule (work, PE, and MP RVUs) are adjusted by geographic practice cost indices (GPCIs) to reflect the variations in the costs of furnishing the services. The GPCIs reflect the relative costs of work, PE, and MP in an area compared to the national average costs for each component.

RVUs are converted to dollar amounts through the application of a CF, which

is calculated based on a statutory formula by CMS's Office of the Actuary (OACT). The formula for calculating the Medicare PFS payment amount for a given service and fee schedule area can be expressed as:

Payment = [(RVU work × GPCI work) + (RVU PE × GPCI PE) + (RVU MP × GPCI MP)] × CF

3. Separate Fee Schedule Methodology for Anesthesia Services

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

B. Determination of Practice Expense (PE) Relative Value Units (RVUs)

1. Overview

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

2. Practice Expense Methodology

a. Direct Practice Expense

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

b. Indirect Practice Expense per Hour Data

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

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

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

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data. Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

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

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS-based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file called ''CY 2018 PFS Final Rule PE/HR'' on the CMS Web site under downloads for the CY 2018 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

Comment: Several commenters recommended that it was time to consider a new nationwide all specialty

PE/HR survey, given the amount of time that has passed since the last survey was conducted. The commenters stated that the practice of medicine has significantly and substantially evolved in the past decade and that many specialties have had extensive changes in physician employment models during that time. The commenters stated that continued use of the outdated PPIS survey leads to an inappropriate and inaccurate distortion of the PE RVUs for current practice.

Response: We have previously identified several concerns regarding the underlying data used in determining PE RVUs in the CY 2014 PFS final rule (78 FR 74246 through 74247). Even when we first incorporated the survey data into the PE methodology beginning in CY 1999 (63 FR 58814), many commenters expressed serious concerns over the accuracy of this or other PE surveys as a way of gathering data on PE inputs from the diversity of providers paid under the PFS. However, we currently lack another source of comprehensive data regarding PE costs, and as a result, we continue to believe that the PPIS survey data is the best data currently available. We continue to seek the best broad-based, auditable, routinely-updated source of information regarding PE costs.

c. Allocation of PE to Services

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

(1) Direct Costs

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

(2) Indirect Costs

We allocate the indirect costs to the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion (see section II.B.2.b of this final rule). The general approach to developing the indirect portion of the PE RVUs is as follows:

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

(3) Facility and Nonfacility Costs

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

Comment: One commenter requested that CMS develop nonfacility PE RVUs for CPT code 31255 (Nasal/sinus endoscopy, surgical; with ethmoidectomy, total (anterior and posterior)), stating that this would be consistent with the migration of many sinus surgery procedures to the office setting. The commenter indicated that the availability of new technology has transformed these services to become minimally invasive, and as a result, they can be safely and effectively performed in the office setting for many patients.

Response: We appreciate the information provided by the commenter. However, we note that CPT code 31255 was reviewed by the RUC for the current CY 2018 rule cycle, and the RUC did not recommend any direct PE inputs for this code in the nonfacility setting. We welcome an ongoing dialogue with stakeholders regarding the direct PE inputs for this code, which we will take under consideration for future rulemaking. We also note that pricing in a particular setting does not constitute a coverage determination.

(4) Services With Technical Components and Professional Components

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

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct interested readers to the file called ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our Web site under downloads for the CY 2018 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. This file contains a table that illustrates the calculation of PE RVUs as described in this final rule for individual codes.

(a) Setup File

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

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

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

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

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

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

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

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

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

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

We generally use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Prior to implementing that policy, we used the most recent year of available claims data to determine the specialty mix assigned to each code.

Under either of these approaches, 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. Prior to adopting the 3-year average of data, for low-volume services (fewer than 100 Medicare allowed services), we assigned the values associated with the specialty that most frequently reported the service in the most recent claims data (dominant specialty). For some time, stakeholders, including the RUC, have requested that we use a recommended ''expected'' specialty for all low volume services instead of the information contained in the claims data. Currently, in the development of PE RVUs we use ''expected specialty'' overrides for only several dozen services based on several code-specific policies we established in prior rulemaking. As we stated in the CY 2016 final rule with comment period (80 FR 70894), we hoped that the 3-year average would mitigate the need to use dominant or expected specialty instead of the specialty identified using claims data. Because we incorporated CY 2015 claims data for use in the CY 2017 proposed rates, we believe that the finalized PE RVUs associated with the CY 2017 PFS final rule provided a first opportunity to determine whether service-level overrides of claims data are necessary.

Although we believe that the use of the 3-year average of claims data to determine specialty mix has led to an improvement in the stability of PE and MP RVUs from year to year, after reviewing the RVUs for low volume services, we continue to see possible distortions and wide variability from year to year in PE and MP RVUs for low volume services. Several stakeholders have suggested that CMS implement service-level overrides based on the expected specialty in order to determine the specialty mix for these low volume procedures. The RUC previously supplied us with a list of nearly 2,000 lower volume codes and their suggested specialty overrides. After reviewing the finalized PE RVUs for the CY 2017 PFS final rule, we agree that the use of service-level overrides for low volume services would help mitigate annual fluctuations and provide greater stability in the valuation of these services. While the use of the 3-year average of claims data to determine specialty mix has helped to mitigate some of the year to year variability for low volume services, it has not fully mitigated what appear to be anomalies for many of these lower volume codes.

Therefore, we proposed 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 proposed to instead use the expected specialty that we identify on a list. For CY 2018, we proposed to use a list that was developed based on our medical review of the list most recently recommended by the RUC, in addition to our own proposed expected specialty for certain other low-volume codes for which we have historically used expected specialty assignments. We would display this list as part of the annual set of data files we make available as part of notice and comment rulemaking. We proposed to consider recommendations from the RUC and other stakeholders on changes to this list on an annual basis.

We also proposed to apply these service-level overrides for both PE and MP, rather than one or the other category. We believe that this would simplify the implementation of service-level overrides for PE and MP, and would also address stakeholder concerns about the year-to-year variability for low volume services. We solicited public comment on the proposal to use service-level overrides to determine the specialty mix for low volume procedures, as well as on the proposed list of expected specialty overrides itself, which is largely based on the recommendations submitted by the RUC last year. The proposed list of expected specialty assignments for individual low volume services is available on our Web site under downloads for the CY 2018 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-*

Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) would be unaffected by this proposal.

The following is a summary of the public comments received on our proposal to use service-level overrides to determine the specialty mix for low volume procedures and our responses:

Comment: Many commenters supported the use of the expected specialty assignments and urged CMS to finalize the proposal. Commenters stated that the proposal was consistent with a longstanding RUC recommendation and the use of the expected specialty assignments would help mitigate some of the year to year variability for low volume services. Commenters supported the creation of a list of these service-level overrides and its maintenance on an annual basis, with several commenters stating that the RUC should review updated claims data each year to determine if any new codes fall below 100 claims and submit an expected specialty recommendation for these additional codes.

Response: We appreciate the comments in support of the proposal. As we stated in the proposed rule, we will consider recommendations from the RUC and other stakeholders on changes to the list of expected specialty assignments on an annual basis.

Comment: Several commenters made specific recommendations about the proposed list of expected specialty assignments for individual low volume services. One commenter recommended that the following CPT codes should be added to the list of expected specialty assignments: Cardiology: 33477; Cardiac surgery: 33238, 33514, 33548, 33951, 33953, 33955, 33957, 33958, 33959, 33962, 33963, 33964, 33965, 33969, 33973, 33985, 33987, 33988, 33989, 33991, 35271; General Surgery: 35251, 43325; Thoracic Surgery: 32672, 33025, 33215, 43135. The same commenter recommended the following changes to the indicated codes on the low volume override list:

- CPT codes 33363 and 33364: The commenter recommended changing the override specialty from cardiology to cardiac surgery.
- CPT codes 33516, 33976 and 35812: The commenter recommended changing the override specialty from thoracic surgery to cardiac surgery.
- CPT codes 35311 and 35526: The commenter recommended changing the override specialty from vascular surgery to cardiac surgery.
- CPT codes 38382, 43108, 43118, 43123, 43360, 43405 and 43425: The commenter recommended changing the override specialty from general surgery to thoracic surgery.

In addition, a different commenter recommended changing the proposed expected specialty for CPT code 43754 from gastroenterology to emergency medicine.

Response: We appreciate the submission of specific recommendations to the proposed list of expected specialty assignments. These recommendations from the commenter included newer information about the typical practice of these CPT codes than what we possessed when initially proposing the low volume services list, which was based, in part, upon a review that took place in CY 2016. After reviewing the recommendations provided by the commenters, and in light of the additional information supplied by the commenter about these codes, we are finalizing the addition of these updated recommendations to the list.

Comment: Several commenters expressed concern regarding the treatment of existing codes with no Medicare volume (as distinct from low volume) reported for any given year. Under the methodology used in the proposed rule, these codes with no utilization data received the average risk factor for all physician specialties rather than the expected specialty assignments on the list of service-level overrides. The commenters recommended that the proposed list of expected specialty overrides be utilized for both low volume and no volume codes.

Response: We agree with the commenters that the RVUs for services with no Medicare volume should be calculated in a manner that is consistent with services with low Medicare volume because our proposal was for fewer than 100 allowed services, and no-volume services would fit within that standard. Therefore, we are finalizing the recommendation from the commenters to use the proposed list of expected specialty overrides for both low volume and no volume codes.

Comment: A commenter agreed with the CMS proposal that there would no longer be a need to apply service-level MP RVU crosswalks for new or revised codes in order to assign a specialty-mix risk factor. The commenter stated that CMS would be able to derive the specialty mix assumption in the first year for a new or revised code from the specialty mix used for purposes of ratesetting. The commenter indicated their support for this change to calculating MP RVUs for new or revised codes.

Response: We are finalizing our proposal to remove service-level MP RVU crosswalks for new or revised codes, and we will instead derive the specialty mix assumption for the first year for a new or revised code from the specialty mix used for purposes of ratesetting.

Comment: One commenter supported the CMS proposal and requested the use of the phrase ''Family Medicine'' for the list of expected specialty assignments rather than the phrase ''Family Practice'', which the commenter stated was a more outdated term.

Response: Regarding the requested update to the name assigned to a specialty, we would direct the commenter to the standard process for updating specialty designations. This change would have to be made to the Medicare enrollment specialty and lies outside the scope of the proposal.

After consideration of comments received, we are finalizing our proposal to use service-level overrides to determine the specialty mix for low volume procedures, with the modifications as discussed in this section. Based on comments, we are also finalizing the use of service-level overrides to determine the specialty mix for no volume procedures. In addition, we are finalizing the proposed list of expected specialty overrides with modifications. We are finalizing the addition of certain CPT codes to the list and updated specialty assignments for certain CPT codes.

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

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

There are two situations where this formula is modified:

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

(**Note:** For global services, the indirect PE allocator is based on both the work

RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

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

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

Apply a scaling adjustment to the indirect allocators.

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

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

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

Calculate the indirect practice cost index.

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

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

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

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

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

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

(d) Calculate the Final PE RVUs

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

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

Comment: One commenter stated that CMS should take a phased in approach to avoid any beneficiary access issues presented by the significant payment decreases caused by PE decreases for imaging services. These decreases could affect the viability of many practices providing these critical services as the new payment rates might create economic hardships for continuation of these services. The commenter stated that CMS should implement the RUC-recommended practice expenses over a phased in period to reduce the financial impact of the PE changes, particularly for codes with a proposed decrease of more than 10 percent.

Response: We agree with the commenter that there is a need to ensure access to patient care and mitigate the potential for economic hardship on the part of providers facing decreases in the valuation of services. We note in response to the commenter that section 1848(c)(7) of the Act already stipulates 19 percent as the maximum 1-year reduction for any service not described by a new or revised code. This phase-in methodology has been in use for PFS ratesetting since CY 2016.

(e) Setup File Information

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

TABLE 1—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION

Specialty code	Specialty description
49	Ambulatory surgical center.
50	Nurse practitioner.

TABLE 1—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION—Continued

Specialty code	Specialty description
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.
B2	Pedorthic personnel.
B3	Medical supply company with pedorthic personnel.

• *Crosswalk certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.

• *Physical therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.

• *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).

• *Payment modifiers:* Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 2 details the manner in which the modifiers are applied.

TABLE 2—APPLICATION OF PAYMENT MODIFIERS TO UTILIZATION FILES

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

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

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

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

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

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

Where:

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

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

Stakeholders have often suggested that particular equipment items are used less frequently than 50 percent of the time in the typical setting and that CMS should reduce the equipment utilization rate based on these recommendations. We appreciate and share stakeholders' interest in using the most accurate assumption regarding the equipment utilization rate for particular equipment items. However, we believe that absent robust, objective, auditable data regarding the use of particular items, the 50 percent assumption is the most appropriate within the relative value system. We welcome the submission of data that illustrates an alternative rate.

Comment: One commenter stated that most ophthalmology diagnostic equipment is in use far less than 50 percent of the time. The commenter indicated that they had developed a survey instrument that asked ophthalmic technicians to provide time usage estimates for the 16 most-utilized pieces of diagnostic testing equipment. The commenter stated that their preliminary survey results produced a utilization rate of 22 percent, much lower than the 50 percent assumption currently used by CMS. The commenter suggested that CMS should work with the RUC to do a robust survey to help determine a more valid utilization rate, including the possibility of specialty-specific equipment utilization rates.

Response: We are always looking for more accurate information to improve our PE methodology. We appreciate and share stakeholders' interest in using the most accurate assumption regarding the equipment utilization rate for particular equipment items, and we will review any information that the RUC's PE Subcommittee or other stakeholders are willing to submit through the public comment process. We concur with the commenter that a wide-ranging survey or similar study designed to address the subject of equipment utilization rates would be an appropriate tool to investigate this subject in further detail. At the moment, we believe that absent robust, objective, auditable data regarding the use of particular items, the 50 percent assumption is the most appropriate within the relative value system. We welcome the further submission of data that illustrates an alternative rate.

Maintenance: This factor for maintenance was finalized in the CY 1998 PFS final rule with comment period (62 FR 33164).

Comment: Several commenters addressed the issue of equipment maintenance costs. One commenter stated that the current maintenance percentage of 5 percent across all types of medical equipment does not adequately address the maintenance costs of imaging equipment in general and particularly not for advanced imaging modalities like CT and MRI. This commenter stated that a CT scanner would have an estimated annual maintenance cost of 7.2 percent. Another commenter supported our willingness to investigate potential avenues for determining variable equipment maintenance costs across a broad range of equipment items. The commenter stated that the standard equipment rate assumption fails to appreciate the significant costs associated with the maintenance of highly technical and particularly complex equipment items, and indicated that that CMS should not persist in an inaccurate approach while it collects additional data.

Response: We appreciate the additional information regarding equipment maintenance rates from the commenters. As we previously stated in the CY 2016 final rule with comment period (80 FR 70897), we agree with the commenters that we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding sources of data containing equipment maintenance rates, commenters were unable to identify an auditable, robust data source that could be used by CMS on a wide scale. We do not believe that voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining maintenance factor, we do not believe that we have sufficient information at present to adopt a variable maintenance factor for equipment cost per minute pricing. We continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.

Interest Rate: In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (see 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). We did not propose any changes to these interest rates for CY 2018. The interest rates are listed in Table 3.

TABLE 3—SBA MAXIMUM INTEREST RATES

Price	Useful life (years)	Interest rate (%)
<$25K	<7	7.50
$25K to $50K	<7	6.50
>$50K	<7	5.50
<$25K	7+	8.00
$25K to $50K	7+	7.00
>$50K	7+	6.00

3. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2018 direct PE input database, which is available on the CMS Web site under downloads for the CY 2018 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

(a) PE Inputs for Digital Imaging Services

In the CY 2017 PFS final rule (81 FR 80179 through 80184), we finalized our proposal to add a professional PACS workstation (ED053) used for interpretation of digital images to a series of CPT codes and to address costs related to the use of film that had previously been incorporated as direct PE inputs for these services. We finalized the following criteria for the inclusion of a professional PACS workstation:

- We did not add the professional PACS workstation to any code that currently lacks a technical PACS workstation (ED050) or lacks a work RVU. We continue to believe that procedures that do not include a technical workstation, or do not have physician work, would not require a professional workstation.
- We did not add the professional PACS workstation to add-on codes. Because the base codes include equipment minutes for the professional PACS workstation, we continue to believe it would be duplicative to add additional equipment time for the professional PACS workstation in the add-on code.
- We also did not add the professional PACS workstation to image guidance codes where the dominant provider is not a radiologist according to the most recent year of claims data, because we believe a single technical PACS workstation would be more typical in those cases.
- We agreed with commenters that because the clinical utility of the PACS workstation is not necessarily limited to diagnostic services, there may be therapeutic codes where it would be reasonable to assume its use to be typical. Based on information provided by commenters and our own medical review, we stated that we believe that the use of the professional PACS workstation is typical for many of the specific codes that were identified. We added the workstation to many of the therapeutic codes requested by commenters, specifically CPT codes listed outside the 70000 series, where we agreed that use of the professional PACS workstation was typical.
- For CPT codes in the 80000 and 90000 series, we expressed our concerns about whether it is appropriate to include the technical PACS workstation in many of these services. PACS workstations were created for imaging purposes, but many of these services that include a technical PACS workstation do not appear to make use of imaging. Although we did not remove the technical PACS workstation from these codes at that time, we did not believe that a professional PACS workstation should be added to these procedures.

Prior to the publication of this CY 2018 PFS proposed rule, a stakeholder expressed concern about our decision not to include the professional PACS workstation in a series of vascular ultrasound codes that use technical PACS workstations. The stakeholder indicated that the vascular ultrasound codes in question do make use of a professional PACS workstation, and that the dominant specialty provider requirement (that is, that the code's dominant specialty provider be diagnostic radiology) would exclude codes for which the professional PACS workstation is typical based on a mistaken assumption. The stakeholder stated that to furnish vascular ultrasound services following the transition from film to digital imaging, both a technical and a professional PACS workstation are required, regardless of whether the practitioner furnishing the service is a radiologist, cardiologist, neurologist, or vascular surgeon.

We appreciate the submission of this additional information regarding the use of the professional PACS workstation in vascular ultrasound codes. Therefore, we solicited comments regarding whether or not the use of the professional PACS workstation would be typical in the following list of CPT and HCPCS codes. The codes brought to our attention by the stakeholder are CPT codes 93880, 93882, 93886, 93888, 93890, 93892, 93893, 93922, 93923, 93924, 93925, 93926, 93930, 93931, 93965, 93970, 93971, 93975, 93976, 93978, 93979, 93980, 93981, 93990, and 76706, and HCPCS code G0365. We considered information submitted in comments to determine whether the professional PACS workstation should be included as a direct PE input for these codes.

The following is a summary of the public comments received regarding whether or not the use of the professional PACS workstation would be typical in the previous list of CPT and HCPCS codes and our responses:

Comment: Several commenters stated that the finalized policy in CY 2017 that did not add the professional PACS workstation to image guidance codes where the dominant practitioner is not a radiologist was an arbitrary decision. The commenters stated that CMS did not provide any rationale for this policy, and that for many services, both a technical and a professional PACS workstation would be typically used regardless of whether the practitioner performing the service is a radiologist or in another specialty. These commenters urged CMS to add a professional PACS workstation in services where its use would be typical without concern for whether diagnostic radiology is the dominant provider.

Response: We agree with the commenters that equipment allocated to each code should be determined based on the resources typically required to furnish the service. In general, we believe that examining Medicare claims data for dominant specialty is a useful and data-driven approach to making educated assumptions regarding typical resources involved in furnishing particular procedures. However, in this case, we are persuaded by commenters who stated that other specialties, outside of diagnostic radiology, utilize the professional PACS workstation. After reviewing the information supplied by the commenters, we agree the use of both a technical and a professional PACS workstation may be typical in some services where diagnostic radiology is not the dominant provider. We welcome feedback from stakeholders in identifying additional services where the use of a professional PACS workstation would be typical.

Comment: One commenter disagreed with the exclusion of add-on codes from the list of codes that included a professional PACS workstation. The commenter stated that the add-on codes require additional time to perform and therefore more time with the technical PACS workstation for the technician, as well as additional time for the review and interpretation performed by the

physician using the professional PACS workstation.

Response: We disagree with the commenter. We continue to believe it would be duplicative to add additional equipment time for the professional PACS workstation in the add-on code, as the base codes already include equipment time for the practitioner's use following the service.

Comment: Many commenters stated that the use of a professional PACS workstation would be typical in the 26 CPT codes detailed previously. Commenters stated that in the wake of the transition from film to digital imaging, use of both a technical and a professional PACS workstations has become typical for many diagnostic imaging services, including vascular ultrasound and digital pathology services. One commenter indicated that the use of the professional PACS workstation served a vital part in coordination of care for their treatment of vascular access issues related to ESRD patients. Another commenter stated that HCPCS code G0365 may have been mistakenly included on this list, as it already includes a professional PACS workstation added in CY 2017, while CPT code 93965 should not be considered for the professional PACS workstation as the code was previously deleted.

Response: We agree with the commenters that the use of the professional PACS workstation would be typical in 21 of the 26 codes listed in the proposed rule. As mentioned by one commenter, CPT code 93965 has been deleted while code G0365 already includes a professional PACS workstation. We disagree with adding a professional PACS workstation to CPT codes 93922, 93923, and 93924 because these codes do not include a technical PACS workstation and we continue to believe that procedures that do not include a technical workstation would not require a professional workstation. We will assign equipment time for the professional PACS workstation in the nonfacility setting according to the equipment time formula finalized in CY 2017. For diagnostic codes, we are assigning equipment minutes equal to half the preservice physician work time plus the full intraservice physician work time, consistent with the previously finalized policy. For the relatively smaller group of diagnostic codes with no service period time breakdown, we are assigning equipment time equal to half of the total physician work time, consistent with the previously finalized policy. The equipment time to be added is shown in Table 4.

TABLE 4—ADDITIONAL CODES WITH PROFESSIONAL PACS WORKSTATION

HCPCS	Procedure type	ED053 minutes
93880	Diagnostic	18
93882	Diagnostic	13
93886	Diagnostic	20
93888	Diagnostic	13
93890	Diagnostic	20
93892	Diagnostic	25
93893	Diagnostic	25
93925	Diagnostic	18
93926	Diagnostic	13
93930	Diagnostic	18
93931	Diagnostic	13
93970	Diagnostic	17
93971	Diagnostic	12
93975	Diagnostic	23
93976	Diagnostic	18
93978	Diagnostic	18
93979	Diagnostic	13
93980	Diagnostic	21
93981	Diagnostic	10
93990	Diagnostic	14
76706	Diagnostic	13

Comment: One commenter stated that the costs associated with storing digital images should be included as a direct PE. The commenter noted that CMS treated film as a supply item for purposes of direct cost determination and cited an MRI study in the 2010 direct PE database with 12 pieces of 14 x 17 film at a price of $1.17 each or $14.04. The commenter stated that this film was not replaced and that digital imaging studies need to be recorded and then archived. The commenter suggested that storage costs for digital images should be added as a maintenance percentage for digital imaging services.

Response: We disagree with the commenter that the costs associated with storing digital images are excluded from digital imaging services, as these costs are incorporated into the indirect PE methodology that cover administrative costs and office rent. We do not pay separately for the storage of digital images as these expenses are not allocable to individual services, just as we do not explicitly incorporate the storage costs of electronic health records (EHRs) as direct PE inputs for the range of practitioners that use EHRs. We understand and agree that we previously treated film itself as direct PE input. However, the film was allocable to an individual patient. We believe that the better analog for the storage of images under the previous assumptions would be the office cabinets and office space in which the film was stored. These items were clearly considered to be indirect PE expenses and, therefore, such costs are included in the specialty-specific data that is used to allocate indirect PE RVUs. We previously replaced the direct PE components of imaging services during the film-to-digital transition that took place in CY 2015 (79 FR 67561).

Comment: One commenter recommended that CMS revisit its definition of room time for imaging procedures. Under the current policy, room time for imaging studies is defined as the time it takes to acquire the images 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. The commenter stated that this definition was inconsistent with how imaging centers actually function, as most patient-related activities take place in the imaging room with the involvement of multiple technologists. The commenter suggested that CMS should return to the previous definition, in which equipment time for highly technical equipment was based on total technologist time.

Response: We disagree with the commenter regarding the current standard equipment time formula for highly technical equipment. As we wrote in the CY 2011 final rule with comment period (75 FR 73350), certain highly technical pieces of equipment and equipment rooms are less likely to be used by a clinician over the full course of a procedure and are typically available for other patients during time that may still be in the intraservice portion of the service. When we identify these services, we adjust those equipment times accordingly. For example, CPT code 74178 (Computed tomography, abdomen and pelvis; without contrast material in more than one body region) includes 3 minutes of intra-service clinical labor time associated with obtaining the patient's consent for the procedure. Since we believe that it would be atypical for this activity to occur within the CT room, we believe these 3 minutes should not be attributed to the CT room. We agree with the commenter that the standard formula used to determine equipment time for highly technical equipment may not be typical for all services, which is why we evaluate equipment time on a case-by-case basis as services are reviewed. We appreciate the information submitted by the commenter, and we will take these comments under consideration as we evaluate codes on an individual basis.

After consideration of comments received, we are finalizing the addition of a professional PACS workstation to the codes listed in Table 4 with the equipment time detailed.

(2) Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640–67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and postservice periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this improvement 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 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 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.

The following is a summary of the public comments received regarding the standardization of clinical labor tasks and our responses:

Comment: One commenter supported the efforts of the AMA RUC to standardize clinical labor activities in the new PE worksheet and urged CMS to accept these standards.

Response: We appreciate the efforts to establish greater organizational consistency through the RUC's use of the new PE worksheet and new clinical labor activity codes in developing and making recommendations to CMS.

Comment: Several commenters stated that, while they supported the revisions to the direct PE database providing the number of clinical labor minutes assigned for each clinical labor activity for each code, they had concerns regarding the over-standardization of clinical labor activities. These commenters indicated that each service requires different clinical labor resources and creating standard times is not possible for all clinical labor activities. Commenters stated that the RUC's PE Subcommittee is the entity best suited to make service-level determinations for clinical labor, and that blanket changes to standardize clinical labor activities outside of RUC review would lead to misvaluation of codes.

Response: We agree with the commenters that there are often important differences between services and that no two services are necessarily identical. We also acknowledge that there is a balance between establishing standards for clinical labor activities and the need for individual review of each code. We concur with the commenters that some services require greater or less time than the clinical labor standards, and we have frequently finalized clinical labor times outside the standard values. The standard times for clinical labor activities are a starting point for our clinical review of individual services, not necessarily an ending point. As we have written in past rulemaking, we believe that the establishment of standard times helps to facilitate greater transparency of information and maintain consistency in review patterns over time. Our goal is to maintain relativity among services, and we believe that the creation of clinical labor standards helps to facilitate that goal.

Comment: One commenter stated that the proposed standardized clinical labor times for CT and MRI codes required additional time due to a need to assess patients for any special needs, review screening sheets with patients, and obtain a clinical history from the patient.

Response: When reviewing clinical labor times for individual codes, we typically work closely with the recommendations provided by the RUC, which did not include additional clinical labor time for these specific activities in these services. While we appreciate the additional information from the commenter, we do not agree that it would serve overall PFS relativity to include additional clinical labor time for these services based on this rationale.

In the following paragraphs, we address a series of issues related to clinical labor tasks, particularly relevant to services currently being reviewed under the misvalued code initiative.

a. Preservice Clinical Labor for 0-Day and 10-Day Global Services

Several years ago, the RUC's PE Subcommittee reviewed the preservice clinical labor times for CPT codes with 0-day and 10-day global periods. The RUC concluded that these codes are assumed to have no preservice clinical staff time (standard time of 0 minutes) unless the specialty can provide evidence that the preservice time is appropriate. In other words, for minor procedures, it is assumed that there is no clinical staff time typically spent preparing for the specific procedure prior to the patient's arrival. However, we note that for CY 2018, 41 of the 53 reviewed codes with 0-day or 10-day global periods include preservice clinical labor of some kind, suggesting that it is typical for clinical staff to prepare for the procedure prior to the patient's arrival. As we review misvalued codes, we believe that the general adherence to values that we have established as standards supports relativity within the PFS. Because 77 percent of the reviewed codes for the current calendar year deviate from the ''standard,'' we sought comment on the value and appropriate application of the standard in our review of RUC recommendations in future rulemaking. In reviewing the inputs included in the direct PE inputs database, we found that for the 1,142 total 0-day global codes, 741 of them had preservice clinical labor of some kind (65 percent). We also noticed a general correlation between preservice clinical labor time and the recent review. We sought comment specifically on whether the standard preservice clinical labor time of 0 minutes should be consistently applied for 0-day and 10-day global codes in future rulemaking.

The following is a summary of the public comments received regarding whether the standard preservice clinical labor time of 0 minutes should be consistently applied for 0-day and 10-day global codes in future rulemaking and our responses:

Comment: Many commenters opposed eliminating clinical staff preservice time from all 0-day and 10-day global procedures in future rulemaking. Several commenters stated that although it is accurate to assume that no clinical staff time is necessary for minor procedures, it is no longer true that all 0-day and 10-day globals can be classified as minor procedures, as increasingly complex services are now performed using this global period. For example, there are several cardiothoracic surgery procedures that in the past would have been valued as

90-day global services but instead were implemented as 0-day global procedures to allow additional flexibility in the delivery of patient care. One commenter stated that the ''trend'' identified in the proposed rule occurred only because of the significant number of 0-day endoscopy and interventional codes that have recently been reviewed. Other commenters stated that the standard preservice clinical labor time of 0 minutes is only applicable if specialties cannot provide evidence of the need for preservice clinical labor, and that the rise in preservice clinical labor time indicated the growing recognition that the use of clinical staff is typical for these services. Many commenters stated that the RUC's PE Subcommittee should review the evidence on a case-by-case basis to determine if individual services justify preservice clinical labor time. Commenters urged CMS to work with the RUC to identify circumstances where deviations from the standard clinical labor times would be appropriate and develop clear definitions and criteria that support compelling reasons for clinical staff time that deviates from the standard for 0-day and 10-day global procedures. A few commenters, including the RUC, acknowledged that the high number of preservice clinical labor exceptions raised the question of the utility of the standard given this high number of exemptions.

Response: We appreciate the responses from the commenters. We note that several commenters also acknowledged the problematic nature of having so many exceptions to the established standard for preservice clinical labor. We appreciate in particular the additional information regarding the increasing use of the 0-day and 10-day global periods for procedures that are not minor in nature. In light of this information, we agree with the commenters who suggested that there is a need to identify circumstances where deviations from the standard clinical labor times would be appropriate and develop clear definitions and criteria for these situations. If an increasingly large number of major procedures are performed using the 0-day and 10-day global periods, we believe that there will be a need for the establishment of new guidelines for the typical allotment of preservice clinical labor. We agree with the commenters that preservice clinical labor must be determined on an individual basis based on the resources typically required to furnish the service. However, the need for individual review of services does not preclude the development of standards which, as we stated above, helps to facilitate greater transparency of information and maintain consistency in review patterns over time.

After consideration of comments received, we do not believe that the standard preservice clinical labor time of 0 minutes should be consistently applied for 0-day and 10-day global codes in future rulemaking. We look forward to working with stakeholders and seeing their recommendations for preservice clinical labor that maintain relativity among the different kind of procedures classified as 0-day and 10-day globals.

b. Obtain Vital Signs Clinical Labor

The direct PE inputs for each CPT code paid under the PFS include minutes assigned to a series of standard clinical labor tasks assumed to be typical for the service in question. The minutes assigned to each of these tasks for each CPT code have been developed over several decades, and what was previously considered to be a standard value in the review of the codes has changed over time. Because each year we perform a detailed review of all of the inputs for only several hundred of the over 7,000 CPT codes paid under the PFS, valuation for individual services can be influenced by shifts in review standards over time rather than purely based on changes in practice.

For example, we traditionally assigned a clinical labor time of 3 minutes for the ''Obtain vital signs'' clinical labor activity, based on the amount of time typically required to check a patient's vitals. Over time, that number of minutes has increased as codes are reviewed. For example, many of the reviewed codes for the current CY 2018 rulemaking cycle have a recommended clinical labor time of 5 minutes for ''Obtain vital signs,'' based on the understanding that these services are measuring two additional vital signs: the patient's height and weight. We do not have any reason to believe that measuring a patient's height and weight is only typical for services described by recently reviewed codes. Instead, we believe that the review standards have changed, perhaps in conjunction with changes in medical practice, and that the change in the minutes assigned for the ''Obtain vital signs'' task for newer-reviewed services is detrimental to relativity among PFS services.

Therefore, to preserve relativity among the PFS codes, we proposed to assign 5 minutes of clinical labor time for all codes that include the ''Obtain vital signs'' task, regardless of the date of last review. We proposed to assign this 5 minutes of clinical labor time for all codes that include at least 1 minute previously assigned to this task. We also proposed to update the equipment times of the codes with this clinical labor task accordingly to match the changes in clinical labor time. For codes that were not recently reviewed and for which we lacked a breakdown of how the equipment time was derived from the clinical labor tasks, we could not determine if the equipment time included time assigned for the ''Obtain vital signs'' task. In these cases, we proposed to adjust the equipment time of any equipment item that matched the clinical labor time of the full service period to match the change in the ''Obtain vital signs'' clinical labor time. The list of all codes affected by these proposed vital signs changes to direct PE inputs is available on the CMS Web site under downloads for the CY 2018 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

The following is a summary of the public comments received on the list of all codes affected by these proposed vital signs changes to direct PE inputs proposals and our responses:

Comment: Many commenters supported the CMS proposal. Commenters agreed that these differences in the minutes assigned to the ''Obtain vital signs'' clinical labor task appeared to be attributed to variances in review standards over time rather than reflecting actual variations in practice. One commenter stated that medical practice typically requires measurement of height and weight when vital signs are measured, while another commenter stated that the new standard time would be an administrative simplification for stakeholders and help streamline reviews. These commenters urged CMS to finalize the proposal to help preserve relativity between PFS codes.

Response: We appreciate the support from the commenters for the proposal.

Comment: Other commenters disagreed with the proposal to establish 5 minutes as the new clinical labor standard for the ''Obtain vital signs'' task. These commenters stated that the RUC PE Subcommittee's standard for vital signs clinical labor, based on the number of vital signs being taken, remained accurate and was the best way to make sure that individual codes are allocated the correct amount of time. These commenters were opposed to changing the clinical labor time of a large number of codes at once, and stressed the need for individual review

of each service. Commenters urged CMS not to finalize this proposal and suggested the issue should be referred to the RUC and its Practice Expense Advisory Committee for further review and input.

Response: We generally agree with commenters that the determinations for individual clinical labor activities are typically made at the code level, such as those recommended by the RUC's PE subcommittee. Therefore, we are not finalizing our proposal to use 5 minutes as the universal input for this clinical labor task. However, since even the comments opposing the proposal did not suggest that the clinical labor associated with taking vital signs has changed over time, only the review standards associated with them, we will assign 5 minutes as the input for all codes that include the ''Obtain vital signs'' task for CY 2018, as proposed. For future rulemaking we will consider code-level recommendations that will help distinguish services that may require fewer or greater than 5 minutes for this activity. We believe that finalizing 5 minutes for the codes as proposed will serve to mitigate the detrimental impact of review standards shifting over time while preserving the principle that the number of minutes involved in obtaining vital signs may vary for different services.

Comment: One commenter asked if CMS would accept vital sign data from fitness wearable devices such as an Apple watch, Garmin, or Fitbit.

Response: Our proposal concerns the number of minutes assumed to be involved in obtaining vital signs for purposes of PFS ratesetting and is not intended to establish requirements regarding how vital signs are obtained.

After consideration of comments received, we are not finalizing our proposal to establish 5 minutes as the new standard for the ''Obtain vital signs'' clinical labor task. However, since we continue to believe that the review standards associated with the clinical labor time for obtaining vital signs have changed over time, we will assign 5 minutes as the input for all codes that include the ''Obtain vital signs'' task for CY 2018, as proposed.

c. Establishment of Clinical Labor Activity Codes

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 for the CY 2019 PFS rulemaking cycle, we understand that the RUC intends to mandate 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 to us would, in turn, help us to simplify and standardize the hundreds of different clinical labor tasks currently listed in our direct PE database.

To help facilitate this transition to the new clinical labor activity codes, we developed a crosswalk to link the old clinical labor tasks to the new clinical labor activity codes. Our crosswalk is for informational purposes only, and would not change either the direct PE input values or the PE RVUs for codes. Instead, we hope that the crosswalk would help us to translate the sprawling, existing data set into a condensed version that would significantly improve the standardization of clinical labor recommendations and improve the ability of commenters to identify concerns with our proposed valuation. For CY 2018 rulemaking, we are displaying 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 as described by the new listing of clinical labor activity codes. These lists are available on the CMS Web site under downloads for the CY 2018 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

(3) Equipment Recommendations for Scope Systems

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

To promote appropriate relativity among the services and facilitate the transparency of our review process, during review of recommended direct PE inputs for the CY 2017 PFS proposed rule, we developed a structure that separates the scope and the associated video system as distinct equipment items for each code. Under this approach, we proposed standalone prices for each scope, and separate prices for the video systems that are used with scopes. We proposed to define the scope video system as including: (1) A monitor; (2) a processor; (3) a form of digital capture; (4) a cart; and (5) a printer. We believe that these equipment components represent the typical case for a scope video system. Our model for this system was the ''video system, endoscopy (processor, digital capture, monitor, printer, cart)'' equipment item (ES031), which we proposed to re-price as part of this separate pricing approach. We obtained current pricing invoices for the endoscopy video system as part of our investigation of these issues involving scopes, which we proposed to use for this re-pricing. We understand that there may be other accessories associated with the use of scopes; we proposed to separately price any scope accessories, and individually evaluate their inclusion or exclusion as direct PE inputs for particular codes as usual under our current policy based on whether they are typically used in furnishing the services described by the particular codes.

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

input prices for these equipment items through future rulemaking.

We proposed these changes only for the reviewed codes for CY 2017 that made use of scopes, along with updated prices for the equipment items related to scopes utilized by these services. But, we did not propose to apply these policies to codes with inputs reviewed prior to CY 2017. We also solicited comment on this separate pricing structure for scopes, scope video systems, and scope accessories, which we could consider proposing to apply to other codes in future rulemaking. In response to comments, we finalized the addition of a digital capture device to the endoscopy video system (ES031) in the CY 2017 PFS final rule. We finalized our proposal to price the system at $33,391, based on component prices of $9,000 for the processor, $18,346 for the digital capture device, $2,000 for the monitor, $2,295 for the printer, and $1,750 for the cart. We also finalized a price of $16,843.87 for the stroboscopy system scope accessory (ES065). We did not finalize price increases for a series of other scopes and scope accessories, as the invoices submitted for these components indicated that they are different forms of equipment with different product IDs and different prices. We did not receive any data to indicate that the equipment on the newly submitted invoices was more typical in its use than the equipment that we were currently using for pricing.

We did not make further changes to existing scope equipment in CY 2017 in order to allow the RUC's PE Subcommittee the opportunity to provide feedback. However, we believed there was some miscommunication on this point, as the RUC's PE Subcommittee workgroup that was created to address scope systems stated that no further action was required following the finalization of our proposal. Therefore, we made further proposals to continue clarifying scope equipment inputs, and sought comments regarding the new set of scope proposals. We welcomed feedback from all stakeholders, including practitioners with direct experience in the use of scope equipment.

We sought comment on several potential categories of scope system PE inputs. We are considering creating a single scope equipment code for each of the five categories detailed in this rule: (1) A rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. Under the current classification system, there are many different scopes in each category depending on the medical specialty furnishing the service and the part of the body affected. We believe that the variation between these scopes is not significant enough to warrant maintaining these distinctions, and we believe that creating and pricing a single scope equipment code for each category would help provide additional clarity. We sought public comment on the merits of this potential scope organization, as well as any pricing information regarding these five new scope categories.

For CY 2018, we proposed two minor changes to PE inputs related to scopes. We proposed to add an LED light source into the cost of the scope video system (ES031), which would remove the need for a separate light source in these procedures. If this proposal were to be finalized, we would remove the equipment time for the separate light source from CPT codes that include the scope video system. We also proposed an increase to the price of the scope video system of $1,000.00 to cover the expense of miscellaneous small equipment associated with the system that falls below the threshold of individual equipment pricing as scope accessories (such as cables, microphones, foot pedals, etc.) We sought comments on the inclusion of the LED light in the scope video system, and the appropriate pricing of the system with the inclusion of these additional equipment items.

We anticipate adopting detailed changes to scope systems at the code level through rulemaking for CY 2019, because we believe that additional feedback from expert stakeholders will improve the details of the proposed changes. We did not propose any additional pricing changes to scope equipment for CY 2018 due to the proposed reorganization into a single type of scope equipment for each of the five scope categories. However, we would consider updating prices for these equipment items through the public request process for price updates, or based on information submitted as part of RUC recommendations.

The following is a summary of the public comments received on the continued organization of scope equipment and our responses:

Comment: Many commenters disagreed with the CMS proposal to create and price a single scope equipment code for each category. Commenters stated that there were significant differences in the scopes used by different specialties, and the proposal to establish a single scope for each category would not sufficiently capture variations across specialties in terms of typical scopes and typical costs. As an example, one commenter stated that the price difference between scopes could be as large as $10,000. Many commenters suggested that CMS should create packages on a per-specialty basis for these five categories of scopes, as applicable.

Response: In light of the information supplied by commenters regarding the significant differences in price and usage across specialties, we will not finalize our proposal to create and price a single scope equipment code for each of the five categories previously identified.

Comment: Commenters supported the CMS proposal to add an LED light source and miscellaneous costs into the price of the scope video system (ES031). Commenters indicated that the addition of the light and $1,000.00 for small various small items like foot pedals and microphones would more accurately describe the resource costs of the scope video system.

Response: We appreciate the comments supporting the proposal. However, we are not finalizing the proposal to add an LED light source and an increase of $1,000 for miscellaneous small equipment to the price of scope video systems for CY 2018. We intend to update the price of the scope video system with these changes for CY 2019 as part of the scope reorganization project.

Comment: Many commenters agreed with the proposal to delay implementation of these proposed changes until CY 2019 and encouraged CMS to request that the RUC review this issue and provide guidance on the correct pricing.

Response: We agree that the anticipated delay on implementation until CY 2019 will allow additional time for stakeholders to provide recommendations on the proper organization and pricing of scope equipment.

Comment: One commenter disagreed with the five categories of scope equipment that CMS identified and finalized in CY 2017. This commenter stated that these five categories did not represent all scope equipment categories and recommended adding a sixth category, a multi-channeled flexible video scope.

Response: We will take the recommendation from the commenter into consideration. We look forward to receiving additional feedback from stakeholders regarding whether adding a sixth category for multi-channeled flexible video scopes would be appropriate as part of the project to organize scope equipment.

Comment: Several commenters stated that some of the scope equipment currently in use was inaccurately priced, and appeared to reflect older technology that has become outdated. One commenter submitted an extensive list of invoices related to the pricing of scope equipment.

Response: We appreciate the submission of additional information related to scope pricing from the commenters. We stated in the proposed rule that we anticipated adopting detailed changes to scope systems at the code level for CY 2019 in order to incorporate additional feedback from expert stakeholders. Since we did not propose any additional pricing changes to scope equipment for CY 2018 due to this proposed reorganization, we believe that it would be more appropriate to delay any price updates until the following year rather than make changes for CY 2018 and, again, shortly thereafter. The general reorganization of scopes taking place in CY 2019 will include updates to scope pricing.

After consideration of comments received, we will not finalize our proposal to create and price a single scope equipment code for each of the five categories previously identified. Instead, we are supportive of the recommendation from the commenters to create scope equipment codes on a per-specialty basis for these five, or potentially six, categories of scopes as applicable. Our goal is to create an administratively simple scheme that will be easier to maintain and helps to reduce administrative burden. We look forward to receiving detailed recommendations from expert stakeholders regarding the number of these scope equipment items that would be typically required for each scope category as well as the proper pricing for each scope.

We are not finalizing our proposal to add an LED light source and an increase to the price of the scope video system of $1,000.00 to cover the expense of miscellaneous small equipment associated. We intend to address these changes for CY 2019 in order to incorporate the aforementioned feedback from expert stakeholders.

(4) Clarivein Kit for Mechanochemical Vein Ablation

In the CY 2017 PFS final rule, we finalized work RVUs and direct PE inputs for two new codes related to mechanochemical vein ablation, CPT codes 36473 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated) and 36474 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites). Following the publication of the final rule, stakeholders contacted CMS and requested that a Clarivein kit supply item (SA122) be added to the direct PE inputs for CPT code 36474, the add-on code for ablation of subsequent veins. They stated that the Clarivein kit was accidentally omitted from the RUC recommendations, and that an additional kit is necessary to perform the service described by the add-on procedure. We solicited comment regarding the use of multiple kits during procedures described by the base and add-on codes to determine whether or not this supply should be included as a direct PE input for CPT code 36474 for CY 2018.

The following is a summary of the public comments received regarding the use of the Clarivein kit supply in CPT code 36474 for CY 2018 and our responses:

Comment: A device manufacturer wrote to explain the proper assembly and use of the Clarivein kit in great detail. The commenter stated that the kit is used to treat a single vein and a separate Clarivein kit is necessary for each vein treated to ensure functionality and safety. The commenter cited an informal survey of their customers which suggested that more than 50 percent of mechanochemical vein ablation procedures require treatment of a subsequent vein. The commenter urged that CMS include the Clarivein kit as a supply input for CPT code 36474.

Response: We appreciate the additional information from the commenter regarding the use of the Clarivein kit supply.

Comment: Several commenters disagreed with the proposed inclusion of the Clarivein kit as a supply input for CPT code 36474. A commenter indicated that a second Clarivein kit might be needed for CPT code 36474 in some cases, but noted that the mechanochemical vein ablation codes have been flagged as new technology and will be reviewed by the RUC during the next two years. This commenter recommended that the number of Clarivein kits necessary for CPT code 36474 should be reviewed at that time.

Response: We agree with the commenter that the decision on whether to include a Clarivein kit in CPT code 36474 should be made as part of a broader review of the direct PE inputs that are typically required to furnish the procedure. We also note that if physicians do not typically use the kit when furnishing services described by the add-on codes, then including the kit as part of the direct PE inputs for the add-on code would represent a significant misvaluation. After consideration of comments received, we are not finalizing the addition of the Clarivein kit to CPT code 36474 at this time, though we will review any recommendations received for consideration in future rulemaking.

(5) Removal of Oxygen From Non-Moderate Sedation Post-Procedure Monitoring

After finalizing the creation of separately billable codes for moderate sedation during the CY 2017 PFS final rule, we received additional recommendations to remove the oxygen gas supply item (SD084) from a series of CPT codes that were previously valued with moderate sedation as an inherent part of the procedure. Because oxygen gas is included in the moderate sedation pack contained within the separately billed moderate sedation codes, we believe that the continued inclusion of the oxygen gas in these codes is a duplicative supply. Therefore, we proposed to remove the oxygen gas from the codes in Table 5.

TABLE 5—CY 2018 PROPOSED REMOVAL OF OXYGEN (SD084) FROM NON-MODERATE SEDATION POST-PROCEDURE MONITORING

HCPCS	NF/F	Current (liters)	Cost
31622	NF	90	−0.27
31625	NF	105	−0.32
31626	NF	135	−0.41
31627	NF	150	−0.45

TABLE 5—CY 2018 PROPOSED REMOVAL OF OXYGEN (SD084) FROM NON-MODERATE SEDATION POST-PROCEDURE MONITORING—Continued

HCPCS	NF/F	Current (liters)	Cost
31628	NF	120	−0.36
31629	NF	105	−0.32
31632	NF	54	−0.16
31633	NF	60	−0.18
31652	NF	180	−0.54
31653	NF	225	−0.68
31654	NF	90	−0.27
52647	NF	10	−0.03
52648	NF	10	−0.03
90870	NF	198	−0.59

Comment: Several commenters supported our proposal to remove the oxygen gas for this list of codes.

Response: We appreciate the support for our proposal. After consideration of the comments, we are finalizing our proposal to remove the oxygen gas from the codes listed in Table 5.

(6) Technical Corrections to Direct PE Input Database and Supporting Files

Subsequent to the publication of the CY 2017 PFS final rule, stakeholders alerted us to several clerical inconsistencies in the direct PE database. We proposed to correct these inconsistencies as described in the proposed rule and reflected in the CY 2018 proposed direct PE input database displayed on the CMS Web site under downloads for the CY 2018 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

For CY 2018, we proposed to address the following inconsistencies:

- For CY 2018, we proposed to make direct PE changes for CPT code 96416 (Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump) to improve payment accuracy, in response to a stakeholder inquiry regarding the use of the ambulatory IV pump equipment for this service. We proposed to add 6 additional minutes of RN/OCN clinical labor (L056A), 4 minutes for the ''Review charts by chemo nurse regarding course of treatment & obtain chemotherapy-related medical hx'' task, and 2 minutes for the ''Greet patient and provide gowning'' task. We proposed to add 1 quantity of the IV infusion set supply (SC018) and proposed to lower the quantity from 2 to 1 of the 20 ml syringe supply (SC053). We proposed to add 1800 minutes for the new ambulatory IV pump equipment, and we proposed to increase the equipment time of the medical recliner chair (EF009) from 83 minutes to 89 minutes to match the increase in RN/OCN clinical labor. For CY 2018, these proposed direct PE changes would be used to calculate the PE RVU for CPT code 96416. We sought comments on these proposed direct PE refinements.
- We proposed to correct an anomaly in the postservice work time for CPT code 91200 (Liver elastography, mechanically induced shear wave (*e.g.*, vibration), without imaging, with interpretation and report) by changing it from 5 minutes to 3 minutes, which also results in a refinement in the total work time for the code from 18 minutes to 16 minutes.
- In the process of making updates to our direct PE database, we discovered a series of discrepancies between the finalized direct PE inputs and the values entered into the database from previous calendar years. To reconcile these discrepancies, we proposed the following direct PE refinements:

TABLE 6—DIRECT PE DATABASE DATA DISCREPANCIES AND PROPOSED CHANGES

HCPCS	Input code	Input code description	NF/F	Old	New	Cost
11307	SF033	scalpel with blade, surgical (#10–20)	NF	1	2	0.69
11311	SG056	gauze, sterile 4in x 4in (10 pack uou)	NF	1	2	0.80
11311	SH046	lidocaine 1% w-epi inj (Xylocaine w-epi)	NF	10	4	−0.38
11719	L037D	Greet patient, provide gowning, ensure appropriate medical records are available.	NF	1	3	0.74
11719	L037D	Provide pre-service education/obtain consent	NF	1	2	0.37
11719	L037D	Prepare room, equipment, supplies	NF	1	2	0.37
11719	L037D	Clean room/equipment by physician staff	NF	1	3	0.74
17312	SL097	OCT Tissue-Tek	NF	8	6	−0.12
17313	SF004	blade, microtome	NF	1	0	−1.72
17313	SF044	blade, surgical, super-sharp	NF	0	1	4.17
17313	SG056	gauze, sterile 4in x 4in (10 pack uou)	NF	3	0	−2.39
17313	SG088	tape, foam, elastic, 2in (Microfoam)	NF	10	8	−0.01
17314	SG056	gauze, sterile 4in x 4in (10 pack uou)	NF	2	0	−1.60
17314	SL097	OCT Tissue-Tek	NF	8	6	−0.12
17315	SL078	histology freezing spray (Freeze-It)	NF	0	0.2	0.29
19283	L043A	Service total costs	NF	55	54	−0.43
19286	L051B	Service total costs	NF	30	31	0.51
19286	EL015	room, ultrasound, general	NF	19	20	1.40
19286	EQ168	light, exam	NF	19	20	0.00
23333	L037D	Post service total costs	F	63	90	9.99
28045	SC029	needle, 18–27g	NF	2	1	−0.09

TABLE 6—DIRECT PE DATABASE DATA DISCREPANCIES AND PROPOSED CHANGES—Continued

HCPCS	Input code	Input code description	NF/F	Old	New	Cost
32405	L041B	Service total costs	NF	52	57	2.05
37765	L037D	Service total costs	NF	91	94	1.11
37766	L037D	Service total costs	NF	121	124	1.11
45171	SJ052	swab, procto 16in	F	2	3	0.12
45172	L037D	Service total costs	F	6	12	2.22
45172	SJ052	swab, procto 16in	F	2	3	0.12
52214	SH047	lidocaine 1%–2% inj (Xylocaine)	NF	1	50	1.72
72120	EL012	room, basic radiology	NF	16	17	0.48
72148	L047A	Service total costs	NF	47	49	0.84
74230	L041B	Technologist QC's images in PACS, checking for all images, reformats, and dose page.	NF	0	2	0.82
91013	EF023	table, exam	NF	0	9	0.03
91013	EF015	mayo stand	NF	0	9	0.01
91013	EQ235	suction machine (Gomco)	NF	0	9	0.02
91013	EQ181	manometry system (computer, transducers, catheter)	NF	0	9	1.15
91013	EQ339	manometry accessory cable	NF	0	9	0.05
91013	ED050	PACS Workstation Proxy	NF	0	9	0.20
91132	EQ019	EGG monitoring system	NF	22	30	0.83
92227	EL006	lane, screening (oph)	NF	12	0	−1.07
92227	EL005	lane, exam (oph)	NF	0	12	1.15
93017	L051A	Preservice total costs	NF	15	5	−5.10
95819	SG079	tape, surgical paper 1in (Micropore)	NF	6	42	0.07

The proposed PE RVUs displayed in Addendum B on our Web site were calculated with the inputs displayed in the CY 2018 proposed direct PE input database.

The following is a summary of the public comments received on these proposed direct PE refinements and our responses:

Comment: Several commenters indicated their support for the proposed direct PE changes for CPT code 96416. Commenters stated that the proposed changes accurately reflected provider time and intensity in providing this service and would help to ensure that cancer care and treatment are appropriately valued and reimbursed. There were no comments opposed to the proposed changes.

Response: We appreciate the support for our proposal from the commenters. We are finalizing the direct PE changes to CPT code 96416 as proposed.

Comment: One commenter was uncertain how CMS arrived at the conclusion that there were discrepancies of the direct PE inputs for the identified codes in Table 5 of the proposed rule. The commenter disagreed with several of the proposed changes to the data discrepancies and requested that CMS clarify the method used to determine these discrepancies in the direct PE inputs.

Response: Prior to the publication of the CY 2018 proposed rule, we identified a series of anomalies in our direct PE database where the entered data did not match the values that had been finalized through rulemaking. For example, in CY 2013 we finalized the RUC recommendation to include 1 surgical super-sharp blade (SF044) in CPT code 17313. However, the direct PE database for CPT code 17313 instead included 1 microtome blade (SF004), which was not included in the finalized PE inputs at all. This discrepancy was due to a technical issue that occurred while inputting the values into the database during the CY 2013 rule cycle. The same pattern applies to the other discrepancies in the data that we identified for the codes on the table above: the information in the database was discrepant with the direct PE inputs that had been finalized in previous calendar years. We proposed this series of changes in order to ensure that the PE inputs in our database matched the inputs that have been finalized through rulemaking. We did not propose to make changes in the direct PE inputs of these codes based on clinical judgment or new recommendations, only to correct the technical anomalies that had crept into the direct PE database via user error. As a result, after consideration of comments received, we are finalizing the proposed changes to the direct PE database detailed in the previous table.

Comment: One commenter alerted CMS to a series of similar technical corrections in the Physician Work Time file. The commenter stated that there was an issue with 108 codes that had incorrect immediate postservice times and total times that had been identified in the CY 2014 final rule as due to an inadvertent error. The commenter also stated that in the CY 2014 PFS final rule with comment period physician work time file, CMS implemented the correct number and level of postoperative visits and correct total times, though inadvertently kept erroneously inflated immediate postservice times for these codes. In addition, the commenter stated that for CY 2015 up to the present, this erroneous immediate postservice time was added back into the total time, resulting in the total times being again incorrect for these 100+ services. The commenter submitted additional data for these codes and requested that CMS implement a technical correction.

Response: After reviewing the data supplied by the commenter, we agree that these 108 codes contained an erroneous amount of total time. As the commenter mentioned, we previously addressed these codes in the CY 2014 PFS final rule with comment period (78 FR 74259) with a technical correction. We believe this correction will populate the physician time file with data that, absent the inadvertent error, would have been present in the time file. We are finalizing a technical correction to the physician work time of these codes as noted in Table 7.

TABLE 7—TECHNICAL CORRECTION TO PHYSICIAN WORK TOTAL TIME

CPT code	CY 2017 total time	CY 2018 total time
19368	830	770
19369	755	690
20100	296	266
20816	809	697
20822	685	590
20824	784	690
20827	728	625

TABLE 7—TECHNICAL CORRECTION TO PHYSICIAN WORK TOTAL TIME—Continued

CPT code	CY 2017 total time	CY 2018 total time
20838	1085	986
20955	1095	957
20969	1216	1048
20970	1156	988
20973	1156	988
21139	458	466
21151	715	686
21154	857	853
21155	972	939
21188	570	572
22100	475	372
22101	490	387
22110	595	479
22112	675	530
22114	685	530
22210	763	609
22212	788	640
22214	763	624
22220	733	585
22222	818	651
22224	808	666
22315	315	252
22325	652	528
22326	600	480
22327	723	604
22548	800	673
22556	693	557
22590	630	501
22595	650	521
22600	595	490
22610	656	549
22630	599	487
22800	695	571
22802	670	538
22804	768	595
22808	691	530
22810	751	595
22812	854	700
32650	400	290
32656	517	377
32658	420	330
32659	492	357
32661	400	300
32664	420	330
32820	1054	854
33236	376	346
33237	516	456
33238	517	472
33243	642	537
33321	949	754
33417	1003	750
33502	973	688
33503	1213	838
33504	1043	789
33600	958	628
33602	928	628
33606	1058	728
33608	938	668
33690	883	636
33702	956	751
33722	908	608
33732	848	578
33735	1073	770
33736	848	548
33750	968	722
33764	1023	750
33767	938	608
33774	1348	998
33788	1033	736

TABLE 7—TECHNICAL CORRECTION TO PHYSICIAN WORK TOTAL TIME—Continued

CPT code	CY 2017 total time	CY 2018 total time
33802	751	556
33803	811	586
33820	558	414
33824	811	615
33840	831	639
33845	978	726
33851	891	700
33852	951	719
33853	998	668
33917	878	608
33920	958	658
33922	756	546
33974	464	314
34502	951	741
35091	995	790
35694	546	456
35901	602	482
35903	506	416
49422	212	182
49429	407	317
50320	598	524
50845	823	613
56632	1013	683
60520	624	474
60521	595	445
60522	703	533
61557	627	510
63700	497	401
63702	567	463
63704	732	609
63706	800	679
64712	245	294

We note that the technical correction to the total work time of these codes will not have a direct effect on the calculation of their individual RVUs, as changes to work time affect code valuation at the specialty level, not the service level, in the ratesetting methodology. For additional information, please see section II.B.2.c. of this final rule regarding the allocation of PE to services.

Comment: In addition to these 108 codes detailed above, the same commenter identified seven additional codes with a need for potential technical corrections in their physician work times. Listed in order, the commenter identified these issues:

- For CPT code 28122 (Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (*e.g.*, osteomyelitis or bossing); tarsal or metatarsal bone, except talus or calcaneus), in the CY2012 Final Rule CMS finalized 0.5 99238 discharge visits. The commenter stated that the CY 2018 Physician Work Time file incorrectly still listed this service as having one 99238 visit.
- For CPT code 46900 (Destruction of lesion(s), anus (*e.g.*, condyloma, papilloma, molluscum contagiosum, herpetic vesicle), simple; chemical), the commenter stated that the CY 2018 Physician Work Time file inadvertently omitted one 99213 post-operative visit for this 10-day global service. When this service was last reviewed by the PEAC in March 2004, the PEAC recommended and CMS finalized 36 minutes of RN/LPN/MTA post-service period time, which corresponds with one 99213 office visit bundled into the 10-day global period. Therefore, the commenter stated that the CY 2018 direct PE inputs and the physician work time file for this service did not match.
- For CPT code 47562 (Laparoscopy, surgical; cholecystectomy), the CY 2013 final rule only detailed refining the preservice work time and made no mention of not accepting the RUC recommended postoperative visits. The commenter stated that the work time file should have two 99213 post-operative visits instead of one.
- For CPT code 76948 (Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation), the commenter stated that the CY 2014 final rule did not mention any refinements to the RUC-recommended times for the interim final valuation of this service. For the CY 2015 final rule, the preamble text discussed removing preservice and postservice work times for a different service in this family of codes, CPT code 76945. The commenter stated that it appeared that this refinement was inadvertently applied to both CPT codes 76948 and 76945 in the work time file.
- For CPT code 77767 (Remote afterloading high dose rate radionuclide skin surface brachytherapy, includes basic dosimetry, when performed; lesion diameter up to 2.0 cm or 1 channel), the commenter stated that the CY 2016 NPRM work time file included the RUC-recommended preservice, intraservice and postservice work times but incorrectly summed the total time (listed as CPT dummy code number 7778A). The commenter stated that this error appeared to have been carried forward to the present, since there was no mention of any work time refinements for this code in the CY 2016 final rule.
- For CPT codes (93668 Peripheral arterial disease (PAD) rehabilitation, per session) and 96904 (Whole body integumentary photography, for monitoring of high risk patients with dysplastic nevus syndrome or a history of dysplastic nevi, or patients with a personal or familial history of melanoma), the RUC had recommended and CMS had agreed that these services do not include physician work. However, the commenter stated that the CY 2018 physician work time file

erroneously listed physician time for these services.

The commenter requested for the work time for these services to be corrected in the CY 2018 Physician Work Time file for the CY 2018 final rule.

Response: After reviewing the data supplied by the commenter, we agree that six of the seven codes identified by the commenter contained an erroneous amount of work time. We do not agree with the commenter regarding CPT code 76948, as the refinements to work time that took place were finalized as intended, and were not due to confusion with CPT code 76945 (80 FR 70970–70971). For the other six codes, we are finalizing technical corrections to the work time file as described by the commenter.

After consideration of comments received, we are finalizing the direct PE changes to CPT code 96416 as proposed, the correction to an anomaly in the postservice work time for CPT code 91200 as proposed, and the proposed changes to the direct PE database detailed in Table 6. We are also finalizing technical corrections in physician work times as detailed above in the preceding paragraphs.

(7) Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. For CY 2018, we proposed the following price updates for existing direct PE inputs.

We proposed to update the price of thirteen supplies and one equipment item in response to the public submission of invoices. For the details of these proposed price updates, please refer to section II.H, of this final rule, Table 16: Invoices Received for Existing Direct PE Inputs.

We did not propose to update the price of the blood warmer (EQ072), the cell separator system (EQ084), or the photopheresor system (EQ206) equipment items. The only pricing information that we received for these three equipment items was an invoice that included a hand-written price over redacted information. We were unable to verify the accuracy of this invoice. We are also not proposing to update the price of the DNA image analyzer (ACIS) (EP001) equipment item, due to the inclusion of many components on the submitted invoice that are not part of the price of the DNA image analyzer. We were unable to determine which of these components were included in the cost of the DNA image analyzer, and which of these components were unrelated types of equipment. To price these equipment items accurately, we believe that we need additional information. We continued to use the current price for these equipment items pending the submission of additional pricing information. We welcomed the submission of updated pricing information regarding these equipment items through valid invoices from commenters and other stakeholders.

We also proposed to change the name of the ED050 equipment from the ''PACS Workstation Proxy'' to the ''Technologist PACS workstation.'' In the CY 2017 final rule (81 FR 80180–80182), we finalized a policy to add a professional PACS workstation (ED053) to the list of approved equipment items, and we believe that renaming ED050 to the technologist PACS workstation would help to alleviate potential confusion between the two PACS workstations.

We routinely accept public submission of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often these invoices are submitted in conjunction with the RUC-recommended values for the codes. For CY 2018, we note that some stakeholders have submitted invoices for new, revised, or potentially misvalued codes after the February 10th deadline established for code valuation recommendations. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline. However, we would consider invoices submitted as public comments during the comment period following the publication of the proposed rule, and would consider any invoices received after February or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices.

The following is a summary of the public comments received on updates to prices for new and existing direct PE inputs and our responses:

Comment: Several commenters supported the price changes that CMS proposed in response to the submission of invoices.

Response: We appreciate the response from the commenters, as well as the timely submission of these invoices prior to the February 10th deadline.

Comment: One commenter, in response to the CMS request for additional updated pricing information for the blood warmer (EQ072), the cell separator system (EQ084), the photopheresor system (EQ206), and the DNA image analyzer (EP001) equipment items, submitted an attachment with current valid invoices. The commenter urged CMS to use these invoices to update the price of these equipment items.

Response: We appreciate the additional invoices from the commenter in response to our request for more information in the proposed rule. We are finalizing updated prices for all four of these equipment items as detailed in Table 16: Invoices Received for Existing Direct PE Inputs. For the first three equipment items, we are finalizing the price indicated on their respective invoices. For the DNA image analyzer (EP001), we are finalizing a price of $248,946.30, based on the submitted price of $258,042.30 minus the price of the user training ($6,800.00), the instructor-led online training ($646.00) and the shipping and handling costs ($1,650.00). These costs are allocated through the indirect allocation under the established PE methodology. We are also finalizing a change in the name of the EP001 equipment from ''DNA image analyzer'' to ''DNA/digital image analyzer'' as requested by commenters.

Comment: Several commenters disagreed with the proposed price of $4.10 for the UV goggles (SJ027) supply and the proposal to treat the patient and clinician goggles used for photodynamic therapy as the same SJ027 supply item rather than create a new supply code. One commenter stated they were concerned with the blended price methodology used by CMS to calculate the proposed price, and indicated that the current market price was higher than the proposed price for the SJ027 supply. Another commenter stated that the goggles used for photodynamic therapy are proprietary to the company that produces aminolevulinic acid and are not available through other sources, which made the use of the proposed blended price inappropriate. Commenters submitted several additional invoices for the price of both the UV goggles and the patient/clinician goggles used for photodynamic therapy.

Response: We appreciate the additional information supplied by the commenters regarding these different types of goggles, especially the additional pricing information included in the invoices. After consideration of the comments, we agree that these are two separate supply items and that it would not be appropriate to blend their prices together. We are finalizing a price of $7.95 for the UV goggles (SJ027) and a price of $6.00 for the new patient/clinician goggles (SD326). Regarding the

new SD326 supply, since these very similar goggles were produced by the same company and sold for the same price, we did not agree that each of them should be described by a separate supply code and will instead group them together as ''patient/clinician goggles'' under a single supply code.

Comment: Several commenters disagreed with the price update to the LMX 4% anesthetic cream (SH092) supply and the use of an online price quote found by CMS. A commenter stated that physicians' only purchased drugs from reputable medical suppliers in order to ensure the safety of their patients and that the current price of the SH092 supply was accurate. The commenters also submitted three additional invoices for the SH092 supply.

Response: We disagree with the commenters that the use of prices obtained online carries an elevated risk of patient complications due to false or improperly prepared medication. We have no reason to believe that healthcare providers will typically purchase medical supplies and equipment at higher than rates generally available on the market, and LMX 4% anesthetic cream is a widely available non-prescription supply item that can be commonly found both online and in pharmaceutical stores. We have no reason to believe the price quote that we obtained online is atypical of market rates or reflects an inferior product that represents a danger to patients. However, given commenters' suggestions that some physicians purchase the item at prices higher than the best market price, we will average together our online price quote together with the three invoices submitted by the commenters. We are therefore finalizing a price of $1.357 for the SH092 supply based on the use of this methodology.

Comment: One commenter addressed the proposed update to the price of the INR test strips (SJ055) supply. The commenter stated that the price change would lead to substantial reductions for HCPCS codes G0248 and G0249, and while the commenter agreed that the market price for INR test strips had changed since the item was priced initially 15 years ago, the current direct PE inputs for these codes did not reflect the resources typically required to furnish the services.

Response: We appreciate the additional information submitted by the commenter. Although we are finalizing the price of the INR test strip (SJ055) at the proposed rate of $5.66, we agree that the current direct PE inputs for these services may not reflect the typical resources that they require. For additional details regarding the INR Monitoring codes and refinements to their direct PE inputs, please refer to the code valuation section (II.H) of this final rule.

Comment: One commenter requested that the cytology, preservative and vial, (cytospin) 88108—30ml (SL501) supply should be deleted from the CMS supply database. The commenter stated that this supply is redundant with the cytology, preservative and vial (Preserv-cyt) (SL040) supply and that the quantity of SL040 for CPT code 88108 should be 1 item. The commenter stated that this was an error made in 2014 and in 2015 when CPT code 88108 code was reviewed and urged CMS to correct this error.

Response: After reviewing the supply inputs for CPT code 88108, we agree with the commenter. The SL501 supply appeared in no other CPT codes and did not have a price. We agree that the resources typically required to furnish CPT code 88108 are more accurately described by including 1 quantity of the SL040 supply. We are finalizing this addition to CPT code 88108 and the removal of the SL501 supply from our database.

Comment: One commenter called attention to the fact that there are a number of supply and equipment items that currently do not have a price. The commenter stated that the lack of a price adversely affects the specialties when they use these supply and equipment items since the cost of the item is not being factored into the formula used to determine the PE RVU. The commenter stated that CMS should ensure that all supplies and equipment have a price included in the database in order to facilitate payment for all the resources associated with a service.

Response: We appreciate the extra attention drawn by the commenter to the supply and equipment items currently present in our database that lack a price. We encourage commenters to submit invoices to update the pricing of these supplies and equipment items through the process detailed above.

Comment: One commenter stated that CMS provides no additional payments for drug-coated balloons and bundles those payments within the payments of existing procedures for office-based procedures. The commenter indicated that CMS proposed to package the device costs of drug coated balloons into the costs of the procedures with which the device is utilized, which meant that angioplasty procedures with drug coated balloons and plain balloons will receive the same payment amount. The commenter detailed the clinical benefits of drug coated balloons in angioplasty and requested an alternate payment structure to avoid patient access barriers to this technology.

Response: We appreciate the additional information supplied by the commenter regarding the use of drug coated balloons. We encourage stakeholders to submit comments with additional information when practice patterns for services may change over time, which may lead to the nomination of individual services as potentially misvalued. However, the commenter did not provide specific CPT codes in which these new treatments would be utilized, nor did the commenter supply evidence to indicate that the use of these drug coated balloons would be typical. We also did not receive recommendations from the RUC or other medical specialty groups requesting the addition of drug coated balloons as a new supply item. As a result, we will retain the current direct PE inputs for angioplasty services unless otherwise mentioned in this final rule.

Comment: One commenter stated concerns regarding the need for more accurate pricing of expensive equipment and disposable supplies. The commenter noted that the current pricing of supplies and equipment, based on the voluntary submission of small numbers of invoices, creates the potential for highly biased, non-representative invoices, and makes these cost inputs relatively unreliable. This potential overestimation of resource costs augments the reimbursement disparities between proceduralists and primary care physicians, inappropriately rewards physicians who perform procedures, and provides an improper incentive for overuse of these services. The commenter suggested addressing this issue through subjecting expensive equipment and supplies to fixed discounting of their costs over time.

Response: We agree with the commenter that the methodology used for price updates to new and existing supplies and equipment has the potential to create disparities in resource cost. As we have stated in past rulemaking, such as in the CY 2016 final rule with comment period (80 FR 70896), we do not believe that very small numbers of voluntarily submitted invoices are likely to reflect typical resource costs and create the potential for overestimation of supply and equipment costs. As part of our authority under section 1848(c)(2)(M) of the Act to collect and use information on physicians' services in the determination of relative values under the PFS, which was added to the statute by section 220(a)(1) of the PAMA, we

have initiated a contract to collect data that we hope will facilitate more accurate prices for supplies and equipment. Based on the data collected and additional stakeholder feedback, we may make proposals to update supply and equipment pricing in future rulemaking. We will also consider other suggestions to address the issues involving high cost supplies and equipment, such as the fixed discounting recommended by the commenter.

After consideration of comments received, we are finalizing the updated supply and equipment prices as detailed in Table 16: Invoices Received for Existing Direct PE Inputs.

4. Adjustment to Allocation of Indirect PE for Some Office-Based Services

As we explain in section II.B.2.c.(2) of this final rule, we allocate indirect costs for each code on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. Indirect expenses include administrative labor, office expense, and all other expenses. For PFS services priced in both the facility and non-facility settings, the difference in indirect PE RVUs between the settings is driven by differences in direct PE inputs for those settings since the other allocator of indirect PE, the work RVU, does not differ between settings. For most services, the direct PE input costs are higher in the nonfacility setting than in the facility setting. As a result, indirect PE RVUs allocated to these services are higher in the nonfacility setting than in the facility setting. When direct PE inputs for a service are very low, however, the allocation of indirect PE RVUs is almost exclusively based on work RVUs, which results in a very small (or no) site of service differential between the total PE RVUs in the facility and nonfacility setting.

Some stakeholders have suggested that for codes in which direct PE inputs for a service are very low, this allocation methodology does not allow for a site of service differential that accurately reflects the relative indirect costs involved in furnishing services in nonfacility settings. Among the services most affected by this anomaly are the primary therapy and counseling services available to Medicare beneficiaries for treatment of behavioral health conditions, including substance use disorders. For example, for the most commonly reported psychotherapy service (CPT code 90834), the difference between the nonfacility and facility PE RVUs is only 0.02 RVUs, which seems unlikely to represent the difference in relative 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 agree with these stakeholders that the site of service differential for these services that is 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 translates to approximately $0.72, would be 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 believe it would be appropriate to modify the existing methodology for allocating indirect PE RVUs in order to better reflect the relative indirect PE resources involved in furnishing these kinds of services in the nonfacility setting.

In examining the range of services furnished in the nonfacility setting that are most affected by this circumstance, we identified HCPCS codes that describe face-to-face services, have work RVUs greater than zero, and are priced in both the facility and nonfacility setting. From among these codes, we further selected those with the lowest ratio between nonfacility PE RVUs and work RVUs. We selected 0.4 as an appropriate threshold based on several factors, including the range of nonfacility PE RVU to work RVU ratios among the codes identified. Based on these criteria, there were fewer than 50 codes that we identified with a ratio of less than 0.4 nonfacility PE RVUs for each work RVU, most of which are primarily furnished by behavioral health professionals, for a potential modification to our indirect PE allocation methodology.

In considering how to address the anomaly and ensure that an appropriate number of indirect PE RVUs are allocated to these services in the nonfacility setting, we looked at the indirect, nonfacility PE RVU for the most commonly billed physician office visit, CPT code 99213, which is billed by a wide range of physicians and non-physician practitioners under the PFS. We believe that the indirect PE costs allocated to services reported with CPT code 99213, including administrative labor and office rent, would be common for a broad range of physicians and non-physician practitioners across the PFS. We recognize that the services we seek to address are primarily furnished by behavioral health professionals who may be unlikely to incur some of the costs incurred by other practitioners furnishing a broader range of medical services. For instance, a practitioner furnishing a broader range of primary care services likely requires separate office and examination room space, and storage for disposable medical supplies and equipment. Some costs, however, such as those for office staff and records maintenance, would be analogous.

We looked at the relationship between indirect PE and work RVUs for CPT code 99213 as a marker because that is the most commonly and broadly reported PFS code that describes face-to-face office-based services. We compared the relationship between indirect PE and work RVUs for the set of HCPCS codes that we identified using the criteria discussed above and found that for the significant majority of codes, that ratio was at least 0.4 nonfacility PE RVUs for each work RVU. We believe the 0.4 nonfacility PE RVUs can serve as an appropriate marker that appropriately reflects the relative resources involved in furnishing these services.

For the fewer than 50 outlier codes identified using the criteria above, we believe it would be appropriate to establish a minimum nonfacility indirect PE RVU that would be a better reflection the resources involved in furnishing these services. We propose to set the nonfacility indirect PE RVUs for these codes using the indirect PE RVU to work RVU ratio for the most commonly furnished office-based, face-to-face service (CPT 99213) as a marker. Specifically, for each of these outlier codes, we propose to compare the ratio between indirect PE RVUs and work RVUs that result from the preliminary application of the standard methodology to the ratio for the marker code, CPT code 99213. Our proposed change in the methodology would then increase the allocation of indirect PE RVUs to the outlier codes to at least one quarter of the difference between the two ratios. We believe this approach reflects a reasonable minimum allocation of indirect PE RVUs, but we do not currently have empirical data that would be useful in establishing a more precise number.

In developing the proposed PE RVUs for CY 2018, we proposed to implement only one quarter of this proposed minimum value for nonfacility indirect PE for the outlier codes. We recognize that this change in the PE methodology could have a significant impact on the allocation of indirect PE RVUs across all PFS services. In making significant changes to the PE methodology in

previous years, we have implemented such changes using 4 year transitions, based largely on concerns that some specialties experience significant payment reductions with changes in PE relativity, and a transition period allows for a more gradual adjustment for affected practitioners. Under the approach we proposed, we estimate that approximately $40 million, or approximately 0.04 percent of total PFS allowed charges, would shift within the PE methodology for each year of the proposed 4-year transition, including for CY 2018. We also note that we proposed to exclude the codes directly subject to this proposed change from the misvalued code target calculation because the proposed change is a methodological change to address an anomaly produced by our indirect PE allocation process as opposed to a change to address misvalued codes. The PE RVUs displayed in Addendum B on our Web site were calculated with the one quarter of the indirect PE adjustment factor implemented.

The following is a summary of the public comments received on our proposed change to the indirect PE methodology for some office-based services.

Comment: Several commenters supported the CMS proposal. Commenters stated that the proposal would more accurately reflect the resource costs incurred by psychiatrists providing services for patients with mental health and substance use disorders in nonfacility settings. One commenter indicated their support for the commitment of greater resources toward behavioral and mental health services given the ongoing opioid crisis. Commenters were also supportive of the proposal to exclude the codes directly impacted by this change in methodology from the misvalued code target.

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

Comment: One commenter disagreed with the CMS proposal. The commenter stated that this change to PE methodology could have a significant impact on the allocation of indirect PE RVUs across all PFS services, with approximately 0.04 percent of the total PFS allowed charges shifting within the PE methodology. The commenter recommended that the proposal should not be finalized until it was discussed through the RUC process, and that the codes in question should be placed on the misvalued code list.

Response: We appreciate the feedback from the commenter on our proposal. We note that the RUC has generally provided recommendations on a routine basis regarding work, work time, and direct PE inputs. We do not believe that placing these codes on the misvalued code list for additional RUC review would serve to address the issues identified in our proposal, as we do not have reason to believe that the work or direct PE inputs assigned to these services are inaccurate. However, we welcome recommendations from the RUC or other interested stakeholders on any aspects of the PFS ratesetting methodology, including elements that have not traditionally been provided such as indirect PE allocation. We believe that CMS receiving public input on potential changes to the methodology is critical and that notice and comment rulemaking is the best way to obtain such input. We do not agree that changes in the methodology need to be developed or discussed as part of the RUC process prior to being implemented through notice and comment rulemaking.

After consideration of comments received, we are finalizing our proposed change to the indirect PE methodology for some office-based services.

C. Determination of Malpractice Relative Value Units (RVUs)

1. Overview

Section 1848(c) of the Act requires that each service paid under the PFS be composed of three components: Work, PE, and malpractice (MP) expense. As required by section 1848(c)(2)(C)(iii) of the Act, beginning in CY 2000, MP RVUs are resource based. Section 1848(c)(2)(B)(i) of the Act also requires that we review, and if necessary adjust, RVUs no less often than every 5 years. In the CY 2015 PFS final rule with comment period, we implemented the third review and update of MP RVUs. For a comprehensive discussion of the third review and update of MP RVUs see the CY 2015 proposed rule (79 FR 40349 through 40355) and final rule with comment period (79 FR 67591 through 67596).

To determine MP RVUs for individual PFS services, our MP methodology is composed of three factors: (1) Specialty-level risk factors derived from data on specialty-specific MP premiums incurred by practitioners, (2) service level risk factors derived from Medicare claims data of the weighted average risk factors of the specialties that furnish each service, and (3) an intensity/complexity of service adjustment to the service level risk factor based on either the higher of the work RVU or clinical labor RVU. Prior to CY 2016, MP RVUs were only updated once every 5 years, except in the case of new and revised codes.

As explained in the CY 2011 PFS final rule with comment period (75 FR 73208), MP RVUs for new and revised codes effective before the next 5-year review of MP RVUs were determined either by a direct crosswalk from a similar source code or by a modified crosswalk to account for differences in work RVUs between the new/revised code and the source code. For the modified crosswalk approach, we adjusted (or scaled) the MP RVU for the new/revised code to reflect the difference in work RVU between the source code and the new/revised work RVU (or, if greater, the difference in the clinical labor portion of the fully implemented PE RVU) for the new code. For example, if the proposed work RVU for a revised code was 10 percent higher than the work RVU for its source code, the MP RVU for the revised code would be increased by 10 percent over the source code MP RVU. Under this approach, the same risk factor was applied for the new/revised code and source code, but the work RVU for the new/revised code was used to adjust the MP RVUs for risk.

In the CY 2016 PFS final rule with comment period (80 FR 70906 through 70910), we finalized a policy to begin conducting annual MP RVU updates to reflect changes in the mix of practitioners providing services (using Medicare claims data), and to adjust MP RVUs for risk, intensity and complexity (using the work RVU or clinical labor RVU). We also finalized a policy to modify the specialty mix assignment methodology (for both MP and PE RVU calculations) to use an average of the 3 most recent years of data instead of a single year of data. Under this approach, for new and revised codes, we generally assign a specialty risk factor to individual codes based on the same utilization assumptions we make regarding the specialty mix we use for calculating PE RVUs and for PFS budget neutrality. We continue to use the work RVU or clinical labor RVU to adjust the MP RVU for each code for intensity and complexity. In finalizing this policy, we stated that the specialty-specific risk factors would continue to be updated through notice and comment rulemaking every 5 years using updated premium data, but would remain unchanged between the 5-year reviews.

In CY 2017, we finalized the eighth GPCI update, which reflected updated MP premium data. We did not propose to use the updated MP premium data to propose updates for CY 2017 to the specialty risk factors used in the calculation of MP RVUs because it was inconsistent with the policy we previously finalized in the CY 2016 PFS

final rule with comment period, whereby we indicated that the specialty-specific risk factors would continue to be updated through notice and comment rulemaking every 5 years using updated premium data, but would remain unchanged between the 5-year reviews. However, we solicited comment on whether we should consider doing so, perhaps as early as for CY 2018, prior to the fourth review and update of MP RVUs that must occur no later than CY 2020. After consideration of the comments received, we stated that we would consider the possibility of using the updated MP data to update the specialty risk factors used in the calculation of the MP RVUs prior to the next 5-year update in future rulemaking (81 FR 80191 through 80192). Since MP premium data are used to update both the MP GPCIs and the MP RVUs, going forward we believe it would be logical to align the update of MP premium data used to determine the MP RVUs with the update of the MP GPCI. Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years. The next review of the GPCIs must occur by CY 2020.

In the CY 2018 PFS proposed rule, we proposed to use the most recent data for the MP RVUs for CY 2018 and to align the update of MP premium data and MP GPCIs to once every 3 years. We sought comment on these proposals, and we also sought comment on methodologies and sources that we might use to improve the next update of MP premium data.

2. Methodology for the Revision of Resource Based Malpractice RVUs

a. General Discussion

The proposed MP RVUs were calculated based on updated malpractice premium data obtained from state insurance rate filings by a CMS contractor. The methodology used in calculating the proposed CY 2018 review and update of resource based MP RVUs largely paralleled the process used in the CY 2015 update. The calculation requires using information on specialty-specific malpractice premiums linked to specific services based upon the relative risk factors of the various specialties that furnish a particular service. Because malpractice premiums vary by state and specialty, the malpractice premium information must be weighted geographically and by specialty. Accordingly, the proposed MP RVUs were based upon four data sources: CY 2014 and CY 2015 malpractice premium data; CY 2016 and 2017 Medicare payment and utilization data; CY 2017 GPCIs, and CY 2018 proposed work and clinical labor RVUs.

Similar to the previous update, we calculated the proposed MP RVUs using specialty-specific malpractice premium data because they represent the actual expense incurred by practitioners to obtain malpractice insurance. We obtained malpractice premium data exclusively from the most recently available data published in the 2014 and 2015 Market Share Reports accessed from the National Association of Insurance Commissioners (NAIC) Web site. We used information obtained from malpractice insurance rate filings with effective dates in 2014 and 2015. These were the most current data available during our data collection process.

We collected malpractice insurance premium data from all 50 States, the District of Columbia, and Puerto Rico. Rate filings were not available in American Samoa, Guam or the Virgin Islands. Premiums were for $1 million/$3 million, mature, claims-made policies (policies covering claims made, rather than those covering services furnished, during the policy term). A $1 million/$3 million liability limit policy means that the most that would be paid on any claim is $1 million and the most that the policy would pay for claims over the timeframe of the policy is $3 million. We made adjustments to the premium data to reflect mandatory surcharges for patient compensation funds (funds to pay for any claim beyond the statutory amount, thereby limiting an individual physician's liability in cases of a large suit) in states where participation in such funds is mandatory.

We included premium information for all physician and NPP specialties, and all risk classifications available in the collected rate filings. Although we collected premium data from all states, the District of Columbia, and Puerto Rico, not all specialties had distinct premium data in the rate filings from all states. Additionally, for some specialties, MP premiums were not available from the rate filings in any state. Therefore, for specialties for which there were not premium data for at least 35 states, and specialties for which there were not distinct premium data in the rate filings, we crosswalked the specialty to a similar specialty, either conceptually or by available premium data, for which we did have sufficient and reliable data.

For example, for radiation oncology, data were only available from 23 states, and therefore this specialty does not meet our 35-state threshold, which determines whether or not a specialty is deemed to have premium data sufficient to construct a unique risk factor. However, based on the 23 states' worth of rate filings for radiation oncology, the resource costs for the premiums suggests a similar, though slightly lesser average than that of the premiums for diagnostic radiology. We developed the proposed MP RVUs for radiation oncology by crosswalking the risk factor for diagnostic radiology as a similar specialty with similar premium data. We sought comment as to the appropriateness of this and the other crosswalks used in developing MP RVUs.

For the proposed CY 2018 MP RVU update, sufficient and reliable premium data were available for 43 specialty types, representing over 76 percent of allowed Medicare PFS services, which we used to develop specialty specific malpractice risk factors.

b. Steps for Calculating Malpractice RVUs

Calculation of the proposed MP RVUs conceptually follows the specialty-weighted approach used in the CY 2015 final rule with comment period (79 FR 67591). The specialty-weighted approach bases the MP RVUs for a given service upon a weighted average of the risk factors of all specialties furnishing the service. This approach ensures that all specialties furnishing a given service are accounted for in the calculation of the MP RVUs. The steps for calculating the proposed MP RVUs are described below.

Step (1): Compute a preliminary national average premium for each specialty.

Insurance rating area malpractice premiums for each specialty are mapped to the county level. The specialty premium for each county is then multiplied by its share of the total U.S. population (from the U.S. Census Bureau's 2014 American Community Survey (ACS) estimates). This is in contrast to the method used for creating national average premiums for each specialty in the 2015 update; in that update, specialty premiums were weighted by the total RVU per county, rather than by the county share of the total U.S. population. We refer readers to the CY 2016 PFS final rule with comment period (80 FR 70909) for a discussion of why we have adopted a weighting method based on a share of the total U.S. population. This calculation is then divided by the average MP GPCI across all counties for each specialty to yield a normalized national average premium for each specialty. The specialty premiums are normalized for geographic variation so that the locality cost differences (as

reflected by the GPCIs) would not be counted twice. Without the geographic variation adjustment, the cost differences among fee schedule areas would be reflected once under the methodology used to calculate the MP RVUs and again when computing the service specific payment amount for a given fee schedule area.

Step (2): Determine which premium class(es) to use within each specialty.

Some specialties had premium rates that differed for surgery, surgery with obstetrics, and non-surgery. These premium classes are designed to reflect differences in risk of professional liability and the cost of malpractice claims if they occur. To account for the presence of different classes in the malpractice premium data and the task of mapping these premiums to procedures, we calculated distinct risk factors for surgical, surgical with obstetrics, and nonsurgical procedures. However, the availability of data by surgery and non-surgery varied across specialties. Consistent with the CY 2015 MP RVU update, because no single approach accurately addressed the variability in premium class among specialties, we employed several methods for calculating average premiums by specialty. These methods are discussed below.

(a) Substantial Data for Each Class: For 10 out of 86 specialties, we determined that there were sufficient data for surgery and non-surgery premiums, as well as sufficient differences in rates between classes. Therefore, we calculated a national average surgical premium and non-surgical premium. We noted that, unlike in the CY 2015 MP RVU update, for CY 2018, there were no specialties that fell under the ''unspecified dominates'' specialty/surgery class scenario; therefore, we omitted that surgical class category.

(b) Major Surgery Dominates: For 9 surgical specialties, rate filings that included non-surgical premiums were relatively rare. For most of these surgical specialties, the rate filing did not include an ''unspecified'' premium. When it did, the unspecified premium was lower than the major surgery rate. For these surgical specialties, we calculated only a surgical premium and used the premium for major surgery for all procedures furnished by this specialty.

(c) Blend All Available: For the remaining specialties, there was wide variation across the rate filings in terms of whether or not premium classes were reported and which categories were reported. Because there was no clear strategy for these remaining specialties, we blended the available rate information into one general premium rate. For these specialties, we developed a weighted average ''blended'' premium at the national level, according to the percentage of work RVUs correlated with the premium classes within each specialty. For example, the surgical premiums for a given specialty were weighted by that specialty's work RVUs for surgical services; the nonsurgical premiums were weighted by the work RVUs for non-surgical services and the unspecified premiums were weighted by all work RVUs for the specialty type.

Step (3): Calculate a risk factor for each specialty.

The relative differences in national average premiums between specialties are expressed in our methodology as a specialty risk factor. These risk factors are an index calculated by dividing the national average premium for each specialty by the national average premium for the specialty with the lowest premiums for which we had sufficient and reliable data, allergy and immunology. For specialties with sufficient surgical and non-surgical premium data, we calculated both a surgical and non-surgical risk factor. For specialties with rate filings that distinguished surgical premiums with obstetrics, we calculated a separate surgical with obstetrics risk factor. For all other specialties, we calculated a single risk factor and applied the specialty risk factor to both surgery and non-surgery services.

We noted that for determining the risk factor for suppliers of TC-only services in the CY 2015 update, we updated the premium data for independent diagnostic testing facilities (IDTFs) that we used in the CY 2010 update. These data were obtained from a survey conducted by the Radiology Business Management Association (RBMA) in 2009; we ultimately used these data to calculate an updated TC specialty risk factor. We applied the updated TC specialty risk factor to suppliers of TC-only services. In the CY 2015 final rule with comment period (79 FR 67595), RBMA voluntarily submitted updated MP premium information collected from independent diagnostic testing facilities (IDTFs) in 2014, and requested that we use the data for calculating the CY 2015 MP RVUs for TC services. We declined to utilize the data and stated that we believe further study is necessary and we would consider this matter and propose any changes through future rulemaking. We believed that data for a broader set of technical component services are needed, and sought comment on appropriate, comparable data sources for such information. We also sought comment on whether the data for IDTFs are comparable and appropriate as a proxy for the broader set of TC services. We endeavor to, in the next update of specialty risk factors, collect more data across a broader set of the technical component services, not just for radiology (as is currently reflected in the RBMA data), but data for services performed by other non-physician practitioners including cytotechnologists, and cardiovascular technologists. In the interim, for CY 2018, we proposed to assign a TC risk factor of 1.0, which corresponds to the lowest physician specialty risk factor.

We assigned the risk factor of 1.0 to the TC services because we did not have comparable professional liability premium data for the full range of clinicians that furnish these services. In lieu of comprehensive, comparable data, we used 1.0 as the default minimum risk factor, though we sought information on the best available data sources for use in the next update, as well as empirical information that would support assignment of an alternative risk factor for these services.

Step (4): Calculate malpractice RVUs for each HCPCS code.

Resource-based MP RVUs were calculated for each HCPCS code that has work or PE RVUs. The first step was to identify the percentage of services furnished by each specialty for each respective HCPCS code. This percentage was then multiplied by each respective specialty's risk factor as calculated in Step 3. The products for all specialties for the HCPCS code were then added together, yielding a specialty-weighted service specific risk factor reflecting the weighted malpractice costs across all specialties furnishing that procedure. The service specific risk factor was multiplied by the greater of the work RVU or PE clinical labor index for that service to reflect differences in the complexity and risk-of-service between services.

Low volume service codes: As we discussed in section II.B. of this final rule, we proposed to use a list of expected specialties instead of the claims-based specialty mix for low volume services in order to address stakeholder concerns about the year to year variability in PE and MP RVUs for low volume services. We solicited comments on the proposal to use these service-level overrides to determine the specialty for low volume procedures, as well as on the list of overrides itself.

The proposed list of codes and expected specialties is available on our Web site under downloads for the CY 2018 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-*

for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. In previous MP RVU updates, as discussed in the CY 2015 final rule with comment period (79 FR 40354), we assigned specialty for low volume services based on dominant specialty. As discussed in the CY 2012 final rule with comment period (76 FR 73187 through 73189), we applied an additional list of service-level overrides for purposes of calculating MP RVUs for a number of cardiothoracic surgery codes. Therefore, we noted that there are certain codes for which we have previously applied expected specialty overrides for purposes of calculating MP RVUs based on assumptions regarding low Medicare volume. Because we are consolidating policies for low volume service expected specialty overrides into a single list for PE and MP, and because we did not believe that there is a reason to assume different specialties for purposes of calculating PE RVUs than for MP RVUs for any particular code, we also proposed to assign the specialty mix solely based on the claims data for any code that does not meet the low volume threshold of 99 allowed services or fewer in the previous year, for the purposes of calculating MP RVUs.

Given that we now annually recalibrate MP RVUs based on claims data, and in light of our proposed introduction of the service-level specialty override for low volume services, we believed that there would no longer be a need to apply service-level MP crosswalks in order to assign a specialty-mix risk factor. Contingent on finalizing this proposal, we also proposed to eliminate general use of an MP-specific specialty-mix crosswalk for new and revised codes. However, we would continue to consider, in conjunction with annual recommendations, specific recommendations from the public and the RUC regarding specialty mix assignments for new and revised codes, particularly in cases where coding changes are expected to result in differential reporting of services by specialty, or where the new or revised code is expected to be low-volume. Absent such information, we would derive the specialty mix assumption for the first year for a new or revised code from the specialty mix used for purposes of ratesetting. In subsequent years when claims data are available, we would assign the specialty based on claims data unless the service does not exceed the low volume threshold (99 or fewer allowed services). If the service is low volume, we would assign the expected specialty, establishing a new expected specialty through rulemaking as needed, which is consistent with our approach for developing PE RVUs.

Step (5): Rescale for budget neutrality.

The statute requires that changes to fee schedule RVUs must be budget neutral. Thus, the last step is to adjust for relativity by rescaling the proposed MP RVUs so that the total proposed resource based MP RVUs are equal to the total current resource based MP RVUs scaled by the ratio of current aggregate MP and work RVUs. This scaling is necessary in order to maintain the work RVUs for individual services from year to year while also maintaining the overall relationship among work, PE, and MP RVUs.

Additional information on our proposed methodology for updating the MP RVUs may be found in our contractor's report, ''Interim Report on Malpractice RVUs for the CY 2018 PFS Proposed Rule,'' which is available on the CMS Web site under the downloads section of the CY 2018 PFS proposed rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

We sought comments on these proposals for calculating the MP RVUs for CY 2018. The following is a summary of the public comments received on our proposals and our responses:

Comment: Several commenters, including the RUC, expressed concerns about the proposed valuation changes, which they believe were not indicative of what is occurring in the professional liability premium market. The RUC stated that, generally, the market has not reflected significant changes in the past several years. The commenters stated that the premium data collected for this update were insufficient, and many noted changes in specialty premiums and risk factors compared to the last update as particularly concerning. Some commenters expressed concern that CMS was unable to obtain sufficient data from all states for common specialties and questioned the validity of the data being used to propose new MP RVUs for CY 2018. The RUC stated that while the crosswalks proposed by CMS appear to be appropriate, they were concerned with the data collection process, and recommended that rather than crosswalking, CMS should acquire adequate premium data. Several commenters, including the RUC, specifically expressed concern about the proposed Cardiology surgical risk factor. The commenters disagreed with the risk factor for Cardiology being classified as a blend rather than split into distinct surgical and non-surgical risk factors as it had been in the past, and recommended that CMS use the Cardiac Surgery Risk Factor as a more appropriate crosswalk to establish a Cardiology surgical risk factor or otherwise maintain the existing risk factors while additional data are gathered. Several commenters, including the RUC, stated that CMS should consider delaying implementation of new premium data until CMS has the opportunity to seek additional data to avoid blending risk factors and crosswalking. While some commenters were generally supportive of more frequent updates of MP premium data and aligning updates of MP RVUs with the triennial MP GPCI updates, they stated that given concerns about accuracy and flaws in the methodology for calculating MP risk factors, that CMS should not accelerate the schedule for updating MP RVUs based on the MP GPCI data at this time. A few commenters recommended that CMS not modify the current 5-year cycle of updating the MP premium data used in the MP RVU calculations to every 3 years; one commenter stated that more frequent updates will cause greater variation in the MP RVU calculations.

Response: We agree that some of the changes are substantial compared to the last update and merit further consideration. However, we believe it is important to delineate the precise cause of these changes, as the shifts were primarily driven by changes in how the rate filings were classified by specialty, rather than inherent deficiencies in the raw rate filing data. We collected malpractice premium data from the NAIC's System for Electronic Rate and Form Filing (SERFF) Access Interface, which is a standardized data source that includes many rate filings from the same insurers that were used in the CY 2015 MP RVU update, as well as additional data. Using SERFF enabled us to collect malpractice data for 32 states. For states that do not participate in the SERFF Access Interface, we contacted state departments of insurance and requested medical malpractice rate filings. Using these methods, we were able to collect a total of 7,212 raw rate filings from all 50 states, the District of Columbia, and Puerto Rico. This is an improvement on the CY 2015 update, for which 3,473 raw rate filings were collected. We note that the number of specialties with sufficient data in this proposed update is very similar to prior years. In the CY 2010 update, sufficient data were found for 44 specialties. In the CY 2015 update, sufficient data were found for 41 specialties, and we found sufficient

data for 43 specialties in the proposed CY 2018 update. Overall, there is very little change in the total number of specialties with sufficient data.

For the the comments that noted differences in which specialties had sufficient data this year, compared to the CY 2015 update, we have determined that this is due to differences in the codes that insurance issuers use to identify the physician speciality on the descriptions on the raw rate filings and/or how these raw data were categorized into CMS specialties. CMS specialty coding information is not available on the raw rate filings, and Insurance Services Office (ISO) codes are only sometimes present. Thus, it is always necessary to use a crosswalk to map malpractice premium data to the CMS specialty classifications. This means that changes in malpractice insurers' premium coding practices or the rate filing categorization process can easily lead to shifts in the number of rate filings across related specialties, which in turn may skew the weighting of the data, which is what we observed in the CY 2018 proposed update.

The Cardiology specialty is illustrative of this issue. In the last update, Cardiology had a surgical risk factor of 6.98 and a non-surgical risk factor of 1.93. In this update, Cardiology did not have sufficient data to compute separate surgical and non-surgical risk factors and was proposed to receive a blended risk factor of 1.90. This change was understandably concerning to several commenters. The reason that Cardiology did not have sufficient data to compute a surgical risk factor was directly due to how the raw rate filings were categorized rather than the data availability itself. In the past, some rate filings that referred to cardiac surgery and interventional cardiology in their specialty descriptions were categorized as Specialty 06: Cardiology, but comparable filings for this year's proposal were categorized as Specialty 78: Cardiac Surgery and C3: Interventional Cardiology. As several commenters suggested, it is possible to mitigate this problem by assigning Cardiology to receive the surgical risk factor of Cardiac Surgery. In the long-term, we understand commenters' concerns and in order to alleviate this issue, we intend to revisit how we categorize all rate filings by specialty. This is particularly important because some physicians may not have updated their specialty codes despite performing surgical and interventional cardiac procedures, and we want to ensure that their rates are properly adjusted if they are still registered as part of the general Cardiology specialty. We also understand that this issue may have occurred for other groups of related specialties and intend to do a comprehensive assessment in the future to avoid potential discrepancies such as those previously described. For these reasons, we are not finalizing our proposal to use the most recent data for the CY 2018 MP RVUs and to align the update of MP premium data and MP GPCIs to once every 3 years. We recognize that, going forward, we need to resolve differences regarding the variances in the descriptions on the raw rate filings as well as how these raw data were categorized to conform with the CMS specialties.

Comment: One commenter expressed concern that the average premiums and risk factors for Interventional Cardiology were not proposed. The Interventional Cardiology specialty code went into effect in January 2015, so the commenter urged CMS to establish risk factors for this specialty.

Response: Because the malpractice rate filings collected for this update were from 2014 and 2015, very little data were available for Interventional Cardiology. Until more data are available, it will be necessary to crosswalk this specialty to receive average premiums and risk factors from cardiac specialties that carry similar levels of risk.

Comment: A few commenters expressed concern about a lack of transparency in the proposed changes to the determination of MP RVUs, and some stated that stakeholders were at a disadvantage and unable to respond to the changes and assumptions used in the proposed update to MP RVUs.

Response: We would like to note that the methodology as well as the steps for calculating MP RVUs were outlined in the preamble text to the proposed rule, and are also included in this final rule; we sought comments on these proposals in the proposed rule. The documentation included in the Downloads section on the CMS Web site support and provide additional technical details and information used in establishing the proposed policies. To the extent that the supporting documentation is material to the proposals we made in the proposed rule, we believe they are within the scope of the rule. Information that provides more context and understanding of the data, and how the data is collected, which can be found in the contractor's report, is material to the rulemaking process, so when stakeholders provide concerns about the supporting documentation we consider those concerns as comments in response to the proposals. We also note that this has been our longstanding process.

Comment: Several commenters, including the RUC, stated that CMS should not crosswalk non-physician specialties to the lowest physician risk factor specialty for which it has premium rates, which is Allergy Immunology. The commenters stated that CMS should collect premium data for the non-physician specialties or otherwise use the data from the AMA's Physician Practice Expense Information Survey from 2006. The commenters expressed that this crosswalk would likely serve as an overestimate of professional liability for non-physician specialties.

Response: We thank commenters for their feedback, and would like to clarify that we did collect whatever data was available for non-physician specialties during our data collection process. This enabled us to find sufficient data for one major non-physician specialty—Nurse Practitioner, which received a blended risk factor of 1.95. Additionally, we note that not all non-physician specialties were mapped to Allergy/Immunology. For example, Certified Nurse Midwife was mapped to Obstetrics and Gynecology, and Certified Registered Nurse Anesthesiologist was mapped to Anesthesiology, which both reflect higher risk than Allergy/Immunology. We revisited the malpractice rate filings we collected for other non-physician specialties, and although they did not meet the 35-state threshold for sufficient data to compute specialty premiums and risk factors, some of the data we do have indicate premiums and risk factors that are close to that of Allergy/Immunology. Therefore, we believe that the proposed crosswalks were reasonable. However, we are not finalizing our proposal.

Comment: One commenter highlighted that the Sleep Medicine specialty did not have sufficient data in this proposed update and was crosswalked to General Practice, which the commenter did not believe was appropriate.

Response: We appreciate the commenter's feedback, and note that this is the same crosswalk that was used in the last update. Additionally, while the surgical risk factor decreases for General Practice in the proposed update, the non-surgical factor increased. We revisited the malpractice rate filings we collected for Sleep Medicine and, although they did not meet the 35-state threshold for sufficient data to compute specialty premiums and risk factors, the data we do have indicate premiums and risk factors that are close to that of General Practice.

Therefore, we believe that the proposed crosswalk was reasonable. However, we are not finalizing our proposal.

Comment: A few specialty societies expressed support for the proposed crosswalks as an appropriate course of action given the lack of available data for most non-physician specialties. One commenter expressed concern that insufficient data was found for Hospice and Palliative Care and it was mapped to Allergy/Immunology. Another commenter expressed support for crosswalking Certified Registered Nurse Anesthesiologist (CRNA) to Anesthesiology, though they question whether Anesthesiology Assistant should have been crosswalked the same way.

Response: We appreciate the commenters' feedback and support. We reviewed the malpractice rate filings that were collected for Hospice and Palliative Care, and although they did not meet the 35-state threshold for sufficient data to compute specialty premiums and risk factors, the data we do have indicate premiums and risk factors that are close to Allergy/Immunology; we also note that insufficient data for this specialty were found in the last update and it was previously crosswalked to Allergy/Immunology. We also reviewed the malpractice rate filings that were collected for Anesthesiology Assistant and similarly, although they did not meet the threshold for sufficient data, the data we do have indicate premium and risk factors that are close to that of Anesthesiology. Therefore, we believe that the proposed crosswalks were reasonable. However, we are not finalizing our proposal.

Comment: A few commenters, including the RUC, questioned whether the 35-state threshold for rate filing data was too high, and suggested that fewer specialties would need to be crosswalked to receive premiums and risk factors from other specialties if that requirement were lowered or removed.

Response: While we agree that lowering the threshold would allow more specialties to receive dedicated premiums and risk factors, we believe that lowering the 35 state threshold would have a direct trade-off with the accuracy and the reliability of the results. Removing or lowering the threshold would increase the likelihood that the resulting premiums and risk factors could fluctuate due to outliers. Additionally, the 35-state threshold is consistent with the past updates to MP RVUs.

Comment: A few commenters urged CMS to use work RVUs instead of regional population counts to weight geographic differences to calculate national average premiums.

Response: We thank the commenters for their feedback, and note this population weighting refinement to the MP RVU methodology was issued through notice and comment rulemaking in the CY 2016 PFS final rule with comment period (80 FR 70909 through 70910), and there were no additional proposals with regard to this matter for CY 2018.

Comment: One commenter recommended that CMS use the phrase ''Family Medicine'' rather than ''Family Practice'' on the basis that the latter is considered outdated.

Response: We appreciate the commenter's feedback. We did not propose changes to the specialty nomenclature; however, we will consider this in future updates.

Comment: A commenter requested that we add HCPCS codes 92992 and 92993 to the list of invasive cardiology procedures classified as surgery for purposes of assigning service level risk factors because cardiac catheterization and angioplasty procedures are similar to surgical procedures for the purpose of establishing MP premium rates and risk factors.

Response: HCPCS codes 92992 and 92993 are contractor-priced codes, for which the Medicare Administrative Contractors (MACs) establish RVUs and payment amounts. Therefore, we are not adding HCPCS codes 92992 and 92993 to the ''Invasive Cardiology Outside of Surgical Range'' list.

Comment: Several commenters, including the RUC, were supportive of the proposal to override claims data for low volume services with an expected specialty for both the PE RVU, and MP RVU valuation process. The commenters also recommended that CMS use the expected specialty overrides lists for codes with no Medicare volume for a given year, as well as low volume codes.

Response: We thank commenters for their support. We refer commenters to section II.B. of this final rule for further discussion of low volume service codes.

After consideration of the comments received, we are not finalizing our proposal to use the most recent data for the CY 2018 MP RVUs and to align the update of MP premium data and MP GPCIs to once every 3 years. Similar to CY 2017, the CY 2018 MP RVUs will continue to be based on the premium data that was collected for the CY 2015 MP RVU update. For CY 2018, the MP RVUs will be calculated based on the existing specialty risk factors (the same risk factors that were used to calculate the CY 2017 MP RVUs); these specialty risk factors are shown in the CY 2018 Final Rule Malpractice Risk Factors and Premium Amounts by Specialty file located on the CMS Web site under the downloads section of the CY 2018 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

For low volume service codes, we thank the commenters for their support, and we are finalizing the proposal to use a list of expected specialties, instead of a claims-based specialty mix, for low volume, which also includes no volume codes, and to apply these overrides for both PE and MP. We believe that this will simplify the implementation of service-level overrides for PE and MP, and will also address stakeholder concerns about year-to-year variability for low volume services. We refer readers to section II.B. of this final rule for further discussion regarding the low volume service codes.

We note that the next MP update must occur by CY 2020. We continue to believe that updating the MP premium data on a more frequent basis would enable the resulting premiums and RVUs to better reflect market trends in malpractice insurance for different specialties. In principle, more frequent updates are optimal, and we will consider this in future rulemaking.

Many of the commenters expressed concerns regarding the sufficiency of the data. As previously explained, this is not a matter of a lack of sufficient or robust data, but an issue regarding how the rate filings are being classified by specialty. We re-examined the data and after further review, we recognize that going forward we need to resolve differences regarding variances in the descriptions on the raw rate filings as well as how these raw data were categorized to conform with the CMS specialties. Understanding that this is a driver of the fluctuations that were reflected in the updated MP RVUs that we proposed, moving forward we will be able to prioritize reconciling the coding changes and categorizations in the raw rate filings in order to avoid data fluctuations between updates that are not representative of the actual data. We thank the commenters for their detailed feedback, and will continue to take it into consideration as we work to make the MP RVUs as accurate as possible for all specialties. We also note that a few commenters noted concerns regarding potential errors in the proposed MP RVUs for specific codes as a result of the proposed updated specialty risk factors; however, since we are not finalizing those MP RVUs based on the proposed updated specialty risk

factors, we are not responding to those comments in this final rule.

The resource based MP RVUs for CY 2018 are shown in Addendum B, which is available on the CMS Web site under the downloads section of the CY 2018 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

C. Medicare Telehealth Services

1. Billing and Payment for Telehealth Services

Several conditions must be met for Medicare to make payments for telehealth services under the PFS. The service must be on the list of Medicare telehealth services and meet all of the following additional requirements:

- The service must be furnished via an interactive telecommunications system.
- The service must be furnished by a physician or other authorized practitioner.
- The service must be furnished to an eligible telehealth individual.
- The individual receiving the service must be located in a telehealth originating site.

When all of these conditions are met, Medicare pays a facility fee to the originating site and makes a separate payment to the distant site practitioner furnishing the service.

Section 1834(m)(4)(F)(i) of the Act defines Medicare telehealth services to include professional consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when furnished via a telecommunications system. We first implemented this statutory provision, which was effective October 1, 2001, in the CY 2002 PFS final rule with comment period (66 FR 55246). We established a process for annual updates to the list of Medicare telehealth services as required by section 1834(m)(4)(F)(ii) of the Act in the CY 2003 PFS final rule with comment period (67 FR 79988).

As specified at § 410.78(b), we generally require that a telehealth service be furnished via an interactive telecommunications system. Under § 410.78(a)(3), an interactive telecommunications system is defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

Telephones, facsimile machines, and stand-alone electronic mail systems do not meet the definition of an interactive telecommunications system. An interactive telecommunications system is generally required as a condition of payment; however, section 1834(m)(1) of the Act allows the use of asynchronous ''store-and-forward'' technology when the originating site is part of a federal telemedicine demonstration program in Alaska or Hawaii. As specified in § 410.78(a)(1), asynchronous store-and-forward is the transmission of medical information from an originating site for review by the distant site physician or practitioner at a later time.

Medicare telehealth services may be furnished to an eligible telehealth individual notwithstanding the fact that the practitioner furnishing the telehealth service is not at the same location as the beneficiary. An eligible telehealth individual is an individual enrolled under Part B who receives a telehealth service furnished at a telehealth originating site.

Practitioners furnishing Medicare telehealth services are reminded that these services are subject to the same non-discrimination laws as other services, including the effective communication requirements for persons with disabilities of section 504 of the Rehabilitation Act of 1973 and section 1557 of the Affordable Care Act, as well as and language access for persons with limited English proficiency, as required under Title VI of the Civil Rights Act of 1964 and section 1557 of the Affordable Care Act. For more information, see *http://www.hhs.gov/ocr/civilrights/resources/specialtopics/hospitalcommunication.*

Practitioners furnishing Medicare telehealth services submit claims for telehealth services to the Medicare Administrative Contractors (MACs) that process claims for the service area where their distant site is located. Section 1834(m)(2)(A) of the Act requires that a practitioner who furnishes a telehealth service to an eligible telehealth individual be paid an amount equal to the amount that the practitioner would have been paid if the service had been furnished without the use of a telecommunications system.

Originating sites, which can be one of several types of sites specified in the statute where an eligible telehealth individual is located at the time the service is being furnished via a telecommunications system, are paid a facility fee under the PFS for each Medicare telehealth service. The statute specifies both the types of entities that can serve as originating sites and the geographic qualifications for originating sites. For geographic qualifications, our regulation at § 410.78(b)(4) limits originating sites to those located in rural health professional shortage areas (HPSAs) or in a county that is not included in a metropolitan statistical area (MSA).

Historically, we have defined rural HPSAs to be those located outside of MSAs. Effective January 1, 2014, we modified the regulations regarding originating sites to define rural HPSAs as those located in rural census tracts as determined by the Federal Office of Rural Health Policy of the Health Resources and Services Administration (HRSA) (78 FR 74811). Defining ''rural'' to include geographic areas located in rural census tracts within MSAs allows for broader inclusion of sites within HPSAs as telehealth originating sites. Adopting the more precise definition of ''rural'' for this purpose expands access to health care services for Medicare beneficiaries located in rural areas. HRSA has developed a Web site tool to provide assistance to potential originating sites to determine their geographic status. To access this tool, see our Web site at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

An entity participating in a federal telemedicine demonstration project that has been approved by, or received funding from, the Secretary as of December 31, 2000 is eligible to be an originating site regardless of its geographic location.

Effective January 1, 2014, we also changed our policy so that geographic status for an originating site would be established and maintained on an annual basis, consistent with other telehealth payment policies (78 FR 74400). Geographic status for Medicare telehealth originating sites for each calendar year is now based upon the status of the area as of December 31 of the prior calendar year.

For a detailed history of telehealth payment policy, see 78 FR 74399.

2. Adding Services to the List of Medicare Telehealth Services

As noted previously, in the CY 2003 PFS final rule with comment period (67 FR 79988), we established a process for adding services to or deleting services from the list of Medicare telehealth services. This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed by us. Under this process, we assign any submitted request to make additions to the list of telehealth services to one of two categories. Revisions to the criteria that we use to review requests in the second category were finalized in the CY 2012

PFS final rule with comment period (76 FR 73102). The two categories are:

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

Some examples of clinical benefit include the following:

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

The list of telehealth services, including the proposed additions described below, is included in the Downloads section to this final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Requests to add services to the list of Medicare telehealth services must be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. To be considered during PFS rulemaking for CY 2019, qualifying requests must be submitted and received by December 31, 2017. Each request to add a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as a vehicle for making changes to the list of Medicare telehealth services, requesters should be advised that any information submitted is subject to public disclosure for this purpose. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, see our Web site at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.*

3. Submitted Requests To Add Services to the List of Telehealth Services for CY 2018

Under our existing policy, we add services to the telehealth list on a category 1 basis when we determine that they are similar to services on the existing telehealth list for the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 PFS final rule with comment period (76 FR 73098), we believe that the category 1 criteria not only streamline our review process for publicly requested services that fall into this category, but also expedite our ability to identify codes for the telehealth list that resemble those services already on this list.

We received several requests in CY 2016 to add various services as Medicare telehealth services effective for CY 2018. The following presents a discussion of these requests, and our proposals for additions to the CY 2018 telehealth list. Of the requests received, we found that three services were sufficiently similar to services currently on the telehealth list to qualify on a category 1 basis. Therefore, we proposed to add the following services to the telehealth list on a category 1 basis for CY 2018:

- HCPCS code G0296 (Counseling visit to discuss need for lung cancer screening using low dose ct scan (ldct) (service is for eligibility determination and shared decision making))

We found that the service described by HCPCS code G0296 is sufficiently similar to office visits currently on the telehealth list. We believed that all the components of this service, which include assessment of the patient's risk for lung cancer, shared decision making, and counseling on the risks and benefits of LDCT, can be furnished via interactive telecommunications technology.

- CPT codes 90839 and 90840 (Psychotherapy for crisis; first 60 minutes) and (Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary service))

We proposed to add CPT codes 90839 and 90840 on a Category 1 basis. We found that these services are sufficiently similar to the psychotherapy services currently on the telehealth list, even though these codes describe patients requiring more urgent care and psychotherapeutic interventions to minimize the potential for psychological trauma. However, we identified one specific element of the services as described in the CPT prefatory language that we concluded may or may not be able to be furnished via telehealth, depending on the circumstances of the particular service. The CPT prefatory language specifies that the treatment described by these codes requires, ''mobilization of resources to defuse the crisis and restore safety.'' In many cases, we believed that a distant site practitioner would have access (via telecommunication technology, presumably) to the resources at the originating site that would allow for the kind of mobilization required to restore safety. However, we also believed that it would be possible that a distant site practitioner would not have access to such resources. Therefore we proposed to add the codes to the telehealth list with the explicit condition of payment that the distant site practitioner be able to mobilize resources at the originating site to defuse the crisis and restore safety, when applicable, when the codes are furnished via telehealth. ''Mobilization of resources'' is a description used in the CPT prefatory language. We believed the critical element of ''mobilizing resources'' is the ability to communicate with and inform staff at the originating site to the extent necessary to restore safety. We solicited comment on whether our assumption that the remote practitioner is able to mobilize resources at the originating site

to defuse the crisis and restore safety is valid.

Although we did not receive specific requests, we also proposed to add four additional services to the telehealth list based on our review of services. All four of these codes are add-on codes that describe additional elements of services currently on the telehealth list and would only be considered telehealth services when billed as an add-on to codes already on the telehealth list. The four codes are:

- CPT code 90785 (Interactive complexity (List separately in addition to the code for primary procedure))
- CPT codes 96160 and 96161 (Administration of patient-focused health risk assessment instrument (*e.g.*, health hazard appraisal) with scoring and documentation, per standardized instrument) and (Administration of caregiver-focused health risk assessment instrument (*e.g.*, depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument))
- HCPCS code G0506 (Comprehensive assessment of and care planning for patients requiring chronic care management services (list separately in addition to primary monthly care management service))

In the case of CPT codes 96160 and 96161, and HCPCS code G0506, we recognized that these services may not necessarily be ordinarily furnished in-person with a physician or billing practitioner. Ordinarily, services that are typically not considered to be face-to-face services do not need to be on the list of Medicare telehealth services; however, these services would only be considered Medicare telehealth services when billed with a base code that is also on the telehealth list and would not be considered Medicare telehealth services when billed with codes not on the Medicare telehealth list. We believed that by adding these services to the telehealth list it will be administratively easier for practitioners who report these services in association with a visit code that is furnished via telehealth as both the base code and the add-on code would be reported with the telehealth place of service.

We also received requests to add services to the telehealth list that do not meet our criteria for Medicare telehealth services. We did not propose adding the following procedures for physical, occupational, and speech therapy, initial hospital care, and online E/M by physician/qualified healthcare professional to the telehealth list, or changing the requirements for ESRD procedure codes furnished via telehealth, for the reasons noted in the paragraphs that follow.

a. Physical and Occupational Therapy and Speech-Language Pathology Services: CPT Codes—

- *CPT code 97001:* Now deleted and reported with CPT codes 97161, 97162, or 97163, as follows: CPT code 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); CPT code 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); or CPT code 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 measurable assessment of functional outcome.)
- *CPT code 97002:* Now deleted and reported as CPT code 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.)
- *CPT code 97003:* Now deleted and reported with CPT codes 97165, 97166, or 97167, as follows: CPT code 97165 (Occupational therapy evaluation, low complexity, requiring these components: An occupational profile and medical and therapy history, which includes a brief history including review of medical and/or therapy records relating to the presenting problem; An assessment(s) that identifies 1–3 performance deficits (*i.e.,* relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of low complexity, which includes an analysis of the occupational profile, analysis of data from problem-focused assessment(s), and consideration of a limited number of treatment options. Patient presents with no comorbidities that affect occupational performance. Modification of tasks or assistance (*e.g.,* physical or verbal) with assessment(s) is not necessary to enable completion of evaluation component); CPT code 97166 (Occupational therapy evaluation, moderate complexity, requiring these components: An occupational profile and medical and therapy history, which includes an expanded review of medical and/or therapy records and additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 3–5 performance deficits (*i.e.,* relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of moderate analytic complexity, which includes an analysis of the occupational profile, analysis of data from detailed assessment(s), and consideration of several treatment options. Patient may present with comorbidities that affect occupational performance. Minimal to moderate modification of tasks or assistance (*e.g.,* physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component)); or CPT code 97167 (Occupational therapy evaluation,

high complexity, requiring these components: An occupational profile and medical and therapy history, which includes review of medical and/or therapy records and extensive additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 5 or more performance deficits (*i.e.,* relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of high analytic complexity, which includes an analysis of the patient profile, analysis of data from comprehensive assessment(s), and consideration of multiple treatment options. Patient presents with comorbidities that affect occupational performance. Significant modification of tasks or assistance (*e.g.,* physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component.)

- *CPT code 97004:* Now deleted and reported as CPT code 97168 (Re-evaluation of occupational therapy established plan of care, requiring these components: An assessment of changes in patient functional or medical status with revised plan of care; An update to the initial occupational profile to reflect changes in condition or environment that affect future interventions and/or goals; and a revised plan of care. A formal reevaluation is performed when there is a documented change in functional status or a significant change to the plan of care is required.)
- CPT code 97110 (Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility)
- CPT code 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)
- CPT code 97116 (Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing))
- CPT code 97535 (Self-care/home management training (*e.g.,* activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes)
- CPT code 97750 (Physical performance test or measurement (*e.g.,* musculoskeletal, functional capacity), with written report, each 15 minutes)
- CPT code 97755 (Assistive technology assessment (*e.g.,* to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes)
- CPT code 97760 (Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(s), lower extremity(s) and/or trunk, each 15 minutes)
- CPT code 97761 (Prosthetic training, upper and/or lower extremity(s), each 15 minutes)
- CPT code 97762 (Checkout for orthotic/prosthetic use, established patient, each 15 minutes)

Section 1834(m)(4)(E) of the Act specifies the types of practitioners who may furnish and bill for Medicare telehealth services as those practitioners under section 1842(b)(18)(C) of the Act. Physical therapists, occupational therapists and speech-language pathologists are not among the practitioners identified in section 1842(b)(18)(C) of the Act. We stated in the CY 2017 PFS final rule (81 FR 80198) that because these services are predominantly furnished by physical therapists, occupational therapists and speech-language pathologists, we did not believe it would be appropriate to add them to the list of telehealth services at this time. In a subsequent submission for 2018, the original requester suggested that we might propose these services to be added to the list so that they can be furnished via telehealth when furnished by eligible distant site practitioners. We considered that possibility; however, since the majority of the codes are furnished by therapy professionals over 90 percent of the time, we believed that adding therapy services to the telehealth list that explicitly describe the services of the kinds of professionals not included on the statutory list of distant site practitioners could result in confusion about who is authorized to furnish and bill for these services when furnished via telehealth. We also noted that several of these services, such as CPT code 97761, require directly physically manipulating the beneficiary, which is not possible to do through telecommunications technology. Therefore, we did not propose adding these codes to the list of Medicare telehealth services.

b. Initial Hospital Care Services: CPT Codes—

- CPT code 99221 (Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity.)
- CPT code 99222 (Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity.)
- CPT code 99223 (Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity.)

We previously considered a request to add these codes to the telehealth list. As we stated in the CY 2011 PFS final rule with comment period (75 FR 73315), while initial inpatient consultation services are currently on the list of approved telehealth services, there are no services on the current list of telehealth services that resemble initial hospital care for an acutely ill patient by the admitting practitioner who has ongoing responsibility for the patient's treatment during the course of the hospital stay. Therefore, consistent with prior rulemaking, we did not propose that initial hospital care services be

added to the Medicare telehealth services list on a category 1 basis.

The initial hospital care codes describe the first visit of the hospitalized patient by the admitting practitioner who may or may not have seen the patient in the decision-making phase regarding hospitalization. Based on the description of the services for these codes, we believed it is critical that the initial hospital visit by the admitting practitioner be conducted in person to ensure that the practitioner with ongoing treatment responsibility comprehensively assesses the patient's condition upon admission to the hospital through a thorough in-person examination. Additionally, the requester submitted no additional research or evidence that the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient; therefore, we also did not propose adding initial hospital care services to the Medicare telehealth services list on a category 2 basis.

We note that Medicare beneficiaries who are being treated in the hospital setting can receive reasonable and necessary E/M services using other HCPCS codes that are currently on the Medicare telehealth list including those for subsequent hospital care, initial and follow-up telehealth inpatient and emergency department consultations, as well as initial and follow-up critical care telehealth consultations.

Therefore, we did not propose to add the initial hospital care services to the list of Medicare telehealth services for CY 2018.

c. Online E/M by physician/QHP: CPT Code—

- CPT code 99444 (Online evaluation and management service provided by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient or guardian, not originating from a related E/M service provided within the previous 7 days, using the Internet or similar electronic communications network)

As we indicated in the CY 2016 final rule with comment period (80 FR 71061), CPT code 99444 is assigned a status indicator of ''N'' (Non-covered service). Under section 1834(m)(2)(A) of the Act, Medicare pays the physician or practitioner furnishing a telehealth service an amount equal to the amount that would have been paid if the service was furnished without the use of a telecommunications system. Because CPT code 99444 is currently non-covered, there would be no Medicare payment if this service were furnished without the use of a telecommunications system. Because this code is a non-covered service for which no Medicare payment may be made under the PFS, we did not propose adding online E/M services to the list of Medicare telehealth services for CY 2018.

d. Monthly Capitation Payment (MCP) for ESRD-Related Services for Home Dialysis, by Age: CPT Codes—

- CPT codes 90963 (End-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); 90964 (End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2–11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); 90965 (End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12–19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); and 90966 (End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older)
- 90967 (End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients younger than 2 years of age); 90968 (End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 2–11 years of age); and 90969 (End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 12–19 years of age); and 90970 (End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 20 years of age and older).

In the CY 2004 PFS final rule with comment period (68 FR 63216), we established HCPCS G-codes for ESRD monthly capitation payments (MCPs), which were replaced by CPT codes in CY 2009 (73 FR 69898). The services described by CPT codes 90963 through 90966 were added to the Medicare telehealth list in CY 2005 (69 FR 66276) and CPT codes 90967 through 90970 were added to the Medicare telehealth list in the CY 2017 PFS final rule (81 FR 80194); however, we specified that the required clinical examination of the vascular access site must be furnished face-to-face ''hands on'' (without the use of an interactive telecommunications system) by a physician, clinical nurse specialist (CNS), nurse practitioner (NP), or physician assistant (PA). The American Telemedicine Association (ATA) submitted a new request for CY 2018 requesting that we allow telehealth coverage of ESRD procedure codes without in-person exam of the catheter access site monthly. Our current policy reflects our understanding that evaluation of the integrity and functionality of the access site is a critical element of the services described by the codes and that this element cannot be performed via telecommunications technology. The requester did not submit evidence to support the assertion that effective examination of the access site can be executed via telecommunications technology. Therefore, for CY 2018, we did not propose any changes to the policy requiring that the MCP practitioner must furnish at least one face-to-face encounter with the home dialysis patient per month for clinical examination of the catheter access site. However, we are interested in more information about current clinically accepted care practices and to what extent telecommunications technology can be used to examine the access site. We are also interested in information about the clinical standards of care regarding the frequency of the evaluation of the access site.

In summary, we proposed adding the following codes to the list of Medicare telehealth services beginning in CY 2018 on a category 1 basis:

- HCPCS code G0296 (Counseling visit to discuss need for lung cancer screening using low dose CT scan (ldct) (service is for eligibility determination and shared decision making))
- HCPCS code G0506 (Comprehensive assessment of and care planning for patients requiring chronic care management services (list separately in addition to primary monthly care management service))
- CPT code 90785 (Interactive complexity (List separately in addition to the code for primary procedure))
- CPT codes 90839 and 90840 (Psychotherapy for crisis; first 60 minutes) and (Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary procedure))
- CPT codes 96160 and 96161 (Administration of patient-focused health risk assessment instrument

(e.g., health hazard appraisal) with scoring and documentation, per standardized instrument) and (Administration of caregiver-focused health risk assessment instrument *(e.g.,* depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument)

The following is a summary of the comments we received regarding the proposed addition of services to the list of Medicare telehealth services:

Comment: Many commenters supported one or more of our proposals to add the counseling visit to discuss need for lung cancer screening using low dose CT scan (LDCT) (HCPCS code G0296) and psychotherapy for crisis (CPT codes 90839 and 90840) to the Medicare telehealth list for CY 2018. Commenters also supported one or more of our proposals to add comprehensive assessment of and care planning for patients requiring chronic care management services (HCPCS code G0506), interactive complexity (CPT code 90785) and administration of health risk assessment (CPT codes 96160 and 96161). Commenters noted that by adding these services to the Medicare telehealth list, CMS was enhancing access and quality of care for Medicare beneficiaries.

Response: We thank commenters for their support of the proposed additions to the list of Medicare telehealth services. After consideration of the public comments received, we are finalizing our proposal to add these services to the list of Medicare telehealth services for CY 2018 on a Category 1 basis.

Comment: Several commenters were supportive of CMS's proposed requirement that the distant site practitioner be able to mobilize resources at the originating site to defuse the crisis and restore safety, when applicable, when furnishing psychotherapy for crisis. One commenter stated that CMS' requirements for mobilization of resources are very important and the distant site practitioner should be aware of available services where the beneficiary is located in the event of a crisis. Another commenter pointed out that social workers who provide telehealth services are required by the National Association of Social Workers to be familiar with the resources in the state in which the patient resides. Several commenters requested that CMS clarify what was meant by ''mobilization of resources'' and provide applicable examples.

Response: We appreciate commenters' responses to the explicit requirement regarding mobilization of resources for the psychotherapy for crisis codes (CPT codes 90839 and 90840). As noted above, ''mobilization of resources'' is a description used in the CPT prefatory language. We would reiterate that, according to CPT, the critical element of ''mobilizing resources'' is the ability to communicate with and inform staff at the originating site to the extent necessary to restore safety.

Comment: Several commenters disagreed with the proposal not to add CPT codes 99221–99223 (inpatient hospital care) to the Medicare telehealth list. One commenter stated that they believe these services could be furnished via Medicare telehealth. They pointed to the fact that for CY 2017, CMS valued the critical care consultation G-codes (HCPCS codes G0508 and G0509) with RVUs similar to those for the inpatient hospital care codes as evidence that CMS believes they are essentially the same service.

Response: As we discussed in the 2018 PFS proposed rule, we do not believe that the full range of services described by CPT codes 99221–99223 can be furnished via telecommunications technology as we believe it is critical that the initial hospital visit by the admitting practitioner be conducted in person to ensure that the practitioner with ongoing treatment responsibility comprehensively assesses the patient's condition upon admission to the hospital through a thorough in-person examination.

We believe that the telehealth critical care consultation codes (HCPCS codes G0508 and G0509) more accurately describe the kind of services that can be furnished to patients via telehealth than the initial inpatient hospital visit E/M codes that describe services with elements that can only be furnished in-person. The valuation for HCPCS codes G0508 and G0509 was developed based on our assessment that the overall work (resources in time and intensity) involved in furnishing the services is similar to the in-person critical care service codes, not that all elements of the services are the same. Many services paid under the PFS share similar, if not exactly the same work RVUs, without necessarily describing the exact same elements of the service. For more on the critical care consultation codes in the context of telehealth, please see the CY 2017 PFS final rule (81 FR 80196 through 80197 and 81 FR 80352).

Comment: Several commenters disagreed with our decision not to add various physical and occupational therapy, and speech language pathology services to the Medicare telehealth list.

Response: As noted above, the majority of the codes requested are furnished by therapy professionals over 90 percent of the time, and we believe that adding therapy services to the telehealth list that are furnished by professionals not included on the statutory list of distant site practitioners could result in confusion about who is authorized to bill for these services when furnished via telehealth. Additionally, some of the codes involve physical manipulation of the patient, which cannot be accomplished via an interactive telecommunications system.

Comment: Several commenters responded to our decision not to remove the requirement for a monthly in-person visit to examine the catheter access site for ESRD services conducted via telehealth. Another commenter encouraged CMS to lessen the requirements by making the in-person visit a quarterly, as opposed to monthly, requirement. Other commenters stated that the examination of the catheter access site could be conducted remotely via telecommunications technology.

Response: We appreciate the feedback on our proposal and we will consider the comments on the frequency of the examination of the catheter access site and whether the examination could be conducted remotely for future rulemaking.

Comment: One commenter disagreed with the decision not to propose to add CPT code 99444 (online E/M) to the Medicare telehealth list, stating that this service would increase access to care, especially for follow-up visits and medication management.

Response: As we noted above, CPT code 99444 is currently non-covered, so there is no Medicare payment for this service. As such, there would be no payment for this service even if we were to add it to the telehealth list. Additionally, because this service does not describe a service typically furnished in-person, it would not be considered a telehealth service under the applicable provisions of law. For both of these reasons, we continue to believe that it would not be appropriate to add CPT code 99444 to the Medicare telehealth list.

Comment: Many commenters provided recommendations for additional services that could be added to the Medicare telehealth list, such as an add-on code for patients requiring care planning for cognitive impairment, follow-up care for liver transplant patients, emergency department visits, oncology and podiatric-specific services, eConsult services, Medical Nutrition Therapy (MNT), and Diabetes Self Management Training (DSMT).

Response: We thank commenters for these suggestions and will consider these for future notice and comment rulemaking. We also wish to remind commenters that requests for specific services to be added to the Medicare telehealth list can be submitted until December 31st of each calendar year to be considered for the next rulemaking cycle. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, see our Web site at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

Since several commenters requested that we add MNT and DSMT to the telehealth list, we also wish to remind commenters that codes for both MNT and DSMT are currently on the Medicare telehealth list. The current list of Medicare telehealth services can be viewed on our Web site, *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.html*.

4. Elimination of the Required Use of the GT Modifier on Professional Claims

We have required distant site practitioners to report one of two longstanding HCPCS modifiers when reporting telehealth services. Current guidance instructs practitioners to submit claims for telehealth services using the appropriate CPT or HCPCS code for the professional service along with the telehealth modifier GT (via interactive audio and video telecommunications systems). For federal telemedicine demonstration programs in Alaska or Hawaii, practitioners are instructed to submit claims using the appropriate CPT or HCPCS code for the professional service along with the telehealth modifier GQ if telehealth services are performed ''via an asynchronous telecommunications system.'' By coding and billing these modifiers with a service code, practitioners are certifying that both the broad and code-specific telehealth requirements have been met.

In the CY 2017 PFS final rule (81 FR 80201), we finalized payment policies regarding Medicare's use of a new Place of Service (POS) Code describing services furnished via telehealth. The new POS code became effective January 1, 2017, and we believe its use is redundant with the requirements to apply the GT modifier for telehealth services. We did not propose to implement a change to the modifier requirements during CY 2017 rulemaking because at the time of the CY 2017 PFS proposed rule, we did not know whether the telehealth POS code would be made effective for January 1, 2017. However, we noted in the CY 2017 PFS final rule that, like the modifiers, use of the telehealth POS code certifies that the service meets the telehealth requirements.

Because a valid POS code is required on professional claims for all services, and the appropriate reporting of the telehealth POS code serves to indicate both the provision of the service via telehealth and certification that the requirements have been met, we believe that it is unnecessary to also require the distant site practitioner report the GT modifier on the claim. Therefore, we proposed to eliminate the required use of the GT modifier on professional claims. Because institutional claims do not use a POS code, we proposed for distant site practitioners billing under CAH Method II to continue to use the GT modifier on institutional claims. For purposes of the federal telemedicine demonstration programs in Alaska or Hawaii, we proposed to retain the GQ modifier to maintain the distinction between synchronous and asynchronous telehealth services, as reflected in statute.

The following is a summary of the public comments received on our proposal to eliminate the required use of the GT modifier on professional claims:

Comment: The majority of the commenters were supportive of eliminating the required use of the GT modifier on professional claims and agreed that this would reduce administrative burden.

Response: We thank the commenters for their support of the proposal. After considering the public comments, we are finalizing the proposal to eliminate the required use of the GT modifier on professional claims.

Comment: One commenter supported the proposal to no longer require the GT modifier on professional claims, but requested that we not delete the GT modifier because other payers who receive Medicare crossover claims might still require its use.

Response: We appreciate the commenters' concerns and reiterate that the GT modifier will be retained for Medicare for use in CAH Method II billing. Our decision to no longer use the modifier for professional claims will not affect its use in other appropriate circumstances.

Comment: One commenter stated that there is significant effort involved in updating computer systems to use the new POS code rather than a modifier, and encouraged CMS to consider that in future rulemaking.

Response: We appreciate the comment. We note that the required use of the telehealth POS code was finalized for CY 2017; however, we have a continuing interest in reducing administrative burden and will consider this for future rulemaking.

Comment: One commenter urged CMS to adopt a uniform method for identification of telehealth services and suggested that we use the 95 modifier, the new CPT modifier for CY 2017.

Response: We appreciate the comment, especially with the possibility that this could reduce administrative burdens associated with multiple modifiers. We will consider use of the 95 modifier for this purpose for future rulemaking.

Comment: A few commenters noted that the policy on the telehealth place of service (POS) code that was finalized for CY 2017 and took effect on January 1, 2017 resulted in a decrease in payment for some distant site practitioners furnishing services via telehealth in the non-facility setting and one commenter requested that we reverse the policy to pay the facility rate for all services furnished via telehealth.

Response: We understand the concerns raised about the current policy of using the facility rate for payment to distant site telehealth practitioners for telehealth services and will also further consider this policy for future rulemaking.

5. Comment Solicitation on Medicare Telehealth Services

We have received numerous requests from stakeholders to expand access to telehealth services. As noted above, Medicare payment for telehealth services is restricted by statute, which establishes the services initially eligible for Medicare telehealth and limits the use of telehealth by defining both eligible originating sites (the location of the beneficiary) and the distant site practitioners who may furnish and bill for telehealth services. Originating sites are limited both by geography and provider setting. We have the authority to add to the list of telehealth services based on our annual process, but cannot change the limitations relating to geography, patient setting, or type of furnishing practitioner because these requirements are specified in statute. For CY 2018, we sought information regarding ways that we might further expand access to telehealth services within the current statutory authority and pay appropriately for services that take full advantage of communication technologies.

Comment: We received many thoughtful comments in response to the

comment solicitation. Commenters were very supportive of CMS expanding access to telehealth services. Many commenters noted that Medicare payment for telehealth services is restricted by statute, but encouraged CMS to continue to explore alternate means to recognize and support technological developments in healthcare. Commenters provided many suggestions for how CMS could expand access to telehealth services within the current statutory authority and pay appropriately for services that take full advantage of communication technologies, such as waiving portions of the statutory restrictions using demonstration authority.

Response: We thank the commenters for their input. We reiterate our commitment to expanding access to telehealth services consistent with statutory authority, and paying appropriately for services that maximize telecommunications technology. We will carefully review the comments and consider commenters' suggestions for future rulemaking and any appropriate sub-regulatory changes.

6. Comment Solicitation on Remote Patient Monitoring

In addition to the broad comment solicitation regarding Medicare telehealth services, we also specifically solicited comment on whether to make separate payment for CPT codes that describe remote patient monitoring. We note that remote patient monitoring services would generally not be considered Medicare telehealth services as defined under section 1834(m) of the Act. Rather, like the interpretation by a physician of an actual electrocardiogram or electroencephalogram tracing that has been transmitted electronically, these services involve the interpretation of medical information without a direct interaction between the practitioner and beneficiary. As such, they are paid under the same conditions as in-person physicians' services with no additional requirements regarding permissible originating sites or use of the telehealth place of service code.

We noted we were particularly interested in comments regarding CPT code 99091 (Collection and interpretation of physiologic data (*e.g.*, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time). This code is currently assigned a procedure status of B (bundled). As with many other bundled codes, we currently assign RVUs for this code based on existing RUC recommendations, even though we have considered the services described by the code to be bundled with other services. In addition to comments on the payment status and valuation for this code (the RUC-recommended value, specifically) we sought information about the circumstances under which this code might be reported for separate payment, including how to differentiate the time related to these services from other services, including care management services. For example, PFS payment for analysis of patient-generated health data is considered included in chronic care management (CCM) services (CPT codes 99487, 99489, and 99490) to the extent that this activity is medically necessary and performed as part of CCM (see the CY 2015 PFS final rule (79 FR 67727), CY 2016 PFS final rule (81 FR 80244), and the CMS FAQ available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Payment_for_CCM_Services_FAQ.pdf*). We also sought comment from beneficiaries and beneficiary advocacy organizations on the value of such services and what protections might be necessary to assure that beneficiaries are properly informed that they are receiving a remote monitoring service, since beneficiaries would be required to pay standard cost sharing for such services. Finally, regarding CPT code 99091, we sought available information regarding potential utilization assumptions we might make for the service for purposes of PFS ratesetting, were we to make it payable for CY 2018 or in the future; since making such assumptions would be necessary to implement separate payment. We noted that since the PFS is a budget neutral system, any increase in payment made for particular services would result in decreases in payment for other services, and the degree of that decrease would depend, in large part, on the utilization assumptions.

We also sought comment on other existing codes that describe extensive use of communications technology for consideration for future rulemaking, including CPT code 99090 (Analysis of clinical data stored in computers (*e.g.*, ECGs, blood pressures, hematologic data)). CPT code 99090 is also assigned a procedure status of B (bundled). CPT code 99090 also has a payment status of bundled; and we do not have RUC-recommended values for this service, and therefore, currently do not assign RVUs.

The following is a summary of the public comments received on our proposals and our responses:

Comment: Commenters were generally supportive of CMS recognizing the increasing importance of remote patient monitoring. Several commenters recommended that CMS make separate payment for CPT code 99091. Other commenters acknowledged that the current code, which has not been separately payable for some time, may not optimally describe the services furnished using current technology. Some of these commenters encouraged CMS to make the services separately payable for CY 2018, but also noted that the CPT Editorial Panel is currently working on codes that more accurately describe remote monitoring.

A few commenters expressed opposition to making CPT codes 99090 and/or 99091 separately payable, noting that these are generic codes and are duplicative of other codes that are more specific, such as CPT codes 93297 ((Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular 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)) and CPT code 93228 (External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional)). Several commenters encouraged CMS to wait for the CPT Editorial Panel to complete its work of reviewing and revising the CPT codes and consider valuing the new codes in the future. Of the commenters who were supportive of unbundling and making separate payment for CPT code 99091, a few suggested that CPT code 99091 could be billed in association with chronic care management (CCM) services.

Response: We agree with commenters that monitoring services can be a significant part of ongoing medical care and that we should recognize these services for separate payment as soon as practicable. However, we also agree with commenters that the two codes in question may not optimally describe these services as currently furnished. In order to reconcile these concerns,

especially considering the expectation that CPT coding revisions are expected in the immediate future, we believe that activating CPT code 99091 for separate payment under Medicare for 2018 will serve to facilitate appropriate payment for these services in the short term. Unlike CPT code 99090, CPT code 99091 specifies that the information is interpreted by a physician or other qualified health care professional, and it specifies that this activity requires a minimum of 30 minutes of time. After consideration of these differences between the two CPT codes, and after consideration of the public comments recommending that we make separate payment for CPT code 99091, we were persuaded to change the status of CPT code 99091 from bundled to active for CY 2018. In addition, as noted in the CY 2018 PFS proposed rule, the RUC had already provided CMS with RVUs for CPT code 99091, whereas it did not provide CMS with RVUs for CPT code 99090. Also, we did not receive specific comments to suggest reasons for changing CPT code 99090 to ''active'' status, so we are retaining the ''bundled'' status for that code. We will consider whether to adopt and establish relative value units for CPT codes that may be developed by the CPT Editorial Panel under our standard process for future years through notice and comment rulemaking. However, the comments make it clear to us that separate payment for this code will not mitigate the need for coding revisions. In order to account for some of the concerns raised by commenters regarding the broad nature of the code that describes professional collection and interpretation of the stored patient data, we believe that we can apply some of the current requirements regarding chronic care management services (CCM) to identify circumstances appropriate for reporting the code. Specifically, given the non face-to-face nature of the services described by CPT code 99091, we are requiring that the practitioner obtain advance beneficiary consent for the service and document this in the patient's medical record. Additionally, for new patients or patients not seen by the billing practitioner within 1 year prior to billing CPT code 99091, we are requiring initiation of the service during a face-to-face visit with the billing practitioner, such as an Annual Wellness Visit or Initial Preventive Physical Exam, or other face-to-face visit with the billing practitioner. Levels 2 through 5 E/M visits (CPT codes 99212 through 99215) would qualify as the face-to-face visit. However, services that do not involve a face-to-face visit by the billing practitioner or are not separately payable under the PFS (such as CPT code 99211, anticoagulant management, online services, telephone and other E/M services) do not qualify as initiating visits. The face-to-face visit included in transitional care management (TCM) services (CPT codes 99495 and 99496) would also qualify. We are also adopting the prefatory language for CPT code 99091, including the requirement that it ''should be reported no more than once in a 30-day period to include the physician or other qualified health care professional time involved with data accession, review and interpretation, modification of care plan as necessary (including communication to patient and/or caregiver), and associated documentation.''

Finally, because we believe the kind of analysis involved in furnishing this service is complementary to CCM and other care management services, for the purposes of Medicare billing, we are allowing that CPT code 99091 can be billed once per patient during the same service period as CCM (CPT codes 99487, 99489, and 99490), TCM (CPT codes 99495 and 99496), and behavioral health integration (BHI) (CPT codes 99492, 99493, 99494, and 99484). We note that under current billing rules, time counted toward the CCM codes generally refers to time spent by clinical staff furnishing care management services; while CPT code 99091 refers to practitioner time. We note that time spent furnishing these services could not be counted towards the required time for both codes for a single month.

We also note that the new separate payment for CPT code 99091 will be excluded from the calculation of the net reduction in expenditures due to changes in coding and valuation for purposes of the misvalued code target, consistent with policies finalized in the CY 2016 PFS final rule with comment period (80 FR 70926). CPT code 99091 describes a service that is newly separately reportable, but for which no corresponding reduction is being made to existing codes and instead reductions under the PFS are being taken exclusively through a budget neutrality adjustment.

We look forward to forthcoming coding changes through the CPT process that we anticipate will better describe the role of remote patient monitoring in contemporary practice and potentially mitigate the need for the additional billing requirements associated with these services.

7. 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. 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 originating site facility fee for telehealth services furnished in CY 2017 is $25.40. The MEI increase for 2018 is 1.4 percent and is based on the most recent historical update through 2017Q2 (1.8 percent), and the most recent historical MFP through calendar year 2016 (0.4 percent). Therefore, for CY 2018, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is 80 percent of the lesser of the actual charge or $25.76. The Medicare telehealth originating site facility fee and the MEI increase by the applicable time period is shown in Table 8.

TABLE 8—THE MEDICARE TELEHEALTH ORIGINATING SITE FACILITY FEE

Time period	MEI increase	Facility fee
10/01/2001–12/31/2002	N/A	$20.00
01/01/2003–12/31/2003	3	20.60
01/01/2004–12/31/2004	2.9	21.20
01/01/2005–12/31/2005	3.1	21.86
01/01/2006–12/31/2006	2.8	22.47
01/01/2007–12/31/2007	2.1	22.94
01/01/2008–12/31/2008	1.8	23.35
01/01/2009–12/31/2009	1.6	23.72
01/01/2010–12/31/2010	1.2	24.00
01/01/2011–12/31/2011	0.4	24.10

TABLE 8—THE MEDICARE TELEHEALTH ORIGINATING SITE FACILITY FEE—Continued

Time period	MEI increase	Facility fee
01/01/2012–12/31/2012	0.6	24.24
01/01/2013–12/31/2013	0.8	24.43
01/01/2014–12/31/2014	0.8	24.63
01/01/2015–12/31/2015	0.8	24.83
01/01/2016–12/31/2016	1.1	25.10
01/01/2017–12/31/2017	1.2	25.40
01/01/2018–12/31/2018	1.4	25.76

E. Potentially Misvalued Services Under the Physician Fee Schedule

1. Background

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

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

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

As MedPAC noted in its March 2009 Report to Congress (*http://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to 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 practice expenses.
- 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 physician fee schedule.
- 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 intra-service work per unit of time.
- Codes with high practice expense relative value units.
- 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 physician fee schedule.

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 plan to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well.

Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed approximately 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the CY 2012 PFS final rule with comment period (76 FR 73055 through 73958), we finalized our policy to consolidate the review of physician work and PE at the same time, and established a process for the annual public nomination of potentially misvalued services.

In the CY 2013 PFS final rule with comment period, we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called ''Harvard-valued codes''). In CY 2009 (73 FR 38589), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth Five-Year Review (76 FR 32410), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 services. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time).

In the CY 2016 PFS final rule with comment period, we finalized for review a list of potentially misvalued services, which included eight codes in the neurostimulators analysis-programming family (CPT 95970–95982). We also finalized as potentially misvalued 103 codes identified through our screen of high expenditure services across specialties.

In the CY 2017 PFS final rule, we finalized for review a list of potentially misvalued services, which included eight codes in the end-stage renal disease home dialysis family (CPT codes 90963–90970). We also finalized as potentially misvalued 19 codes identified through our screen for 0-day global services that are typically billed with an evaluation and management (E/M) service with modifier 25.

3. CY 2018 Identification and Review of Potentially Misvalued Services

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

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

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

a. Public Nomination of Arthrodesis of Sacroiliac Joint (CPT Code 27279)

After we issued the CY 2017 PFS final rule, we received a nomination and supporting documentation for one code to be considered as potentially misvalued. We evaluated the supporting documentation for this nominated code to ascertain whether the submitted information demonstrated that the code should be proposed as potentially misvalued.

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) was nominated for review as a potentially misvalued code because the current work RVU is potentially undervalued and stakeholders recommended that it should be increased to 14.23. We proposed this code as a potentially misvalued code in the CY 2018 PFS proposed rule.

The following is a summary of the public comments received on whether CPT code 27279 should be reviewed under the misvalued code initiative and our responses:

Comment: One commenter disagreed with CMS' proposal of CPT code 27279 as potentially misvalued, while many other commenters supported the proposal because they believe the service is significantly undervalued relative to other PFS services. While some commenters suggested the work RVU should be increased relative to other joint replacement procedures, like CPT code 63030 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar) which has a work RVU of 13.18, other commenters recommended increasing the work RVU to 14.23 because they stated that value better reflects the technical difficulty and increased time required to perform the procedure. Other commenters suggested specific work RVUs that were higher than 14.23 for similar reasons.

A few commenters noted that CPT code 27279 is scheduled for review by the RUC in October 2018 as part of its standard review process. As a result, some commenters suggested that CMS should wait until the RUC makes a recommendation regarding the appropriate valuation of the code. Some commenters noted that the RUC intends to review this service in October 2018 and suggested that the timeframe for that review would mean that the code could not be appropriately valued prior to CY 2020.

Response: After reviewing the range of public comments, we agree with commenters that CPT code 27279 is a potentially misvalued, and believe that a comprehensive review of the code values is warranted.

While we appreciate the comments that included suggestions regarding the specific work RVUs that might represent more appropriate valuation, we agree with those commenters that urged us to wait for the code to be reviewed by the RUC. We note that should the RUC and other relevant stakeholders expedite their review process, we would be able to consider making changes during next year's rulemaking. If the RUC review process is not completed in time, we may not be able to make changes in next year's rulemaking and would wait for the RUC to complete its process before making changes in subsequent rulemaking.

b. Comment Solicitation on Dialysis Vascular Access Codes (CPT Codes 36901–36909)

In the CY 2017 PFS final rule, we noted that the assertions by some commenters regarding appropriate values for the dialysis vascular access codes newly created in CY 2017 (CPT codes 36901 through 36909) did not include data that would warrant increases to the work RVUs we proposed and finalized in that rule (81 FR 80290–80297). However, we urged interested stakeholders to consider submitting robust data regarding costs for these and other services (81 FR 80290–80297). We have continued to receive feedback from stakeholders regarding the work valuation of these codes. Stakeholders have expressed concerns regarding the typical patient for these procedures as reflected in the information included in the RUC recommendations for CY 2017 and the importance of appropriate payment for ensuring access to care for Medicare beneficiaries. Therefore, we sought additional comment and requested robust data regarding the potentially misvalued work RVUs for CPT codes 36901 through 36909 and considered alternate work valuations for CY 2018, such as the RUC-recommended work RVUs from CY 2017, or other potential values based on submission of data through the public comment process. We noted that the RUC-recommended work RVUs for these services were displayed in the CY 2017 PFS final rule (81 FR 80290 through 80296).

The following is a summary of the public comments received on CPT codes 36901–36909 and our responses:

Comment: Many commenters were concerned that the values currently assigned to the dialysis circuit family of codes have already and will continue to compromise patient access to vascular access services; with one commenter specifically requesting that CMS promptly reevaluate these codes. Several commenters supported increases to the work RVUs and explained that the greater complexity of the patient population for these services involved greater relative intensity than other services, especially since the codes involve obtaining new access as well as secondary access to the dialysis circuit, while the codes used as crosswalks for the current valuation involve colonoscopy through an existing access.

The overwhelming majority of commenters suggested we finalize the CY 2017 RUC-recommended work RVUs for CPT codes 36901–36909.

Response: We appreciate commenters' responses to our request for new information. After further reflection, we are persuaded by commenters' explanations regarding the complexities of care related to this patient population specifically and after reviewing these additional remarks, agree that these services are currently misvalued. Therefore for CY 2018, we are finalizing the CY 2017 RUC-recommended work RVUs for CPT codes 36901–36909, consistent with the requests of public commenters.

c. CMS Nomination of Flow Cytometry Codes (CPT Codes 88184 and 88185)

We have received conflicting information about the direct PE inputs for CPT codes 88184 (Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker) and 88185 (Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; each additional marker (List separately in addition to code for first marker)). In the CY 2018 PFS proposed rule, we proposed these codes as potentially misvalued so that they can be reviewed again because some stakeholders have suggested the clinical labor and supplies that were previously finalized are no longer accurate.

Comment: We received several comments regarding various clinical labor and supply inputs for CPT codes 88184 and 88185 urging CMS to use the RUC recommendations for CY 2017 in developing final PE RVUs for these services instead of recommending additional review of these codes under the misvalued code initiative.

Response: We appreciate these comments and, based on this

suggestion, we have re-examined the CY 2017 RUC-recommended direct PE inputs for these services in light of specific comments. We refer readers to section II.H of this final rule. This section describes the direct PE input changes between CY 2017 and CY 2018 for specific services.

d. Comment Solicitation on Emergency Department Payment Rates (CPT Codes 99281–99385)

We received information suggesting that the work RVUs for emergency department visits did not appropriately reflect the full resources involved in furnishing these services. Specifically, stakeholders expressed concerns that the work RVUs for these services have been undervalued given the increased acuity of the patient population and the heterogeneity of the sites, such as freestanding and off-campus emergency departments, where emergency department visits are furnished. Therefore, we sought comment on whether CPT codes 99281–99385 (Emergency department visits for the evaluation and management of a patient) should be reviewed under the misvalued code initiative.

The following is a summary of the public comments received on whether CPT codes 99281–99385 should be reviewed under the misvalued code initiative and our responses:

Comment: Most commenters had no objection to review of these codes. Several commenters stated that the work RVUs for the emergency department evaluation and management (E/M) services, like most other E/M services, are undervalued given the increased acuity of the patient population and the heterogeneity of the sites where emergency department visits are furnished. One commenter suggested that CMS evaluate alternatives to the misvalued code initiative for review of these codes, but another commenter explicitly stated that review of these services should be undertaken by the RUC rather than CMS. In its comment, the RUC stated if CMS finalizes the codes as potentially misvalued, it will add these codes to its list of potentially misvalued services.

In contrast, one commenter stated that the problem of under-reimbursement for these services would be better addressed by streamlining the E/M process for documenting the higher level of care. Another commenter stated that given the significant changes to documentation guidelines for E/M services that may be forthcoming in this rule cycle, it is premature and somewhat difficult to advise on potential revaluation of any E/M codes, pending details on how the documentation guideline revisions are resolved.

Response: We agree with the majority of commenters that these services may be potentially misvalued given the increased acuity of the patient population and the heterogeneity of the sites where emergency department visits are furnished. As a result, we look forward to reviewing the RUC's recommendations regarding the appropriate valuation of these services for our consideration in future notice and comment rulemaking. Additionally, regarding the commenters' concerns about documentation guidelines for E/M services, we refer readers to section II.I for details regarding our comment solicitation on documentation for E/M guidelines more generally.

e. Comment Solicitation on New Potentially Misvalued Code Screens

For over a decade, CMS has collaborated with the RUC to regularly prioritize codes for review by using the categories specified in the statute or as determined appropriate. We generally have referred to these categories as ''misvalued code screens.'' To supplement ongoing RUC identification of potentially misvalued codes through established screens, CMS regularly uses PFS rulemaking to identify other screens for use in identifying potentially misvalued codes. For example, in recent years, CMS has prioritized the following screens:

- Codes with low work RVUs commonly billed in multiple units per single encounter.
- Codes with high volume and low work RVUs.
- Codes with site-of-service-anomalies.
- E/M codes.
- PFS high expenditure services.
- Services with standalone PE procedure time.
- Services with anomalous time.
- Contractor Medical Director identified potentially misvalued codes.
- Codes with higher total Medicare payments in office than in hospital or ASC.
- Publicly nominated potentially misvalued codes.
- 0-day global services that are typically billed with an evaluation and management (E/M) service with modifier 25.

Although we did not propose a new screen for CY 2018, we continue to believe that it is important to prioritize codes for review under the misvalued code initiative. As a result, we solicited public comment on the best approach for developing screens, as well as what particular new screens we might consider. We will consider these comments for future rulemaking.

The following is a summary of the public comments received on the best approach for developing screens, as well as what particular new screens we might consider and our responses:

Comment: One commenter suggested revisiting two recent efforts funded by CMS, reports by the Urban Institute and RAND, for prioritization of codes for review under the misvalued code initiative. Both reports include examination on the relationship between service times and work RVUs, in some cases for specific services. One commenter suggested that we no longer utilize potentially misvalued code screens due to the burden it causes the specialty societies. Other commenters suggest that CMS work in collaboration with the RUC to identify potentially misvalued codes and to not re-review codes that were recently reviewed by the RUC.

Response: We thank commenters for their input and will consider all recommendations for future rulemaking.

F. Payment Incentive for the Transition from Traditional X-Ray Imaging to Digital Radiography and Other Imaging Services

Section 502(a)(1) of Division O, Title V of the Consolidated Appropriations Act of 2016 (Pub. L. 114–113) amended section 1848(b) of the Act by establishing a new paragraph (9) of subsection (b). Section 1848(b)(9)(B) of the Act provides for a 7 percent reduction in payments for the technical component (TC) for imaging services made under the PFS that are X-rays (including the technical component portion of a global service) taken using computed radiography technology furnished during CYs 2018 through 2022, and for a 10 percent reduction for the technical component of such imaging services furnished during CY 2023 or a subsequent year. Computed radiography technology is defined for purposes of this paragraph as cassette-based imaging that utilizes an imaging plate to create the image involved. Section 1848(b)(9) of the Act also requires implementation of the reduction in payments through appropriate mechanisms, which can include the use of modifiers. In accordance with section 1848(c)(2)(B)(v)(X) of the Act, the adjustments under section 1848(b)(9)(A) of the Act are exempt from the budget neutrality requirement.

We stated in the CY 2017 PFS proposed rule that because the required reductions in PFS payment for the TC

of imaging services (including the TC portion of a global service) that are X-rays taken using computed radiography technology did not apply for CY 2017, we would address implementation of section 1848(b)(9)(B) of the Act in future rulemaking. Therefore, to implement the provisions of section 1848(b)(9)(B) of the Act relating to the payment reduction for the TC (including the TC portion of a global service) of X-rays taken using computed radiography technology during CY 2018 or subsequent years, we proposed in the CY 2018 PFS proposed rule to establish a new modifier to be used on claims for these services.

We proposed that beginning January 1, 2018, this modifier would be required to be used when reporting imaging services for which payment is made under the PFS that are X-rays (including the X-ray component of a packaged service) taken using computed radiography technology. The modifier would be required on claims for the technical component of the X-ray service, including when the service is billed globally because the PFS payment adjustment is made to the technical component regardless of whether it is billed globally, or billed separately using the TC modifier. The modifier must be used to report the specific services that are subject to the payment reduction and accurate use is subject to audit. The use of this proposed modifier to indicate an X-ray taken using computed radiography would result in a 7 percent reduction for CYs 2018 through 2022 and a 10 percent reduction for CY 2023 or a subsequent calendar year to the payments for the TC for such imaging services furnished as specified under section 1848(b)(9)(B) of the Act.

The following is a summary of the public comments received and our responses:

Comment: One commenter noted support for the computed radiography to digital X-ray payment differential but sought clarification regarding its implementation. The commenter stated that a new modifier will be designated to denote the CPT codes for computed radiography and HCPCS X-ray codes that are subject to the payment reduction; however, no listing of such codes was provided in the proposed rule. The commenter noted that similarly last year it requested a listing of the X-ray codes to which the modifier would apply. CMS declined to provide such a list on the basis that the payment differential would apply to any service performed using the film X-rays. The commenter stated that the listing of the film and computed radiography CPT and HCPCS codes would facilitate easy implementation, prevent ambiguity, be less burdensome, and prevent risk of audit.

Response: We considered the commenter's concerns and recommendation that we maintain a list of CPT and HCPCS codes to which the policy applies. However, we do not agree that such a list would facilitate easy implementation, prevent ambiguity, be less burdensome, or prevent the risk of audit. We believe that the professionals who furnish and bill for these services are in the best position to determine whether a particular imaging service is appropriately described as X-rays taken using computed radiography.

Comment: Some commenters expressed concern that rural and underserved areas are particularly penalized by this provision and that the use of a modifier places a burden on all providers and creates another opportunity for miscoding.

Response: We appreciate the commenters' concerns, but under current law, we do not currently believe that we have authority to provide exemptions from the policy. We believe that the use of a modifier is the least burdensome method to identify the services to which the payment reduction applies, and to implement the required payment reduction for services that are X-rays taken using computed radiography.

Comment: One commenter opined that the continued overall trend in imaging payment reductions is not sustainable for any quality imaging provider and that CMS should look for more creative solutions such as the AUC program, as well as reductions in mandated reporting.

Response: We thank the commenter for the suggestions and will take these recommendations into consideration for future rulemaking.

Comment: One commenter requested that CMS work with Congress to delay or eliminate the payment reductions, and ensure that clinicians are thoroughly educated and outreach is provided to ensure that stakeholders are thoroughly aware of the new requirements.

Response: We will include information to educate clinicians regarding the new modifier requirement for services that are X-rays taken using computed radiography as part of ongoing provider education activities, though we acknowledge that we also appreciate assistance from private, national organizations, such as medical specialty societies in educating their membership. We appreciate the commenters' concerns regarding the overall merits of the statutory provision, but we do not believe that we have the authority to alter the application of the provision.

Comment: Some commenters urged that physician practices be held harmless from financial and criminal penalties if the new modifiers are omitted or incorrectly applied at least for the first 3 years of the program (2017–2019). In addition, the commenter stated that audits by the Recovery Audit Contractors (RACs) related to the implementation of the transition from traditional X-ray imaging to digital radiology using the modifier should not be approved for the same time period.

Response: We appreciate these suggestions and concerns but note that this final rule specifically addresses the payment policies related to the statutory provision. The kinds of enforcement activities addressed by these commenters are outside the scope of this final rule.

Comment: Some commenters supported the use of the modifier to implement this requirement, but requested that the modifier be released as soon as possible in order to allow radiology practices to work out the logistics associated with compliance with the new requirement.

Response: To implement this provision, we created modifier ''FY'' (X-ray taken using computed radiography technology/cassette-based imaging). Beginning in 2018, claims for X-rays taken using computed radiography/cassette-based imaging must include modifier ''FY'' that will result in the applicable payment reduction.

Comment: One commenter supported the use of the modifier as the best indicator for the use of traditional X-rays or digital radiology. Another commenter supported the transition to digital imaging services because, according to the commenter, it is essential to reach widespread interoperability.

Response: We thank commenters for their support.

After consideration of the public comments, we are finalizing the proposal without modification.

G. Payment Rates Under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital

1. Background

Sections 1833(t)(1)(B)(v) and (t)(21) of the Act require that certain items and

services furnished by certain off-campus provider-based departments (PBDs) (collectively referenced here as nonexcepted items and services furnished by nonexcepted off-campus PBDs) shall not be considered covered OPD services for purposes of payment under the OPPS, and payment for those nonexcepted items and services furnished on or after January 1, 2017 shall be made under the applicable payment system. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79713), we finalized the PFS as the ''applicable payment system'' for most nonexcepted items and services furnished by off-campus PBDs.

As part of that discussion, we indicated that, in response to public comments received on the proposed payment policies for nonexcepted items and services, we would issue an interim final rule with comment period (the CY 2017 interim final rule, 81 FR 79720 through 79729) to establish payment policies under the PFS for nonexcepted items and services furnished on or after January 1, 2017. In the following paragraphs, we summarize what we proposed for the payment policies under the PFS for nonexcepted items and services furnished during CY 2018. The CY 2017 interim final rule can be found on the Internet at *https://www.gpo.gov/fdsys/pkg/FR-2016-11-14/pdf/2016-26515.pdf*.

2. Payment Mechanism

Coding and payment policies under the PFS have long recognized the differences between the portions of services for which direct costs generally are incurred by practitioners and the portions of services for which direct costs generally are incurred by facilities. At present, the coding and RVUs established for particular groups of services under the PFS generally reflect such direct cost differences. As described in section II.B of this final rule, we establish separate nonfacility and facility RVUs for many HCPCS codes describing particular services paid under the PFS. For many other services, we establish separate RVUs for the professional component and the technical component of the service described by the same HCPCS code. For other services, we establish RVUs for the different HCPCS codes that segregate and describe the discrete professional and technical aspects of particular services.

Because hospitals with nonexcepted off-campus PBDs that furnish nonexcepted items and services are likely to furnish a broader range of services than other provider or supplier types for which there is a separately valued technical component under the PFS, for CY 2017, we established a new set of payment rates under the PFS that reflected the relative resource costs of furnishing the technical component of a broad range of services to be paid under the PFS specific to the nonexcepted off-campus PBD of a hospital with packaging (bundling) rules that are unique to the hospital outpatient setting under the OPPS.

In principle, the coding and billing mechanisms required to make appropriate payment to hospitals for nonexcepted items and services furnished by nonexcepted off-campus PBDs are parallel to those used to make payment for the technical component services for a range of supplier types paid under the PFS. That is, payments to hospitals are made for the technical aspect of services, while physicians and other practitioners report the professional aspect of these same services. In some cases, the entities reporting the technical aspect of services use the same coding that is used by the individuals reporting the professional services. In other cases, different coding applies. We proposed to maintain this coding and billing mechanism for CY 2018.

Comment: A number of commenters supported our proposal to continue to allow hospitals to bill using an institutional claim with the modifier ''PN'' to indicate that the nonexcepted items and services are furnished by nonexcepted PBDs.

Response: We appreciate the comments in support of our proposal to allow hospitals to continue to bill for nonexcepted items and services furnished by nonexcepted off-campus PBDs using an institutional claim for CY 2018.

3. Establishment of Payment Rates

Using the relativity among OPPS payments to establish rates for the nonexcepted items and services furnished by nonexcepted off-campus PBDs and billed by hospitals under the PFS was only one aspect of establishing the necessary relativity of these services under the PFS more broadly. It was necessary to estimate the relativity of these services compared to PFS services furnished in other settings paid under the PFS. For CY 2017, we used our best estimate of the more general relativity between the technical component of PFS services furnished in nonexcepted off-campus PBDs and all other PFS services furnished in other settings using the limited information available to us at that time. As described in the CY 2017 interim final rule (81 FR 79722 through 79726), we estimated that for CY 2017, scaling the OPPS payment rates downward by 50 percent would strike an appropriate balance that avoided potentially underestimating the relative resources involved in furnishing services in nonexcepted off-campus PBDs as compared to the services furnished in other settings for which payment was made under the PFS. Specifically, we established site-specific rates under the PFS for the technical component of the broad range of nonexcepted items and services furnished by nonexcepted off-campus PBDs to be paid under the PFS that was based on the OPPS payment amount for the same items and services, scaled downward by 50 percent. We called this adjustment the ''PFS Relativity Adjuster.'' The PFS Relativity Adjuster refers to the percentage of the OPPS payment amount paid under the PFS for a nonexcepted item or service to the nonexcepted off-campus PBD under this policy.

a. Methodology for Establishing CY 2017 PFS Relativity Adjuster

In developing the CY 2017 interim final rule, we began by analyzing hospital outpatient claims data from January 1 through August 26, 2016, that contained the ''PO'' modifier signifying that they were billed by an off-campus department of a hospital paid under the OPPS other than a remote location, a satellite facility, or a dedicated emergency department (ED). We noted that the use of the ''PO'' modifier was a new mandatory reporting requirement for CY 2016. We limited our analysis to those claims billed on the 13X Type of Bill because those claims were used for Medicare Part B billing under the OPPS. We then identified the top (most frequently billed) 25 major codes that were billed by claim line; that is, items and services that were separately payable or conditionally packaged. Specifically, we restricted our analysis to codes with OPPS status indicators ''J1'', ''J2'', ''Q1'', ''Q2'', ''Q3'', ''S'', ''T'', or ''V''. We did not include separately payable drugs or biologicals in this analysis because those drugs or biologicals were not paid under the PFS under the CY 2017 interim final rule. As such, under the CY 2017 interim final rule, the PFS Relativity Adjuster did not apply to separately payable drugs and biologicals furnished by a nonexcepted off-campus PBD. Similarly, we excluded codes assigned an OPPS status indicator ''A'' because the services described by those codes were already paid at a rate under a fee schedule other than the OPPS and payment for those nonexcepted items and services was not changed by the rates established under

the CY 2017 interim final rule. Next, for the same major codes (or analogous codes in the rare instance that different coding applies under the OPPS than the PFS), we compared the CY 2016 payment rate under the OPPS to a CY 2016 payment rate under the PFS attributable to the nonprofessional relative resource costs involved in furnishing the services.

The most frequently billed service with the ''PO'' modifier was described by HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), which is paid under APC 5012; the total number of CY 2016 claim lines for that service was approximately 6.7 million as of August 2016. In CY 2016, the OPPS payment rate for APC 5012 was $102.12. Because there were multiple CPT codes (CPT codes 99201 through 99215) used under the PFS for billing that service, an exact comparison between the $102.12 OPPS payment rate for APC 5012 and the payment rate for a single CPT code billed under the PFS was not possible. Therefore, for purposes of the analysis, we examined the difference between the nonfacility payment rates and the facility payment rates under the PFS for CPT codes 99213 and 99214, which were the billing codes for a Level III and a Level IV office visit. Although we did not have data to precisely determine the equivalent set of PFS visit codes to use for the comparison, we believed that, based on the distribution of services billed for the visit codes under the PFS and the distribution of the visit codes under the OPPS from the last time period the CPT codes were used under the OPPS in CY 2014, those two codes provided reliable points of comparison. For CPT code 99213, the difference between the nonfacility payment rate and the facility payment rate under the PFS in CY 2016 was $21.86, which was 21 percent of the OPPS payment rate for APC 5012 of $102.12. For CPT code 99214, the difference between the nonfacility payment rate and the facility payment rate under the PFS in CY 2016 was $29.02, which was 28 percent of the OPPS payment rate for APC 5012. However, we recognized that, due to the more extensive packaging that occurred under the OPPS for services provided along with clinic visits relative to the more limited packaging that occurred under the PFS for office visits, those payment rates were not entirely comparable.

We then assessed the next 24 major codes most frequently billed on the 13X claim form by hospitals. We removed HCPCS code 36591 (Collection of blood specimen from a completely implantable venous access device) because, under current PFS policies, the code is used only to pay separately under the PFS when no other service was on the claim. We also removed HCPCS code G0009 (Administration of Pneumococcal Vaccine) because there was no payment for the code under the PFS. For the remaining 22 major codes most frequently billed, we estimated the amount that would have been paid to the physician in the office setting under the PFS for practice expenses not associated with the professional component of the service. As indicated in Table 9, this amount reflected (1) the difference between the PFS nonfacility payment rate and the PFS facility rate, (2) the technical component, or (3) in instances where payment would have been made only to the facility or only to the physician, the full nonfacility rate. This estimate ranged from zero percent to 137.8 percent of the OPPS payment rate for a code. Overall, the average (weighted by claim line volume times rate) of the nonfacility payment rate estimate for the PFS compared to the estimate for the OPPS for the 22 remaining major codes was 45 percent.

TABLE 9—COMPARISON OF CY 2016 OPPS PAYMENT RATE TO CY 2016 PFS PAYMENT RATE FOR TOP HOSPITAL CODES BILLED USING THE ''PO'' MODIFIER

HCPCS code	Code description	Total claim lines	CY 2016 OPPS payment rate	CY 2016 applicable PFS technical payment amount estimate	Col (5) as a percent of OPPS	PFS estimate
(1)	(2)	(3)	(4)	(5)		(6)
96372	Injection beneath the skin or into muscle for therapy, diagnosis, or prevention.	338,444	$42.31	$25.42	60.1	Single rate paid exclusively to either practitioner or facility: Full nonfacility rate.
71020	X-ray of chest, 2 views, front and side	333,203	60.80	16.83	27.7	Technical component: Full nonfacility rate.
93005	Routine electrocardiogram (EKG) with tracing using at least 12 leads.	318,099	55.94	8.59	15.4	Technical component: Full nonfacility rate.
96413	Infusion of chemotherapy into a vein up to 1 hour.	254,704	280.27	136.41	48.7	Single rate paid exclusively to either practitioner or facility: Full nonfacility rate.
93798	Physician services for outpatient heart rehabilitation with continuous EKG monitoring per session.	203,926	103.92	11.10	10.7	Nonfacility rate—Facility rate.
96375	Injection of different drug or substance into a vein for therapy, diagnosis, or prevention.	189,140	42.31	22.56	53.3	Single rate paid exclusively to either practitioner or facility: Full nonfacility rate.
93306	Ultrasound examination of heart including color-depicted blood flow rate, direction, and valve function.	179,840	416.80	165.77	39.8	Technical component: Full nonfacility rate.
77080	Bone density measurement using dedicated X-ray machine.	155,513	100.69	31.15	30.9	Technical component: Full nonfacility rate.
77412	Radiation treatment delivery	137,241	194.35	267.86	137.8	Technical component (Full nonfacility rate) based on weighted averages for the following PFS codes: G6011; G6012; G6013; and G6014.
90853	Group psychotherapy	123,282	69.65	0.36	0.5	Nonfacility rate—Facility rate.
96365	Infusion into a vein for therapy, prevention, or diagnosis up to 1 hour.	122,641	173.18	69.82	40.3	Nonfacility rate—Facility rate.
20610	Aspiration and/or injection of large joint or joint capsule.	106,769	223.76	13.96	6.2	Nonfacility rate—Facility rate.
11042	Removal of skin and tissue first 20 sq cm or less.	99,134	225.55	54.78	24.3	Nonfacility rate—Facility rate.

TABLE 9—COMPARISON OF CY 2016 OPPS PAYMENT RATE TO CY 2016 PFS PAYMENT RATE FOR TOP HOSPITAL CODES BILLED USING THE ''PO'' MODIFIER—Continued

HCPCS code	Code description	Total claim lines	CY 2016 OPPS payment rate	CY 2016 applicable PFS technical payment amount estimate	Col (5) as a percent of OPPS	PFS estimate
(1)	(2)	(3)	(4)	(5)		(6)
96367	Infusion into a vein for therapy prevention or diagnosis additional sequential infusion up to 1 hour.	98,930	42.31	30.79	72.8	Single rate paid exclusively to either practitioner or facility: Full nonfacility rate.
93017	Exercise or drug-induced heart and blood vessel stress test with EKG tracing and monitoring.	96,312	220.35	39.74	18.0	Technical component: Full nonfacility rate.
77386	Radiation therapy delivery	81,925	505.51	347.30	68.7	Technical component: Nonfacility rate for CPT code G6015 (analogous code used under the PFS).
78452	Nuclear medicine study of vessels of heart using drugs or exercise—multiple studies.	79,242	1,108.46	412.82	37.2	Technical component: Full nonfacility rate.
74177	CT scan of abdomen and pelvis with contrast.	76,393	347.72	220.20	63.3	Technical component: Full nonfacility rate.
71260	CT scan chest with contrast	75,052	236.86	167.21	70.6	Technical component: Full nonfacility rate.
71250	CT scan chest	74,570	112.49	129.61	115.2	Technical component: Full nonfacility rate.
73030	X-ray of shoulder, minimum of 2 views	71,330	60.80	19.33	31.8	Technical component: Full nonfacility rate.
90834	Psychotherapy, 45 minutes with patient and/or family member.	70,524	125.04	0.36	0.3	Nonfacility rate—Facility rate.
Weighted Average (claim line volume * rate) of the PFS payment compared to OPPS payment for the 22 major codes:						45%

As noted with the clinic visits, we recognized that there were limitations to our data analysis, including that OPPS payment rates include the costs of packaged items or services billed with the separately payable code, and therefore the comparison to rates under the PFS was not a one-to-one comparison. Also, we included only a limited number of services, and noted that additional services may have different patterns than the services described. After considering the payment differentials for major codes billed by off-campus departments of hospitals with the ''PO'' modifier and based on the data limitations of our analysis, we adopted, with some exceptions noted below, a set of PFS payment rates that were based on a 50 percent PFS Relativity Adjuster to the OPPS payment rates (inclusive of packaging) for nonexcepted items and services furnished by nonexcepted off-campus PBDs in the CY 2017 interim final rule. Generally speaking, we arrived at the 50 percent PFS Relativity Adjuster by examining the 45 percent comparison noted above, the ASC payment rate—which was roughly 55 percent of the OPPS payment rate on average—and the payment rate differential for the large number of OPPS and PFS E/M services, as described above. We recognized that the equivalent PFS nonfacility rates may be higher or lower on a code-specific basis than the rates that result from applying the overall PFS Relativity Adjuster to the OPPS payment rates on a code-specific basis. However, we believed that, on the whole, the percentage reduction did not underestimate the overall relativity between the OPPS and the PFS based on the limited data that were available. We were concerned, however, that the 50 percent PFS Relativity Adjuster might overestimate PFS nonfacility payments relative to OPPS payments. For example, if we were able at the time to sufficiently estimate the effect of the packaging differences between the OPPS and PFS, we suspected that the equivalent portion of PFS payments for evaluation and management codes, and for PFS services on average, would likely have been less than 50 percent for the same services. We considered the 50 percent PFS Relativity Adjuster for CY 2017 to be a transitional policy until such time that we had more precise data to better identify and value nonexcepted items and services furnished by nonexcepted off-campus PBDs and billed by hospitals.

We established several significant exceptions to the application of the 50 percent PFS Relativity Adjuster. For example, we did not apply the 50 percent PFS Relativity Adjuster to services that are currently paid under the OPPS based on payment rates from other Medicare fee schedules (including the PFS) on an institutional claim. The items and services that are assigned status indicator ''A'' in Addendum B to the CY 2017 OPPS/ASC final rule with comment period (available on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1656-FC.html*) continue to be reported on an institutional claim and paid under the required Medicare fee schedule such as the PFS, the CLFS, or the Ambulance Fee Schedule without a payment reduction. Similarly, drugs and biologicals that are separately payable under the OPPS (identified by status indicator ''G'' or ''K'' in Addendum B to the CY 2017 OPPS/ASC final rule with comment period) are paid in accordance with section 1847A of the Act (that is, typically ASP + 6 percent), consistent with payment rules in the physician office setting. Drugs and biologicals that are unconditionally packaged under the OPPS and are not separately payable (that is, those drugs and biologicals assigned status indicator of ''N'' in Addendum B to the CY 2017 OPPS/ASC final rule with comment period) are bundled into the PFS payment and are not separately paid to hospitals billing for nonexcepted items and services furnished by nonexcepted off-campus PBDs. The full range of exceptions and adjustments to the otherwise applicable OPPS payment rate that were adopted in the new PFS site-of-service payment rates in the CY 2017 interim final rule can be found on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/*

CMS-1656-FC-2017-OPPS-Status-Indicator.zip.

All nonexcepted items and services furnished by nonexcepted off-campus PBDs and billed by a hospital on an institutional claim with modifier ''PN'' (Nonexcepted service provided at an off-campus, outpatient, provider-based department of a hospital) are currently paid under the PFS at the rate established in the CY 2017 interim final rule. Specifically, nonexcepted off campus PBDs must report modifier ''PN'' on each UB–04 claim line to indicate a nonexcepted item or service, and otherwise continue to bill as they currently do. Further billing instructions on the PN modifier can be found in the January 2017 OPPS Quarterly Update (transmittal 3685, Change Request 9930) released December 22, 2016, available on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3685CP.pdf*.

b. PFS Relativity Adjuster

As noted in the CY 2017 interim final rule, we considered the CY 2017 PFS Relativity Adjuster of 50 percent to be a transitional policy until such time that we had more precise data to better identify and value nonexcepted items and services furnished by nonexcepted off-campus PBDs and billed by hospitals. At present, we do not have more precise data than were available when we established the PFS Relativity Adjuster in the CY 2017 interim final rule, and we do not anticipate having such data until after the end of CY 2017, at the earliest. However, in developing a policy for CY 2018, we have continued to explore options for modifying the calculation of the CY 2018 PFS Relativity Adjuster.

There is no consensus among stakeholders regarding the appropriate PFS Relativity Adjuster. Many stakeholders have suggested that making separate facility fee payments to hospitals under the PFS for all services that are separately paid under the OPPS itself undermines site neutral payment because practitioners are only paid a single combined fee for many services when furnished in an office setting, while there are two separate fees (professional and facility) paid when the service is furnished in the hospital setting. We acknowledge that there are many cases where single fees are paid to practitioners for services furnished in an office setting while fees for comparable services when furnished in the hospital setting are paid to both the professional and facility entities. However, we do not agree that this necessarily means that overall payment cannot be site neutral. We point out that the sum of the professional and the facility portions of payment for a service furnished in a nonexcepted off-campus PBD or in a different institutional setting could be equivalent to a single fee paid to the professional in the office setting. In the case of some services, in fact, the single payment made under the PFS at the nonfacility rate exceeds the sum of the separate payments Medicare makes to the professional at the facility rate under the PFS and to the facility under the OPPS. We also note that there are many separately reportable services under the PFS (for example, the vast majority of services described by add-on codes) for which separate payment is made to physician offices but no separate payment is made under either the OPPS or under the site-specific PFS payments made to hospitals billing for nonexcepted items and services furnished by nonexcepted off-campus PBDs. For these reasons, we believe that the overall total payment made for services is more relevant to the goal of site neutrality than the quantity of individual payments made. Nonetheless, we continue to recognize and share stakeholders' concerns regarding the importance of equivalent overall payment for services, regardless of setting.

In considering the appropriate PFS Relativity Adjuster for CY 2018, we continue to believe that claims data from CY 2017, which are not yet available, are needed to guide potential changes to our general approach. In the absence of such data, however, we have continued to consider the appropriate PFS Relativity Adjuster based on the information that is available. In the analysis we used to establish the PFS Relativity Adjuster for CY 2017, we attempted to identify the appropriate value by comparing OPPS and PFS payment rates for services frequently reported in off-campus departments of a hospital and described by the same codes under the two payment systems. As we acknowledged in the CY 2017 interim final rule, that data analysis did not include the most frequently billed service furnished in off-campus departments of a hospital, outpatient clinic visits. Outpatient clinic visits are reported using a single G-code under the OPPS and by one of ten different codes under the PFS.

Consistent with our previously stated concern that the PFS Relativity Adjuster for CY 2017 might be too small, generally resulting in greater overall payments to hospitals for services furnished by nonexcepted off-campus PBDs than would otherwise be paid under the PFS in the non-facility setting, we believed it was appropriate to propose changing the PFS Relativity Adjuster in order to ensure that payment made to these nonexcepted off-campus PBDs better aligns with these services that are the most frequently furnished in this setting.

In the CY 2018 PFS proposed rule, we proposed to revise the PFS Relativity Adjuster for nonexcepted items and services furnished by nonexcepted off-campus PBDs to be 25 percent of the OPPS payment rate. We arrived at this PFS Relativity Adjuster by making a code-level comparison for the service most commonly billed in the off-campus PBD setting under the OPPS: A clinic visit reported using HCPCS code G0463. In order to determine the analogous payment for the technical aspects of this service under the PFS in nonfacility settings, we compared the CY 2017 OPPS national payment rate for HCPCS code G0463 ($102.12) to the difference between the nonfacility and facility PFS payment amounts under the PFS using CY 2016 rates for the weighted average of outpatient visits (CPT codes 99201–99205 and CPT codes 99211–99215) billed by physicians and other professionals in an outpatient hospital department as the place of service.

The proposed PFS Relativity Adjuster of 25 percent was based solely on the comparison for the single service that reflects more than 50 percent of services billed in off-campus PBDs. We continue to recognize that the comparison between the OPPS and PFS rates for other services varies greatly, and that there are other factors, including the specific mix of services furnished by nonexcepted off-campus PBDs, policies related to packaging of codes under OPPS, and payment adjustments like MPPRs and bundling under the PFS that rely on empirical information about whether or not codes are billed on the same day, that contribute to the differences in aggregate payment amounts for a broader range of services. However, for CY 2018, as for CY 2017, we are setting the PFS Relativity Adjuster using currently available data from CY 2016 because we have not had the opportunity to study the CY 2017 claims data that may allow us to consider and incorporate many more factors, including the ones stated above. When we established the PFS Relativity Adjuster for CY 2017 at 50 percent, we stated that we did so with the goal of ensuring adequate payment but remained concerned that the resulting reduction was too conservative. For CY 2018, we were focused on ensuring that we did not overestimate the appropriate overall payment relativity for these nonexcepted items and services. Until

we are able to analyze the CY 2017 claims data, we believed that the comparison between PFS and OPPS payment for the most common services furnished in off-campus PBDs, an outpatient clinic visit, was a better proxy to base the adjuster than our previous approach.

We welcomed stakeholder input with regard to this analysis and the resulting PFS Relativity Adjuster. We also requested comment on whether we should adopt a different PFS Relativity Adjuster, such as 40 percent, that represents a relative middle ground between the CY 2017 PFS Relativity Adjuster, selected to ensure adequate payment to hospitals and our proposed CY 2018 PFS Relativity Adjuster, selected to ensure that hospitals are not paid more than others would be paid through the PFS nonfacility rate. We intend to continue to study this issue and welcomed comments regarding potential future refinements to payment rates for nonexcepted items and services furnished by nonexcepted off-campus PBDs as we gain more experience with these new site-of-service PFS rates.

Finally, we noted that for CY 2018, as in recent years, the annual update to OPPS payments exceeds the annual update to PFS payments. Because we proposed to make a single, across-the-board and, by necessity, imprecise adjustment to OPPS payment rates to establish PFS payment rates for nonexcepted items and services furnished by nonexcepted off-campus PBDs, we expected that the actual difference between OPPS and PFS payment rates for nonexcepted items and services furnished by nonexcepted off-campus PBDs falls in a range which includes our proposed PFS Relativity Adjuster (that is, the actual differential may differ from our proposed PFS Relativity Adjuster). As such, taking into account the differential between the OPPS and PFS annual updates by making an adjustment to the PFS Relativity Adjuster, our proposal for CY 2018 presumed a level of precision in our estimates that is simply not present in our analysis. Therefore, we did not adjust our proposal to reflect the relative updates to PFS and OPPS between CY 2017 and CY 2018, and instead noted that the differential between the OPPS and PFS payment update for CY 2018 is a factor that suggests that the PFS Relativity Adjuster may underestimate PFS nonfacility payment relative to OPPS payments; in future years, we intend to more precisely account for any differential between these two update factors.

c. Geographic Adjustments

For CY 2017, we established class-specific geographic practice cost indices (GPCIs) under the PFS exclusively used to adjust these site-specific, technical component rates for nonexcepted items and services furnished in nonexcepted off-campus PBDs. These class-specific GPCIs are parallel to the geographic adjustments made under the OPPS based on the hospital wage index. We believed it was appropriate to adopt the hospital wage index areas for purposes of geographic adjustment because nonexcepted off-campus PBDs are still considered to be part of a hospital, and the PFS payments to these entities will be limited to the subset of PFS services furnished by hospitals. We also believed it was appropriate, as an initial matter for CY 2017, to adopt the actual wage index values for these hospitals in addition to the wage index areas. The PFS GPCIs that would otherwise currently apply are not based on the hospital wage index areas. For CY 2018, we proposed to continue using the authority under section 1848(e)(1)(B) of the Act to maintain a class-specific set of GPCIs for these site-specific technical component rates that are based both on the hospital wage index areas and the hospital wage index value themselves. For purposes of payment to hospitals, this means that the geographic adjustments used under the OPPS continue to apply.

d. Coding Consistency

For most services, the same HCPCS codes are used to describe services paid under both the PFS and the OPPS. There are two notable exceptions that describe high-volume services. The first is the set of codes that describe evaluation and management (E/M) services which are reported under the PFS using the 5 levels of CPT codes describing new or established patient visits (for a total of 10 codes). However, since CY 2014, these visits have been reported under the OPPS using the single HCPCS code G0463 (Hospital Outpatient Clinic Visit) (see 78 FR 75042). We proposed to maintain the current coding and PFS payment rate for HCPCS code G0463 based on the OPPS payment rate modified by the PFS Relativity Adjuster.

The second exception is a set of radiation treatment delivery and imaging guidance services that are reported using different codes under the PFS and the OPPS. CMS established HCPCS Level II G-codes to describe radiation treatment delivery services when furnished in the physician office setting (see 79 FR 67666 through 67667). However, these HCPCS G-codes are not recognized under the OPPS; rather, CPT codes are used to describe these services when furnished in the HOPD. Both sets of codes were implemented for CY 2015 and were maintained for CY 2016. Under the PFS, there is a statutory provision under section 1848(c)(2)(K) of the Act that requires maintenance of the CY 2016 coding and payment inputs for these services for CY 2017 and also for CY 2018. Accordingly, the CY 2018 PFS rates for these services are calculated based on the maintenance of the CY 2016 coding and payment inputs. Because nonexcepted items and services furnished by a nonexcepted off-campus PBD are paid under the PFS starting in CY 2017, and we are required to maintain the CY 2016 coding and payment inputs for these services under the CY 2018 PFS, we proposed to maintain coding and payment amounts for nonexcepted items and services furnished by a nonexcepted off-campus PBD consistent with the payments that would be made to other facilities under the PFS. That is, nonexcepted off-campus PBDs submitting claims for these nonexcepted items and services will continue to bill the HCPCS G-codes established under the PFS to describe radiation treatment delivery services. Under this proposal, the nonexcepted off-campus PBD must append modifier ''PN'' to each applicable claim line for these nonexcepted items and services, even though the PFS Relativity Adjuster will not apply, on the institutional claim. The payment amount for these services would be set to reflect the technical component rate for the code under the PFS.

4. OPPS Payment Adjustments

In the CY 2017 interim final rule, we adopted the packaging payment rates and MPPR percentage that applied under the OPPS to establish the PFS payment rates for nonexcepted items and services furnished by nonexcepted off-campus PBDs and billed by hospitals. That is, the claims processing logic that was used for payments under the OPPS for comprehensive APCs (C–APCs), conditionally and unconditionally packaged items and services, and major procedures, was incorporated into the newly established PFS rates. We continue to believe it is necessary to incorporate the OPPS payment policies for C–APCs, packaged items and services, and the MPPR in order to maintain the integrity of the PFS Relativity Adjuster because the adjuster is intended, in part, to account for the methodological differences between the OPPS and the PFS rates that would otherwise apply. We also

direct interested stakeholders to related policies under the OPPS, since prospective changes in the applicable adjustments and policies would generally apply to nonexcepted items and services furnished by nonexcepted off-campus PBDs for CY 2018. We were interested in comments regarding the applicability of particular prospective OPPS adjustments to nonexcepted items and services.

In order to apply these OPPS payment policies and adjustments to nonexcepted items and services, we proposed that hospitals continue to bill on an institutional claim form that will pass through the Outpatient Code Editor and into the OPPS PRICER for calculation of payment. This approach will yield data based on claims for nonexcepted items and services furnished by nonexcepted off-campus PBDs, which can be used to refine PFS payment rates for these services in future years.

There were several OPPS payment adjustments that we did not adopt in the CY 2017 interim final rule, including, but not limited to, outlier payments, the rural sole community hospital (SCH) adjustment, the cancer hospital adjustments, transitional outpatient payments, the hospital outpatient quality reporting payment adjustment, and the inpatient hospital deductible cap to the cost-sharing liability for a single hospital outpatient service. We believed these payment adjustments were expressly authorized for, and should be limited to, hospitals that are paid under the OPPS for covered OPD services in accordance with section 1833(t) of the Act. We believed that these policies should not apply to nonexcepted items and services furnished by nonexcepted off-campus PBDs, and did not propose that they apply for CY 2018.

5. Partial Hospitalization Services

For partial hospitalization programs (PHP), which are intensive outpatient psychiatric day treatment programs furnished to patients as an alternative to inpatient psychiatric hospitalization or as a stepdown to shorten an inpatient stay and transition a patient to a less intensive level of care, section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital, to its outpatients, or by a Community Mental Health Center (CMHC). In the CY 2017 OPPS/ASC proposed rule (81 FR 45690), in the discussion of the proposed implementation of section 603 of Bipartisan Budget Act of 2015, we noted that because CMHCs also furnish PHP services and are ineligible to be provider-based to a hospital, a nonexcepted off-campus PBD would be eligible for PHP payment if the entity enrolls and bills as a CMHC for payment under the OPPS. We further noted that a hospital may choose to enroll a nonexcepted off-campus PBD as a CMHC, provided it meets all Medicare requirements and conditions of participation.

Commenters expressed concern that without a clear payment mechanism for PHP services furnished by nonexcepted off-campus PBDs, access to partial hospitalization services would be limited, and pointed out the critical role PHPs play in the continuum of mental health care. Many commenters believed that Congress did not intend for partial hospitalization services to no longer be paid for by Medicare when such services are furnished by nonexcepted off-campus PBDs. Several commenters disagreed with the notion of enrolling as a CMHC in order to receive payment for PHP services. These commenters stated that hospital-based PHPs and CMHCs are inherently different in structure, operation, and payment, and noted that the conditions of participation for hospital departments and CMHCs are different. Several commenters requested that CMS find a mechanism to pay hospital-based PHPs in nonexcepted off-campus PBDs.

Because we shared the commenters' concerns, in the CY 2017 OPPS/ASC final rule with comment period and interim final rule with comment period (81 FR 79715, 79717, and 79727), we adopted payment for partial hospitalization items and services furnished by nonexcepted off-campus PBDs under the PFS. When billed in accordance with the CY 2017 interim final rule, these partial hospitalization services are paid at the CMHC per diem rate for APC 5853, for providing three or more partial hospitalization services per day (81 FR 79727).

In the CY 2017 OPPS/ASC proposed rule (81 FR 45681), the CY 2017 OPPS/ASC final rule with comment period, and interim final rule with comment period (81 FR 79717 and 79727), we noted that when a beneficiary receives outpatient services in an off-campus department of a hospital, the total Medicare payment for those services is generally higher than when those same services are provided in a physician's office. Similarly, when partial hospitalization services are provided in a hospital-based PHP, Medicare pays more than when those same services are provided by a CMHC. Our rationale for adopting the CMHC per diem rate for APC 5853 as the PFS payment amount for nonexcepted off-campus PBDs providing PHP services is because CMHCs are freestanding entities that are not part of a hospital, but they provide the same PHP services as hospital-based PHPs (81 FR 79727). This is similar to the differences between freestanding entities paid under the PFS that furnish other services also provided by hospital-based entities. Similar to other entities currently paid for their technical component services under the PFS, we believe CMHCs would typically have lower cost structures than hospital-based PHPs, largely due to lower overhead costs and other indirect costs such as administration, personnel, and security. We believe that paying for nonexcepted hospital-based partial hospitalization services at the lower CMHC per diem rate aligns with section 603 of Bipartisan Budget Act of 2015, while also preserving access to PHP services. In addition, nonexcepted off-campus PBDs will not be required to enroll as CMHCs in order to bill and be paid for providing partial hospitalization services. However, a nonexcepted off-campus PBD that wishes to provide PHP services may still enroll as a CMHC if it chooses to do so and meets the relevant requirements. Finally, we recognize that because hospital-based PHPs are providing partial hospitalization services in the hospital outpatient setting, they can offer benefits that CMHCs do not have, such as an easier patient transition to and from inpatient care, and easier sharing of health information between the PHP and the inpatient staff.

In the CY 2018 PFS proposed rule, we did not propose to require these PHPs to enroll as CMHCs but instead we proposed to continue to pay nonexcepted off-campus PBDs providing PHP items and services under the PFS. Further, in that CY 2018 PFS proposed rule, we proposed to continue to adopt the CMHC per diem rate for APC 5853 as the PFS payment amount for nonexcepted off-campus PBDs providing three or more PHP services per day in CY 2018.

The following is a summary of the public comments received on potential changes to our methodology and our responses:

Comment: We received several comments in response to the CY 2018 PFS proposals pertaining to nonexcepted off-campus PBDs providing PHP services. Many of the commenters believed that paying nonexcepted off-campus PBDs providing PHP services at the CMHC per diem rate does not compensate enough for financial viability and would jeopardize access to critically needed mental health services. Other

commenters were concerned that the payment rate under section 603 of the Bipartisan Budget Act of 2015 or the lower CMHC payment rate would affect access by hindering needed expansion of PHPs or limiting the ability of PHPs to address the growing substance abuse/opioid crisis. One commenter stated that now is not the time to reduce resources and treatments for behavioral health, and expressed concern that payment reductions could push some behavioral health care providers beyond the point of financial viability. One commenter suggested that the proposed cuts could force outpatients requiring intensive services, like beneficiaries in PHPs, back into the inpatient setting.

One commenter had concerns about the accuracy and stability of the CMHC claims data or CMHC rates, and asked for fair and equitable payments. A few commenters suggested alternatives, such as exempting PHP APC codes from section 603 of the Bipartisan Budget Act of 2015 entirely, researching other payment methods, or paying at the hospital-based PHP rate.

Response: We believe that the CMHC per diem rate provides appropriate payment for partial hospitalization services. In the CY 2017 OPPS/ASC proposed rule (81 FR 45681) and earlier in this section of this CY 2018 MPFS final rule, we noted that when a beneficiary receives services in an excepted off-campus PBD, the Medicare payment for those services is generally higher than when those same services are provided in a physician's office. Similarly, when partial hospitalization services are provided in a hospital-based PHP, Medicare pays more than when those same services are provided by a CMHC. CMHCs are freestanding providers that are not part of a hospital, and that have lower cost structures than hospital-based PHPs. This is similar to the differences between freestanding entities paid under the MPFS that furnish other services also provided by hospital-based entities. We believe that the cost structure for nonexcepted off-campus PBDs providing PHP items and services is similar to CMHCs. We continue to believe that paying for nonexcepted hospital-based partial hospitalization services at the lower CMHC per diem rate is in alignment with section 603 of Bipartisan Budget Act of 2015 and results in fair and equitable payments, while also preserving access to the PHP benefit. As such, we do not believe that the lower CMHC payments made to nonexcepted off-campus PBDs providing PHP services would result in these PHP patients being shifted into inpatient care.

Regarding the comment about the accuracy of CMHC claims and rates, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70466) and the CY 2017 OPPS/ASC final rule with comment period (81 FR 79680 through 79686) for details on the ratesetting methodology, including policies that we believe result in stable and accurate PHP payment rates. Furthermore, we note that the final CY 2018 CMHC per diem rate is higher than that proposed in the CY 2018 OPPS/ASC proposed rule (82 FR 33639). The final CY 2018 CMHC per diem rate is 68.8 percent of the final CY 2018 hospital-based PHP per diem rate under the OPPS (see the CY 2018 OPPS/ASC final rule with comment period for details). This is a significantly higher percentage of payment than was proposed for most other items or services provided in nonexcepted off-campus PBDs that derive their payment amount from CY 2018 OPPS APC rates, and we believe it will help to address commenters' concerns about ensuring access to valuable PHP services.

In response to the alternatives that commenters suggested, we are unable to pay nonexcepted off-campus PBDs that are PHPs at the same rate that hospital-based PHPs are paid under the OPPS or to exempt PHP APC codes from the requirements of section 603 of the Bipartisan Budget Act of 2015 because doing so would not meet the requirements of the amendments made by section 603 of the Bipartisan Budget Act of 2015. Regarding the comment about considering other payment methodologies for PHP services, we will take these comments under advisement in considering whether to propose a different methodology for PHP services in future rulemaking.

In summary, after considering the public comments, we are finalizing our proposals as proposed. Therefore, in CY 2018, we are identifying the PFS as the applicable payment system for PHP services furnished by a nonexcepted off campus PBDs, and we are setting the PFS payment rate for these PHP services as the per diem rate that would be paid to a CMHC in CY 2018.

6. Supervision Rules

The supervision rules that apply for hospitals continue to apply for nonexcepted off-campus PBDs that furnish nonexcepted items and services. The amendments made by section 603 of the Bipartisan Budget Act of 2015 did not change the status of these PBDs, only the status of, and payment mechanism for, the services they furnish. These supervision requirements are specified in § 410.27.

7. Beneficiary Cost-Sharing

Under the PFS, the beneficiary copayment is generally 20 percent of the fee schedule amount, unless there is an applicable exception in accordance with the statute. All cost-sharing rules that apply under the PFS in accordance with section 1848(g) of the Act and section 1866(a)(2)(A) of the Act continue to apply for all nonexcepted items and services furnished by nonexcepted off-campus PBDs, regardless of the cost-sharing obligation under the OPPS.

8. CY 2019 and Future Years

We continue to believe the amendments made to the statute by section 603 of the Bipartisan Budget Act of 2015 intended to eliminate the Medicare payment incentive for hospitals to purchase physician offices, convert them to off-campus PBDs, and bill under the OPPS for items and services they furnish there. Therefore, we continue to believe the payment policy under this provision should ultimately equalize payment rates between nonexcepted off-campus PBDs and physician offices to the greatest extent possible, while allowing nonexcepted off-campus PBDs to bill in a straight-forward way for services they furnish.

We note that a full year of claims data regarding the mix of services reported using the ''PN'' modifier (from CY 2017) will first be available for use in PFS ratesetting for CY 2019. Under the current methodology, we would expect to use that data in order to ensure that Medicare payment to hospitals billing for nonexcepted items and services furnished by nonexcepted off-campus PBDs under the PFS would reflect the relative resources involved in furnishing the items and services relative to other PFS services. We recognize that under our current approach, payment rates would not be equal on a procedure-by-procedure basis. However, the application of the PFS Relativity Adjuster would move toward equalizing payment rates in the aggregate between physician offices and nonexcepted off-campus PBDs to the extent appropriate. Therefore, for certain specialties, service lines, and nonexcepted off-campus PBD types, total Medicare payments for the same services might be either higher or lower when furnished by a nonexcepted off-campus PBD rather than in a physician office.

Depending on the mix of services for particular off-campus PBDs, we remain concerned that such specialty-specific patterns in payment differentials could result in continued incentives for hospitals to buy certain types of

physician offices and convert them to excepted off-campus PBDs; these are the incentives we believe Congress intended to avoid. However, continuing a policy similar to the one we proposed in the proposed rule would allow hospitals to continue billing through a facility claim form and would allow for continuation of the packaging rules and cost report-based relative payment rate determinations under OPPS, which we believe are preferable to using the current valuation methodologies under the PFS that are not well-suited for nonexcepted items and services furnished by nonexcepted off-campus PBDs. Therefore, for CY 2019 and for future years, we intend to examine the claims data in order to determine not only the appropriate PFS Relativity Adjuster(s), but also to determine whether additional adjustments to the methodology are appropriate—especially with the goal of attaining site neutral payments to promote a level playing field under Medicare between physician office settings and nonexcepted off-campus PBD settings, without regard to the kinds of services furnished by particular off-campus PBDs. We solicited comments on potential changes to our methodology that would better account for these specialty-specific patterns.

The following is a summary of the public comments received on the potential changes to our methodology and the PFS Relativity Adjuster.

Comment: We received many comments from stakeholders opposing our proposal to reduce the PFS Relativity Adjuster to 25 percent. The majority of commenters questioned why CMS would propose a different PFS Relativity Adjuster for CY 2018 than is currently in place for CY 2017 given the absence of any additional data to inform a more precise estimate. A number of commenters, including MedPAC, also mentioned the large variation in the rate differential between the PFS and the OPPS across the top 22 services, and stated that a PFS Relativity Adjuster calculated from a single outpatient clinic visit does not represent the mix of services provided by PBDs.

In addition, several commenters stated their concern that CMS's approach in developing the PFS Relativity Adjuster fails to account for the extensive packaging that occurs for outpatient clinic visits (billed using HCPCS code G0463 under the OPPS) and other common services. They stated that additional services are often provided with a single code, and that the PFS Relativity Adjuster does not account for the resources required to furnish these additional services. They note that CMS does not account for packaging that occurs under the OPPS, despite recognizing the importance of such differences between the payment systems. Some commenters offered their own estimates of the value of packaging that occurs under the OPPS for the top 22 HCPCS codes and provided suggestions for incorporating those estimates into our analysis.

Response: We agree with the commenters' concerns about the proposed change to the PFS Relativity Adjuster for CY 2018, specifically that the single code level comparison of the service most commonly billed in the off-campus setting under the OPPS doesn't adequately reflect the large variation in services furnished in off-campus PBDs. Furthermore, we recognize the possibility that our proposed PFS Relativity Adjuster of 25 percent may overcorrect for the possibility that the CY 2017 PFS Relativity Adjuster of 50 percent was an overestimate of the relativity between the OPPS and PFS. We also agree with commenters who stressed the need to account for packaging rules that apply under the OPPS. However, we have clearly outlined the challenges we face in calibrating the PFS Relativity Rate to account for the effect of packaging.

After consideration of the public comments, we believe that an approach in which we integrate the code-level comparison for the service most commonly billed in the off-campus PBD setting under the OPPS (a clinic visit reported using HCPCS code G0463), which was the basis of our proposed PFS Relativity Adjuster for CY 2018 of 25 percent, with the comparison of relative PFS to OPPS rates for the top 25 (most frequently billed) major codes, which was the basis of our PFS Relativity Adjuster for CY 2017 of 50 percent, addresses many of the concerns and comments we received.

For this approach, we updated the list of the 25 major codes billed by off-campus hospital departments using the ''PO'' modifier to reflect a full year of claims data for CY 2016 (see Table 10). We did not exclude HCPCS code G0463 from the analysis, but we retained all other parameters that we described in the CY 2017 interim final rule, including the exclusion of separately payable drugs and biologics, services assigned an OPPS status indicator ''A''. We removed HCPCS code 36591 (Collection of blood specimen from a completely implantable venous access device) because, under PFS policies, the code is used only to pay separately under the PFS when no other service was on the claim. We also removed HCPCS code G0009 (Administration of Pneumococcal Vaccine) and HCPCS code G0008 (Administration of influenza vaccine) because there is no payment for these codes under the PFS. Two of these codes, CPT 36591 and HCPCS G0009, were also removed from our calculation of the top major codes when we calculated the PFS Relativity Adjuster in the CY 2017 interim final rule. HCPCS code G0008 was not on the list of the top major codes when we initially analyzed claims data for CY 2016 available through August 26, 2016, but it appears on the list of the top codes that contained a ''PO'' modifier when we analyzed the same data through the end of CY 2016.

We determined the analogous payment for each of the top major HCPCS codes, including HCPCS code G0463, using the same logic that we applied in our calculation of the top 22 codes for the CY 2017 interim final rule. Table 10 shows data for the OPPS rates, the analogous PFS rates, and the full year utilization for these codes. The resulting utilization-weighted average comparison between the PFS and the OPPS for the top 22 codes, following the approach described above, is 35 percent. In other words, on average, the applicable payment amount under the PFS is 35 percent of the amount that would have been paid under the OPPS.

In the CY 2018 PFS proposed rule, we sought comment on whether a different PFS Relativity Adjuster, such as 40 percent, would reflect a middle ground between the CY 2017 PFS Relativity Adjuster of 50 percent, selected to ensure adequate payment to hospitals, and our proposed CY 2018 PFS Relativity Adjuster of 25 percent, selected to ensure that hospitals are not paid more than others would be paid through the PFS nonfacility rate. Since, as we acknowledged in response to public comments, we are unable at this time to fully calculate the effects of packaging under the OPPS, we believe that a 40 percent PFS Relativity Adjuster, which is an upward adjustment to the 35 percent calculation described above, is appropriate. We are, therefore, finalizing a PFS Relativity Adjuster of 40 percent for CY 2018.

Comment: Several commenters requested clarification with regard to payment for drugs that are packaged under the OPPS. One commenter stated its belief that many drugs and biological therapies are not paid separately under the OPPS and therefore would be subject to the adjuster in the PBD setting. The commenter suggested that the new Level I and II drug administration codes conditionally packaged under the OPPS, as finalized in the OPPS CY 2018, would be subject

to the PFS Relativity Adjuster. Other commenters requested clarification regarding how CMS will handle 340B drug payment for nonexcepted off-campus PBDs under section 603 of the Bipartisan Budget Act of 2015. One commenter wrote that CMS did not specify whether it will reduce the payment for 340B drugs furnished in nonexcepted off-campus PBDs, and that there could be a large payment differential for these drugs furnished in nonexcepted vs. excepted off-campus PBDs.

Response: We appreciate the commenters' request for clarification. In prior rulemaking, we established the policy that drugs and biologicals that are separately payable under the OPPS (identified by status indicator ''G'' or ''K'' under the OPPS) are paid in accordance with section 1847A of the Act, consistent with payment rules in the physician office setting. Drugs and biologicals that are unconditionally packaged under the OPPS will continue to be packaged when furnished in a nonexcepted off-campus PBD. Drug administration services subject to conditional packaging (identified by status indicator ''Q1'' under the OPPS) will be packaged under the OPPS if the relevant criteria are met; otherwise they are separately paid. We refer commenters to the file ''Nonexcepted Items and Services Payment by OPPS Status Indicator'', available on the CMS Web site under downloads for the CY 2018 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*, for information about the services, by OPPS status indicator, which are subject to the PFS Relativity Adjuster. Drugs that are acquired under the 340B program and furnished by nonexcepted off-campus PBDs are paid under the PFS and are not subject to the OPPS drug payment policies. We did not propose to adjust payment for 340B-acquired drugs in nonexcepted off-campus PBDs in CY 2018 but will be monitor drug utilization in these PBDs. Please refer to section V.B.7 of the CY 2018 OPPS/ASC final rule with comment for a detailed discussion of the 340B payment policy.

Comment: Several commenters stated their belief that the appropriate comparison between the PFS and OPPS for purpose of determining the PFS Relativity Adjuster is the full PFS nonfacility rate rather than the difference between the facility and the nonfacility rate.

Response: We disagree with commenters that the total PFS nonfacility rate should be used to assess relativity between the PFS and OPPS. As we have stated previously, the practice expense portion of the nonfacility rate reflects both direct and indirect costs that would be incurred by the physician in furnishing the service. The facility rate reflects the relative resources involved in furnishing the service in a facility setting, where the billing professional does not incur practice expense costs because they are incurred by the facility. We believe the most appropriate code-level comparison between the PFS and the OPPS would reflect the technical component (TC) of each HCPCS code under the PFS. However, we do not currently calculate a separate technical component rate for all HCPCS codes under the PFS—only for those for which the professional and technical components of the service are distinct and can be separately billed by two different practitioners or other suppliers under the PFS. We continue to believe that, for HCPCS codes for which there is a different payment for facility and nonfacility settings, it is appropriate to compare the difference under the PFS between the nonfacility and the facility rate with the OPPS rate.

Comment: We received a few comments suggesting that the PFS rate for services should be established as a payment floor for nonexcepted items and services furnished by nonexcepted off-campus PBDs or, alternatively, that some items and services should be excluded from the PFS Relativity Adjuster. A few commenters noted that the reduced rate from applying the PFS Relativity Adjuster would be lower, for certain services, than what is paid for the technical component for these services under the PFS. A few commenters specifically cited CPT codes for PET imaging procedures (CPT codes 78459, 79491, 78492, 78608, and 78811–78816), which are subject to payment policies under the Deficit Reduction Act (DRA) of 2005.

Response: We appreciate the commenters' concerns. We recognize that the PFS payment for some services will be lower or higher, on a code by code basis, than the PFS payment for nonexcepted items and services furnished by nonexcepted PBDs calculated using the PFS Relativity Adjuster. We also recognize that there are certain CPT codes that are subject to payment rules limiting the payment amount for services. We will consider whether it would be appropriate to set a floor using the PFS, or otherwise address codes subject to statutory payment restrictions, in future rulemaking.

Comment: We received support from several commenters about our proposal to reduce the PFS Relativity Adjuster to 25 percent. Generally, the commenters indicated that the proposed rate more accurately represents the intent of the statute, which is to reduce financial incentives for hospitals to purchase freestanding physician practices. Several commenters, including a major national health insurer, were supportive of efforts in general to establish more equitable payment across sites of service.

Response: We thank commenters for their support. We are encouraged by the amount of interest generated in response to the implementation of section 603 of the Bipartisan Budget Act of 2015. As we stated above, we were persuaded by commenters that the establishment of the proposed PFS Relativity Adjuster of 25 percent derived from a single HCPCS code for outpatient clinic visits may overcorrect for the risk that the CY 2017 PFS adjuster overstated relativity between the OPPS and the PFS. We believe that our revised approach, which builds the relative payment for clinic visits between the PFS and the OPPS into our prior analysis of the top 22 HCPCS codes, is a more appropriate approach for payment in CY 2018, in response to these concerns. Therefore, using such an approach, we are finalizing a PFS Relativity Adjuster of 40 percent for CY 2018.

Comment: Several commenters pointed out that nonexcepted off-campus PBDs face higher operational and regulatory costs than freestanding physician offices, and that intent of the statute could not have been to equalize payments between nonexcepted off-campus PBDs and freestanding physician offices.

Response: We do not disagree that there may be additional regulatory and operational costs faced by off-campus PBDs. However, we continue to believe that the amendments made to the statute by section 603 of the Bipartisan Budget Act of 2015 are intended to eliminate the Medicare payment incentive for hospitals to purchase physician offices and bill under the OPPS for items and services furnished there. We believe that, by removing the financial incentive for hospitals to purchase freestanding facilities, we allow market forces to determine the appropriate number and distribution of hospital PBDs and physician offices based on regional costs, practice patterns, patient needs.

Comment: We received comments expressing general frustration with the longstanding differences in payment policies between the PFS and the OPPS. The commenters stated their belief that the PFS underpays for the value of services furnished in nonfacility

settings, thereby driving physicians into hospital employment agreements. They stated that this general pattern detracts from developing and implementing more cost efficient models of care. Moreover, disparate payments between OPPS and PFS drive the creation of health system monopolies, which generally increase the overall cost of care for the population and reduce the feasibility of operating independent physician practices.

Response: We appreciate the perspectives of the commenters. We note that payments made under the PFS and the OPPS are established under different statutory authorities using wholly different bases and methodologies, and therefore often result in differential payment amounts for similar services. We do not have the legal authority, with limited exceptions such as section 603 of the Bipartisan Budget Act of 2015, to develop or implement modified payment rates that would broadly reduce the differences in payment between physician offices and hospital outpatient departments.

Comment: Many commenters described the importance of hospital off-campus PBDs in meeting the needs of rural and high risk patients. They maintained that payments made using the PFS Relativity Adjuster, particularly at the proposed rate of 25 percent, would be so low as to prohibit hospitals from providing needed services to high risk populations and may even require some hospital locations to close. A commenter specifically requested that CMS conduct an impact assessment before continuing with implementation of the statute.

Response: We appreciate the comment and understand the stakeholders' concerns about access to care for rural populations. As you know, section 603 amended the statute at section 1833(t) of the Act to carve out certain items and services furnished by certain off-campus outpatient departments of a provider from the definition of covered outpatient services, and from payment under the OPPS beginning on January 1, 2017. We do not believe that section 603 of the Bipartisan Budget Act of 2015 restricts options for patients in rural and underserved areas, and moreover, we do not believe the statutory amendments have been implemented in a manner that restricts access to care for rural populations.

We have previously stated that we consider the PFS Relativity Adjuster to be an interim policy until a complete year of claims data from CY 2017 are available for analysis. Once such data are available, we expect to calculate and propose a more precise payment rate. Additionally, we continue to consider options for nonexcepted off-campus PBDs to bill for nonexcepted items and services using a PFS claim, effectively allowing us to develop and pay a code-specific amount representing the technical component of furnishing a service.

Comment: A couple of commenters indicated their belief that CMS is making drastic changes to payment policies for nonexcepted items and services furnished by nonexcepted off-campus PBDs and that this adversely impacts the ability of hospitals and physician offices to conduct long term planning. One commenter stated that our proposal to change the PFS Relativity Adjuster for CY 2018 contradicts CMS's statement in the CY 2017 interim final rule (81 FR 79720 through 79729) in which we articulated that, unless there are significant changes to the policies set forth in the interim final rule, we anticipate continuing to use the same method to determine PFS payment amounts for nonexcepted items and services furnished by nonexcepted off-campus PBDs in the near term. Several commenters indicated that they had interpreted CMS's statements as a promise that the PFS Relativity Adjuster would remain at 50 percent until such time that we had required data available to more precise calculation. The commenters, representing hospital stakeholders, suggested that they may not have moved forward with planned expansions of new off-campus PBDs if they had known we would change the PFS Relativity Adjuster.

Response: We thank commenters for their concerns. We do not agree that our statements in the CY 2017 interim final rule reflected a promise not to change the PFS Relativity Adjuster over the next two to three years. Rather, we stated that the general approach, in which we calculate an overall reduction—the PFS Relativity Adjuster—to nonexcepted items and services furnished by nonexcepted off-campus PBDs when billed with a ''PN'' modifier, would remain in place until we were able to establish code-specific reductions that represent the technical component of services furnished under the PFS or until we were able to implement system changes needed to enable nonexcepted off-campus PBDs to bill for the technical component of nonexcepted items and services using a professional claim. We are required by law to implement payment changes for nonexcepted PBDs. Through notice and comment rulemaking in the CY 2017 interim final rule and the CY 2018 PFS proposed rule, we have been as transparent as possible in our methodology for determining the PFS Relativity Adjuster, including limitations related to data availability. We believe we have given sufficient information about our underlying concerns and objectives, including the transitory nature of this payment policy until we have the opportunity to analyze CY 2017 claims data. In addition, while we currently lack both the data and the infrastructure to require hospitals to bill for nonexcepted items and services furnished by nonexcepted off-campus PBDs using a professional claim, we are continuing to explore the changes that would be needed to do so for future years. This change would allow nonexcepted off-campus PBDs to report services using the same coding as would be used by practitioners and suppliers under the PFS and to bill specifically for nonexcepted items and services at rates that represent the technical component of services furnished under the PFS.

Comment: Several stakeholders commented on topics related to policies we addressed in prior rulemaking or policies that are outside the scope of this final rule. Commenters urged CMS to expand excepted status of an off-campus PBD that is changing location or ownership. Other commenters, however, suggested that we remove the excepted status for off-campus PBDs entirely, even for those billing as a PBD prior to November 2, 2015.

Response: We appreciate commenters' concerns regarding these topics. However, we note that the implementation of section 603 of the Bipartisan Budget Act of 2015 was finalized in the CY 2017 CY OPPS/ASC final rule with comment period (81 FR 79699 through 79719), and we did not make any proposals in the CY 2018 PFS proposed rule related to defining the applicable items and services furnished by certain off-campus outpatient departments of a provider, which will not be considered covered OPD services on or after January 1, 2017 (that is, how we defined nonexcepted items and services furnished by nonexcepted off-campus PBDs). Thus, comments addressing such issues are outside the scope of this rulemaking. Comments submitted with technical billing questions are addressed through applicable program instructions. For policies related to patient cost sharing under the OPPS and for guidance related to cost reporting for nonexcepted items and services furnished by nonexcepted PBDs, we direct commenters to the OPPS CY 2018 final rule.

Comment: We received several comments questioning why we have not responded to comments on the CY 2017 OPPS interim final rule in which we implemented the CY 2017 PFS Relativity Adjuster of 50 percent. The same commenters also questioned whether our proposal to reduce the PFS Relativity Adjuster to 25 percent might be a violation of our rulemaking obligations under the Administrative Procedure Act (APA) (5 U.S.C. 553) insofar as we indicated our intention to develop a revised PFS relativity adjuster based on claims data when they became available, and there are not yet claims data available to develop a more appropriate payment adjustment. Some commenters further suggested that our policies regarding the PFS relativity adjuster, made in the absence of specific data to support them as explained in the CY 2017 interim final rule, are arbitrary and capricious.

Response: We appreciate the commenters' concerns about adhering to the rulemaking requirements of the APA. To meet our rulemaking obligations, we generally respond to comments on an interim final rule at the time that we adopt final policies relating to that interim final rule. On the whole, commenterson the CY 2017 interim final rule who disagreed with setting the CY 2017 PFS Relativity Adjuster at 50 percent articulated concerns about the approach we used to arrive at that rate. In particular, commenters highlighted the differences in packaging rules under the PFS and the OPPS, and suggested that CMS should use the total nonfacility rate (rather than the nonfacility minus facility rate) to compare relative payments between PFS and OPPS. We are currently addressing, through notice and rulemaking for CY 2018, the concerns raised by commenters and stakeholders related to the policies that we proposed and are finalizing for CY 2018. However, we note that the public comments on the CY 2017 interim final rule and on the CY 2018 PFS proposed rule express many of the same views and concerns about how we should set the PFS relativity adjuster.

We presented the analysis and reasons that led us to the proposed PFS Relativity Adjuster of 25 percent for CY 2018; and we responded to public comments on that proposal with a revised analysis and the final PFS Relativity Adjuster of 40 percent for CY 2018. We have provided the data required to replicate our analysis, consistently based upon CY 2016 payment rates under the PFS and OPPS, for the CY 2017 interim final, and for the proposed and final CY 2018 PFS relativity adjusters. Furthermore, we have been as transparent as possible in our approach, including the limitations related to data availability, and our inability to develop a precise adjustment to the relative payment rates that would account for differences between the two payment systems, including packaging. We believe we are moving as judiciously as possible, given these limitations, to meet the requirements of the statute, providing public transparency into our policy considerations, and in full accordance with our notice and comment rulemaking obligations. We are finalizing a PFS Relativity Adjuster of 40 percent for CY 2018 as discussed earlier in this section.

Comment: Several commenters requested that CMS move all of the rulemaking, including requests for comments, comment summaries and our responses, for policies relating to the implementation of section 603 of the Bipartisan Budget Act of 2015 from the PFS rule to the OPPS rule. They cited the additional burden of responding to such interrelated policies in different rules.

Response: We appreciate the commenters' concern about the challenges presented by addressing policies that implicate two payment systems that are issued in two separate rulemaking processes. However, because the policies included in this final rule relate to payments that are made under the PFS to nonexcepted off-campus PBDs furnishing nonexcepted items and services, we believe it is appropriate that these issues be addressed in rulemaking for the PFS. We note that policies related to interpretation of the OPPS statute will continue to be addressed in OPPS rulemaking.

TABLE 10—COMPARISON OF CY 2016 OPPS PAYMENT RATE TO CY 2016 PFS PAYMENT RATE FOR TOP HOSPITAL CODES BILLED USING THE "PO" MODIFIER

HCPCS code	Code description	CY 2016 total claim lines	CY 2016 OPPS payment rate	CY 2016 applicable PFS technical payment amount estimate	Col (5) as a percentage of OPPS	PFS estimate
(1)	(2)	(3)	(4)	(5)		(6)
G0463	Hospital outpt clinic visit	13,835,921	$102.12	$26.71	26.16	Nonfacility rate—Facility rate based on the average of ten PFS CPT codes: 99201—99205 and 99211 0 99215.
96372	Ther/proph/diag inj sc/im	725,665	42.31	25.42	60.1	Single rate paid exclusively to either practitioner or facility; full nonfacility rate.
71020	Chest x-ray 2vw frontal&latl	719,451	60.80	16.83	27.7	Technical component: Full nonfacility rate.
93005	Electrocardiogram tracing	662,763	55.94	8.59	15.4	Single rate paid exclusively to either practitioner or facility; full nonfacility rate.
96413	Chemo iv infusion 1 hr	563,245	280.27	136.41	48.7	Single rate paid exclusively to either practitioner or facility: Full nonfacility rate.
93798	Cardiac rehab/monitor	448,130	103.92	11.10	10.7	Nonfacility rate—Facility rate.
96375	Tx/pro/dx inj new drug addon	408,751	42.31	22.56	53.3	Single rate paid exclusively to either practitioner or facility; full nonfacility rate.
93306	Tte w/doppler complete	369,856	416.80	165.77	39.8	Technical component: full nonfacility rate.
77080	Dxa bone density axial	344,118	100.69	31.15	30.9	Technical component: full nonfacility rate.
90853	Group psychotherapy	299,446	69.65	0.36	0.5	Nonfacility rate—Facility rate.
77412	Radiation treatment delivery	296,601	194.35	266.86	137.3	Technical component (Full nonfacility rate) based on weighted averages for the following PFS codes: G6011; G6012; G6013; and G6014.
96365	Ther/proph/diag iv inf init	269,899	173.18	69.82	40.3	Single rate paid exclusively to either practitioner or facility: Full nonfacility rate.
20610	Drain/inj joint/bursa w/o us	221,922	223.76	13.96	6.2	Nonfacility rate—Facility rate.

TABLE 10—COMPARISON OF CY 2016 OPPS PAYMENT RATE TO CY 2016 PFS PAYMENT RATE FOR TOP HOSPITAL CODES BILLED USING THE "PO" MODIFIER—Continued

HCPCS code	Code description	CY 2016 total claim lines	CY 2016 OPPS payment rate	CY 2016 applicable PFS technical payment amount estimate	Col (5) as a percentage of OPPS	PFS estimate
(1)	(2)	(3)	(4)	(5)		(6)
96367	Tx/proph/dg addl seq iv inf	217,098	42.31	30.79	72.8	Single rate paid exclusively to either pracitioner or facility: Full nonfacility rate.
11042	Deb subq tissue 20 sq cm/<	215,734	225.55	54.78	24.3	Nonfacility rate—Facility rate.
93017	Cardiovascular stress test	196,183	220.35	39.74	18.0	Single rate paid exclusively to either practitioner or facility; full nonfacility rate.
77386	Ntsty modul rad tx dlvr cplx	182,989	505.51	347.30	68.7	Technical component: Nonfacility rate for CPT code G6015 (analogous code used under the PFS).
74177	Ct abd & pelv w/contrast	167,549	347.72	220.20	63.3	Technical component: Full nonfacility rate.
71260	Ct thorax w/dye	163,756	236.86	167.21	70.6	Technical component: Full nonfacility rate.
71250	Ct thorax w/o dye	160,956	112.49	129.61	115.2	Technical component: Full nonfacility rate.
78452	Ht muscle image spect mult	159,219	1,108.46	412.82	37.2	Technical component: Full nonfacility rate.
96415	Chemo iv infusion addl hr	151,700	42.31	28.64	67.7	Single rate paid exclusively to either practitioner or facility; full nonfacility rate.
Weighted Average (claim line volume * rate) of the PFS payment compared to OPPS payment for the 22 major codes:						35%

H. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011. 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 have identified a number of potentially misvalued codes each year using various identification screens, as discussed in section II.E.4 of this final rule. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule for a year. Then, during the 60-day period following the publication of the final rule, we accepted public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values, and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period, we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule, the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we established interim final values in the CY 2016 PFS final rule with comment period, we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period, and re-proposed values for those codes in the CY 2017 PFS proposed rule.

We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values. For CY 2017, we did not identify any new codes that described such wholly new services. Therefore, we did not establish any code values on an interim final basis.

2. Methodology for Establishing Work RVUs

For each code identified in this section, we conducted a review that included the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs have generally included, but have not been limited to, a review of information provided by the RUC, the Health Care Professionals Advisory Committee (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 have also assessed the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs,

including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process. We have used the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code.

Components that we have used in the building block approach may have included preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. 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 have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. The statute specifically defines the work component as the resources in time and intensity required in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we have refined the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently there are preservice time packages for services typically furnished in the facility setting (for example: Preservice time packages reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the nonfacility setting.

We developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an evaluation and management (E/M) service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we have believed that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we have adjusted the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we have removed 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we have also removed a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we have not believed 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.

We note that many commenters and stakeholders have expressed concerns over time with our ongoing adjustment of work RVUs based on changes in the best information we have 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 have used to make the adjustments is derived from their survey process. We are statutorily obligated 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 have 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 begun by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs have not appeared 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 have sometimes used the relationship between the old time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we have used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe had not otherwise been reflected in the RUC-recommended value. When we have believed that such changes in time have already been accounted for in the RUC recommendation, then we have not made such adjustments. Likewise, we have not arbitrarily applied time ratios to current work RVUs to calculate proposed work RVUs. We have used the ratios to identify potential work RVUs and considered these work RVUs as potential options relative to the values developed through other options.

We do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we have believed that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC recommendation had appeared to disregard or dismiss the

changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we have generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several stakeholders, including the RUC, in general have objected to our use of these methodologies and deemed our actions in adjusting the recommended work RVUs as inappropriate; other stakeholders have also expressed concerns with CMS refinements to RUC recommended values in general. In the CY 2017 PFS final rule (81 FR 80272 through 80277) we responded in detail to several comments that we received regarding this issue. In the CY 2017 PFS proposed rule, we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives as requested.

In developing proposed values for new, revised, and potentially misvalued codes for CY 2018, we considered the lack of alternative approaches to making the adjustments, especially since many stakeholders have routinely urged us to propose and finalize the RUC-recommended values. We also considered the RUC's consistent reassurance that these kinds of concerns (regarding changes in time, for example) had already been considered, and either incorporated or dismissed, as part of the development of their recommended values. These have led us to shift our approach to reviewing RUC recommendations, especially as we believe that the majority of practitioners paid under the PFS, though not necessarily those in any particular specialty, would prefer CMS rely more heavily on RUC recommended values in establishing payment rates under the PFS.

For CY 2018, we generally proposed the RUC-recommended work RVUs for new, revised, and potentially misvalued codes. We proposed these values based on our understanding that the RUC generally considers the kinds of concerns we have historically raised regarding appropriate valuation of work RVUs. However, during our review of these recommended values, we identified some concerns similar to those we have recognized in prior years. Given the relative nature of the PFS and our obligation to ensure that the RVUs reflect relative resource use, we included descriptions of potential approaches we might have taken in developing work RVUs that differ from the RUC-recommended values. We sought comment on both the RUC-recommended values as well as the alternatives considered.

The following is a summary of the public comments received on both the RUC-recommended values as well as the alternatives we considered in developing work RVUs and our responses:

Comment: Several commenters generally support the proposed use of the RUC-recommended work RVUs, without refinement. One commenter encouraged further collaboration between the RUC and CMS to improve the relativity within the payment system.

Response: We thank the commenters for their input and support of the proposals. We also agree that collaboration is a critical element in our establishment of work RVUs. In our review of work RVUs and time inputs, we have and will continue to consider information from various public commenters, medical literature, the HCPAC, information provided by the RUC, Medicare claims data, and other relevant sources.

Comment: One commenter stated that the RUC thoroughly vets the times and values of the procedures it reviews, applies the right valuation methodology to appropriately value the procedures that are being reviewed, and usually adjusts the times identified by the survey if the times seem unreasonable. Another commenter stated that recommendations by the RUC remain the most robust mechanism for collecting data and establishing relative values. A few commenters stated that CMS should depend on RUC-recommended values instead of trying to create an arbitrary, new methodology that lacks reliability or reflects significantly flawed rationales. A few commenters stated that CMS work value reductions are done with complete disregard for the rigorous process conducted by the RUC with input from medical specialty societies to develop data driven recommendations for physician work values and without presenting data to support these reductions.

Response: We agree that the RUC provides critically important information for our review process. However, our review of recommended work RVUs and time inputs also generally includes review of various sources, in addition to the RUC, such as information provided by other public commenters, comparative databases, and medical literature which are also vital sources of information. We disagree with the commenters that CMS has created arbitrary, unreliable work value reductions that have disregarded the RUC process. We have historically used the RUC-recommended values or existing values as a starting point in our review, and then applied adjustments as necessary, particularly when we find that the RUC recommendation does not appropriately account for recommended changes in time, and provides no explanation as to why this would be appropriate.

Comment: One commenter expressed disappointment with situations where CMS rejects recommended work valuations and direct PE inputs that would have resulted in expenditure decreases, and was concerned that all professionals are impacted. The commenter stated that CMS should accept RUC-recommended values and inputs that would result in expenditure decreases or hold all other healthcare professionals harmless for the decision to reject them.

Response: We appreciate the commenter's views, but note that we are required to establish appropriate valuations and ensure that RVUs are reflective of relative resources involved in furnishing a service. In reviewing specific codes, we make these decisions the same way regardless of whether the decisions would result in increases or decreases to overall expenditures under the PFS. Additionally, we do not have authority to exempt the rates for particular services from budget neutrality adjustments, relativity adjustments, or the effects of the misvalued code target recapture adjustments based on differences between what the RUC recommends and what CMS finalizes through notice and comment rulemaking.

Comment: Some commenters expressed concern about the effect of the misvalued code reviews on particular specialties and settings. The commenters recommended insulating particular settings or specialties from the impact of the code reviews.

Response: We are required to periodically review the accuracy of RVUs for all services furnished under the PFS. We do not believe it would be appropriate, nor do we have any specific authority, to insulate particular settings or specialties from the impact of this review. We also note that most misvalued code reviews and revaluations are triggered by the identification of codes under the potentially misvalued code categories that are enumerated in the statute.

Comment: One commenter stated that it is open to supporting our alternative methods of valuation if the methods are disclosed and there is ample time to review, comment, and iterate on suggestions. The commenter stated that the RUC process currently allows for this. Another commenter stated that it appreciates CMS providing stakeholders with discussion of alternative approaches that the agency might have used to reach a different value, rather than proposing those values. The commenter stated that this gives specialties an opportunity to consider the alternative values, while also providing a pathway for us to finalize an alternative value based on information provided by stakeholders. The commenter also stated that it believes many of these alternative methods could be raised during deliberations at RUC meetings when specialties and their expert physician advisors are available to engage in a dialogue with CMS representatives. In addition, the commenter stated that CMS representatives who attend the RUC meetings should engage more actively in discussion with society representatives about the agency's issues and concerns with work and direct PE inputs, rather than first sharing concerns in the proposed rule when dialogue is restricted due to the rulemaking process.

Response: While the comment period does not provide for an iterative process as suggested by one of the commenters, it does provide an opportunity for all interested parties to review and have an opportunity to comment on the proposals and alternative valuations considered. While we acknowledge that discussion and consideration of different valuations occurs during the RUC process, we also note that not all interested parties have the opportunity to participate in the RUC process, and not all relevant stakeholders are members of the RUC. Additionally, we would like to reiterate that, while we appreciate that some commenters believe that CMS staff could offer useful perspectives by regularly attending and participating more fully in the RUC meetings, we do not believe that would be appropriate for many reasons, not least of which is that CMS staff participation in the RUC process cannot supplant our obligation to establish through notice and comment rulemaking what we determine to be appropriate RVUs for each reviewed code. Accordingly, we disagree with the commenter's suggestion that CMS staff should preemptively address the concerns of work and PE values during the RUC meeting, instead of through notice and comment rulemaking. Formal notice and comment rulemaking allows all interested parties the opportunity to review our proposals and provide feedback, as well as to submit supplemental information about our proposals, and address any concerns or alternatives we have expressed in making our proposals.

Comment: Several commenters expressed concern and disappointment with our proposed approach for valuing codes for CY 2018. MedPAC stated that it believes CMS is moving in the wrong direction by proposing to accept all of the RUC recommendations for work RVUs for CY 2018 without modification, and that this approach is inconsistent with MedPAC's longstanding view that CMS relies too heavily on input from the RUC, which is made up of practitioners who have a financial stake in the payment rates for services paid under the PFS. MedPAC stated that the Secretary is responsible for establishing RVUs for services, and this authority should not be delegated to a private entity; therefore, CMS should independently evaluate the RUC-recommended RVUs based on objective data and revise them when they are inaccurate. MedPAC also stated that CMS should collect data from a set of efficient practices to validate the time estimates and establish more accurate RVUs. Other commenters stated that from their perspective, CMS is abandoning its responsibility to set work RVUs under the PFS. One commenter stated that CMS should actively supervise and take responsibility for setting physician payments based on reliable, objective evidence. Another commenter stated that while it appreciates the work of the RUC, they had concerns that primary care is undervalued by the RUC, and stated that the RUC tends to favor more procedural and specialty-based services. The commenter stated that if CMS steps away from taking an active role in determining RVUs under its own PFS, the agency would be inflating the role of the RUC and thus underemphasizing primary care in the process. The commenter also stated that the RUC's final recommendations do not necessarily strike the balance across different provider types and services, and that it is the responsibility of CMS, not the RUC, to set RVUs under the PFS; and therefore, CMS should retain an active role in evaluating information and data and setting reimbursement rates for services across the PFS.

Response: We would like to clarify that we are not relinquishing our obligation to independently establish appropriate RVUs for services paid under the PFS. We will continue to thoroughly review and consider information we receive from the RUC, the 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. We also note that given the critical role of the resource of time in establishing work RVUs and the concerns that have been raised about time values used in rate-setting, we contracted with the Urban Institute to develop empirical time estimates based on data collected from several health systems with multispecialty group practices. We refer readers to the CY 2017 PFS final rule for discussion of the Urban Institute report (81 FR 80203). While generally proposing the RUC-recommended work RVUs for new, revised, and potentially misvalued codes was our approach for CY 2018, we note that we also included alternative values where we believed there was a possible opportunity for increased precision.

We also want to clarify that as part of our obligation to establish RVUs for the PFS, we annually make an independent assessment of the available recommendations, supporting documentation, and other available information from the RUC and other commenters to determine the appropriate valuations. Where we concur that the RUC recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we propose those values as recommended. Additionally, we will continue to engage with stakeholders, including the RUC, with regard to our approach for accurately valuing codes.

CMS appreciates the efforts of the RUC to deliberate on highly technical matters involving clinical care. The RUC is comprised of 31 physicians, the majority of whom are appointed by major medical specialty societies. Commenters have noted concerns with the range of expertise represented in the RUC membership and have advocated for more balanced representation from across the medical community. Commenters have also suggested that the RUC should consider how to further engage the public in its deliberative processes. CMS encourages the RUC to consider acting on these comments and suggestions in its ongoing deliberations.

This action could involve improving the ability of stakeholders or the public to meaningfully participate in or learn about the deliberations, considering the balance of primary care and specialty expertise on the committee, and examining how payers are included in this process. Stakeholder input could include surveying retired physicians and nurses in addition to physicians, and receiving additional information about how payers view relative resource use for services. CMS may also consider updating its internal review of RUC recommendations in the future.

Comment: One commenter stated that data obtained through the RUC survey process, based on subjective physician perceptions of work and time, may not always be the most accurate data available. The commenter stated that CMS should be open to reviewing additional sources of objective and validated work time data furnished by stakeholders. Such sources might include peer reviewed and published studies of comparative surgery times among different procedures in the same institution using standardized metrics.

Response. We continue to be open to reviewing additional and supplemental sources of data furnished by stakeholders. We encourage stakeholders to continue to provide such information for CMS consideration in establishing work RVUs.

Comment: One commenter stated that nurse practitioners have had little opportunity to participate in RUC activities, and since the fee schedule recommendations from the RUC impact all clinicians, it is important that all clinicians, including nurse practitioners, have input in that process. Another commenter stated that the process for setting the fee schedule should be accurate and robust, include input from multiple stakeholders, and be an open process that should have oversight from, and be transparent to, the many stakeholders who are affected by the PFS.

Response: We concur that the process of valuing codes should be accurate and robust, and, as previously stated, we consider input from various sources when determining the appropriate valuation. Notice and comment rulemaking provides for an open process whereby we welcome input from all interested parties, and encourage the commenters to provide feedback regarding our annual proposed valuations.

We look forward to continuing to engage with stakeholders and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes, and will continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process. We refer readers to section II.H.4 of this final rule for detailed discussion of the proposed valuation, and alternative valuation considered for specific codes. Table 12 contains a list of codes for which we proposed work RVUs; this includes all codes for which we received RUC recommendations by February 10, 2017. The proposed work RVUs, work time and other payment information for all proposed CY 2018 payable codes are available on the CMS Web site under downloads for the CY 2018 PFS final rule. Table 12 also contains the CPT code descriptors for all proposed, new, revised, and potentially misvalued codes discussed in this section.

3. Methodology for the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code by code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table 13 details our refinements of the RUC's direct PE recommendations at the code-specific level. In this final rule, we address several refinements that are common across codes, and refinements to particular codes are addressed in the portions of this section that are dedicated to particular codes. We note that for each refinement, we indicate the impact on direct costs for that service. We note that, on average, in any case where the impact on the direct cost for a particular refinement is $0.30 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. We also note that nearly half of the refinements listed in Table 13 result in changes under the $0.30 threshold and are unlikely to result in a change to the RVUs.

We also note that the direct PE inputs for CY 2018 are displayed in the CY 2018 direct PE input database, available on the CMS Web site under the downloads for the CY 2018 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. The inputs displayed there have also been used in developing the proposed CY 2018 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 continue to 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 have 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 post- operative visits included in the global period for a service, the equipment time would also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also note that we believe these same assumptions would apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question would be available if the room is not being occupied by a particular patient. For additional information, we refer readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there are 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 final rule for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We have addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. Some recommendations, however, include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2018, we received invoices for several new supply and equipment items. Tables 13 and 14 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this final rule, we encourage stakeholders to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage stakeholders to provide invoices or other information to improve the accuracy of pricing for these items in the direct PE database during the 60-day public comment period for this final rule. We expect that invoices received outside of the public comment period would be submitted by February 10th of the following year for consideration in future rulemaking, similar to our new process for consideration of RUC recommendations.

We remind stakeholders that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 13 and 14 also include the number of invoices received, as well as the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that stakeholders will note the impact the particular price might have on PE relativity, as well as to identify items that are used frequently, since we believe that stakeholders are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs and we encourage stakeholders to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we have included the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the proposed PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our proposed inputs did not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address proposed code-specific refinements to clinical labor in the individual code sections.

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

We note that the public use files for the PFS proposed and final rules for each year display both the services subject to the MPPR lists on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services and therapy services 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 for the upcoming calendar year. The public use files for CY 2018 are available on the CMS Web site under downloads for the CY 2018 PFS final rule at For more information regarding the history of the MPPR policy, we refer readers to the CY 2014 PFS final rule (78 FR 74261–74263). For more information regarding the history of the OPPS cap, we refer readers to the CY 2007 PFS final rule (71 FR 69659–69662).

4. Proposed Valuation of Specific Codes for CY 2018

(1) Anesthesia Services for Gastrointestinal (GI) Procedures (CPT Codes 00731, 00732, 00811, 00812, and 00813)

In the CY 2016 PFS proposed rule (80 FR 41686), we discussed that in reviewing Medicare claims data, a separate anesthesia service is typically reported more than 50 percent of the time that various colonoscopy procedures are reported. We discussed that given the significant change in relative frequency with which anesthesia codes are reported with colonoscopy services, we believed the relative values of the anesthesia services should be reexamined and proposed to identify CPT codes 00740 (Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum) and 00810 (Anesthesia for lower intestinal endoscopic procedures, endoscopy introduced distal to duodenum) as potentially misvalued.

For CY 2018, the CPT Editorial Panel is deleting CPT codes 00740 and 00810 and creating new codes for anesthesia services furnished in conjunction with and in support of gastrointestinal endoscopic procedures: Two codes for upper GI procedures, CPT code 00731 (Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum; not otherwise specified) and CPT code 00732 (Anesthesia for upper gastrointestinal endoscopic procedures, endoscopy introduced proximal to duodenum; endoscopic retrograde cholangiopancreatography (ERCP)); and two codes for lower GI procedures, CPT code 00811 (Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; not otherwise specified) and CPT code 00812 (Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; screening colonoscopy); and one code for upper and lower GI procedures, CPT code 00813 (Anesthesia for combined upper and lower gastrointestinal endoscopic procedures, endoscope introduced both proximal to and distal to the duodenum).

In the CY 2018 PFS proposed rule, we proposed the RUC-recommended base units without refinement for CPT codes 00731 (5.00 base units), 00732 (6.00 base units), 00811 (4.00 base units), 00812 (4.00 base units) and 00813 (5.00 base units). We considered 3.00 base units for CPT code 00812 based on our comparison of the surveyed post-induction anesthesia-intensity allocation for CPT code 00812 to codes with similar allocations, such as CPT code 01382 (Anesthesia for diagnostic arthroscopic procedures of knee joint). We found that CPT code 01382, which was also valued with 3 base units, had similar allocations compared to the survey results for CPT code 00812. We received comments from anesthesia providers and professional specialty societies, including the RUC that specifically addressed the codes in this family.

Comment: Regarding CPT code 00812, the RUC stated that its recommendation of 4.00 base units was made on an interim basis since the initial survey response rate did not meet the RUC's required minimum threshold based on the high utilization of predecessor CPT code 00810. Subsequently, the RUC included as part of its public comments a revised final recommendation of 3.00 base units for CPT code 00812 based on its review of new survey data, with the majority of survey respondents choosing CPT code 00910 (3.00 base units) as the key reference code more closely related to the work of CPT code 00812. Some commenters suggested that CMS should finalize its proposed values for each code in this family, including the proposed 4.00 base units for CPT code 00812, and suggested that CPT codes 00812 and 00811 represent similar work. A few commenters indicated that CPT code 00410 (4.00 base units) was a better comparator and crosswalk than the alternative crosswalk to CPT code 01382 that CMS considered for CPT code 00812.

Response: We reviewed additional information submitted by the RUC as part of its public comment, which included an analysis of new survey data. We find this additional data persuasive and believe that 3.00 base units better reflects the work of CPT code 00812.

Comment: Several commenters expressed concerns about the process used for identifying CPT codes 00740 and 00810 as potentially misvalued. Commenters requested that we maintain the CY 2017 payment levels for CY 2018, suggesting that if we were to finalize the proposed base units for each code in this family, it would discourage use of anesthesia during GI procedures.

Response: We continue to believe that the physician performing the GI procedure is in the best position to consider the beneficiary's needs when determining whether to utilize moderate sedation or anesthesia services. Additionally, while we understand the commenters' concerns, section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(K) of the Act identifies several categories of services as potentially misvalued, including codes that have experienced the fastest growth, along with codes as determined appropriate by the Secretary. Therefore, as discussed in the CY 2016 PFS proposed rule (80 FR 41686), we indicated that given the significant change in relative frequency with which anesthesia codes are reported with colonoscopy services, we believed the relative values of the anesthesia services should be reexamined as potentially misvalued.

Comment: Commenters raised concerns about how a change in valuation for anesthesia services would affect payments made by private insurers.

Response: While we appreciate commenters' concerns, this final rule

addresses valuation of services for purposes of Medicare payments made under the PFS. Valuation and payment determinations made by private insurers are outside the scope of this final rule.

After consideration of comments received that specifically addressed the codes in this family, for CY 2018, we are finalizing 5.00 base units for CPT codes 00731, 6.00 base units for CPT code 00732, 4.00 base units for CPT code 00811, 3.00 base units for CPT code 00812, and 5.00 base units for CPT code 00813.

(2) Acne Surgery (CPT Code 10040)

CPT code 10040 (Acne surgery (*e.g.,* marsupialization, opening or removal of multiple milia, comedones, cysts, pustules) was identified as potentially misvalued on a screen of Harvard-valued codes with utilization over 30,000 in CY 2014. In the CY 2018 PFS proposed rule, we proposed the RUC-recommended work RVU of 0.91 for CPT code 10040 and the RUC-recommended work time values. We considered using the current number of 0.5 post-procedure office visits of CPT code 99212 (Office/outpatient visit est) rather than the RUC-recommended number of 1.0 post-procedure office visits. For CPT code 10040, the RUC stated that it is a low intensity service that can be performed by a nurse under a physician's supervision, and that the average number of office visits in the follow-up period of acne surgery is 0.4. We sought public comments regarding the typical number of postoperative visits for this code, considering there have been no changes made to the code descriptor and we have not found evidence of changes to the typical patient population.

We proposed the RUC-recommended direct PE inputs for CPT code 10040 without refinement. We considered refinements to the clinical labor for ''Assist physician in performing procedure'' from 10 minutes to 3 minutes. CPT code 10040 previously used about one third of the intraservice work time for this clinical labor activity (5 minutes out of 14 minutes), and the RUC-recommended value of 10 minutes would have increased this to 100 percent of the intraservice work time without rationale for the change. We considered 3 minutes for this clinical labor activity, which is about one third of the intraservice work time (3 minutes out of 10 minutes) and would have maintained the current ratio between clinical labor time and work time. For CY 2018, we proposed the RUC-recommended work RVUs and direct PE inputs for CPT code 10040 and sought comment on our proposed and alternative values.

Comment: Commenters supported the proposed values for CPT code 10040 but disagreed with the alternative values.

Response: We continue to welcome information from all interested parties regarding valuation of services for consideration through our rulemaking process. We will continue to consider alternative work RVUs as we propose the valuation of services for future notice and comment rulemaking.

After consideration of comments received, for CY 2018, we are finalizing the work RVUs and direct PE inputs for CPT code 10040 as proposed.

(3) Muscle Flaps (CPT Codes 15734, 15736, 15738, 15730, and 15733)

CPT codes 15732 and 15736 were identified via a screen of high level E/M visits included in their global periods. This screen identified that a CPT code 99214 office visit was included for CPT codes 15732 and 15736 but not included in the other codes in this family. During the CPT Editorial Panel's review process for this family of codes, CPT code 15732 was deleted and replaced with two new codes, CPT codes 15730 and 15733, to better differentiate and describe the work of large muscle flaps performed on patients with head and neck cancer depending on the site where the service was performed.

For CY 2018, we proposed the RUC-recommended work RVUs of 23.00 for CPT code 15734, 17.04 for CPT code 15736, 19.04 for CPT code 15738, 13.50 for CPT code 15730, and 15.68 for CPT code 15733. For CPT code 15730, we considered a work RVU of 12.03, crosswalking to CPT code 36830 (Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); nonautogenous graft (*e.g.,* biological collagen, thermoplastic graft)). We had concerns because the RUC-recommended work RVU of 13.50 would represent nearly double the intensity of CPT codes 15734 through 15738, as well as nearly double the intensity of deleted CPT code 15732. The RUC-recommended work RVU for CPT code 15730 is also based on a direct crosswalk to CPT code 36832 (Revision, open, arteriovenous fistula; without thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure)), which has the same intraservice time, but with 20 additional minutes of total time. We considered a potential crosswalk to another code in the same family, CPT code 36830, which also shares the same intraservice time with CPT code 15730 but differs by only 8 minutes of total time. However, we sought comment on whether the RUC recommendation was appropriate given the significant variation in intensity among these services.

We considered a work RVU of 14.63 for CPT code 15733 (survey 25th percentile), crosswalking to CPT code 36833 (Revision, open, arteriovenous fistula; with thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure)), which has the same intraservice time, 1 minute of additional total time, and a work RVU of 14.50. We sought comment on the effect that an alternative work RVU of 14.50 would have on relativity among the codes in this family.

We considered refining the clinical labor time for ''Check dressings & wound/home care instructions'' for CPT code 15730 from 10 minutes to 5 minutes. We sought comment on the typical time input for checking dressings, and whether removing and replacing dressings would typically take place during the intraservice or postservice period.

We also sought comments regarding the use of the new ''plate, surgical, mini-compression, 4 hole'' (SD189) supply included in CPT code 15730, including whether use of this supply would be typical, and if so, whether it should be included in the work description. We noted that SD189 is mentioned in the direct PE recommendations, but the supply does not appear in the work description. In the work description, the fixation screws are applied to the orbital rim and lateral nasal wall, not the surgical plate.

Comment: Several commenters supported the proposed values for all five of the codes but disagreed with the alternative values.

Response: We continue to welcome information from all interested parties regarding valuation of services for consideration through our rulemaking process. We will continue to consider alternative work RVUs as we propose the valuation of services for future notice and comment rulemaking.

Comment: Several commenters stated that the use of the ''plate, surgical, mini-compression, 4 hole'' (SD189) supply was typical in CPT code 15730. Commenters mentioned that this supply had a number of clinical benefits, such as greater stability, less risk of infection, fewer screws, and a wide area of support. Commenters stated that the recommendation forms that accompany the work descriptor do not normally list all supplies or materials used before, during, or after the surgery in great detail.

Response: We appreciate the additional information supplied by the commenters regarding the use of the SD189 supply. While we agree that the work descriptor for a procedure would not necessarily list all of the supplies used before, during, or after a surgery, we remain puzzled at the lack of any mention of the surgical plate in the description of work for this service. The surgical plate is an expensive ($226) supply that appears to be integral to the work being performed in this service. The deleted predecessor code for this service, CPT code 15732, did not include a surgical plate among its direct PE inputs, and if the use of the surgical plate is now typical for the new CPT code 15730, we believe that the description of work for this service would more accurately explain the work taking place by detailing the use of the supply. We agree with the commenters regarding the clinical benefits of the surgical plate, and believe that this should be reflected in the description of work for this service.

After consideration of comments received, for CY 2018, we are finalizing the work RVUs and direct PE inputs for the codes in the muscle flaps family as proposed.

(4) Application of Rigid Leg Cast (CPT Code 29445)

CPT code 29445 (Application of rigid total contact leg cast) appeared on a high growth screen of all services with total Medicare utilization of 10,000 or more services that increased by at least 100 percent from 2008 through 2013. This screen also indicated that the code was last surveyed more than 10 years previously, and that the dominant specialty had changed during that time.

For CY 2018, we proposed the RUC-recommended work RVU of 1.78 for CPT code 29445. For the direct PE inputs, we proposed to refine the clinical labor time for ''Check dressings & wound/home care instructions'' from 5 minutes to 3 minutes. We believed that the additional 2 minutes of clinical labor time that we proposed to remove would take place during the monitoring time following the procedure and be accounted for in that clinical labor time.

We also considered refining the clinical labor time for ''Remove cast'' from 22 minutes to 11 minutes: 1 minute for room prep, 10 minutes for assisting the physician, and 0 minutes for the additional activities described in the RUC recommendations, which would have only taken place during the initial casting. We had concerns that the RUC-recommended clinical labor regarding the ''remove cast'' task is based only on an initial visit where a new cast would be applied and 22 minutes may be an appropriate length of time. However, the RUC recommendations suggested that four to twelve cast changes are common for patients, and we sought comment on whether the initial application of a new cast would be typical for CPT code 29445. We reviewed the Medicare claims data for CPT code 29445 and found that three or more castings took place for 52 percent of beneficiaries, which suggests that three or more castings may be the typical case. A single casting only took place for 30 percent of services reported with CPT code 29445.

Comment: Several commenters supported the proposed values for CPT code 29445 but disagreed with the alternative values.

Response: We continue to welcome information from all interested parties regarding valuation of services for consideration through our rulemaking process. We will continue to consider alternative work RVUs as we propose the valuation of services for future notice and comment rulemaking.

Comment: One commenter stated that they disagreed with our proposal to refine the clinical labor time for ''Check dressings & wound/home care instructions'' from 5 minutes to 3 minutes. The commenter did not supply any rationale for its disagreement.

Response: We continue to believe that the additional 2 minutes of clinical labor time that we proposed to remove would take place during the monitoring time following the procedure and be accounted for in that clinical labor time, since we did not receive any information to suggest otherwise for CPT code 29445.

After consideration of comments received, for CY 2018, we are finalizing the work RVUs and direct PE inputs for CPT code 29445 as proposed.

(5) Strapping Multi-Layer Compression (CPT Codes 29580 and 29581)

The RUC reviewed CPT code 29580 since it appeared on the screen for high expenditure services and reviewed CPT code 29581 as part of this family of codes. For CY 2018, the CPT Editorial Panel is deleting two additional codes in the family: CPT codes 29582 (Application of multi-layer compression system; thigh and leg, including ankle and foot, when performed) and 29583 (Application of multi-layer compression system; upper arm and forearm).

For CY 2018, we proposed the RUC-recommended work RVUs for CPT code 29580 (a work RVU of 0.55) and CPT code 29581 (a work RVU of 0.60).

However, we were concerned about the changes in preservice time reflected in the specialty surveys compared to the RUC-recommended work RVUs. For instance, for CPT code 29580, we considered a work RVU of 0.46, crosswalking to CPT code 98925 (Osteopathic manipulative treatment (OMT); 1–2 body regions involved)), which has a work RVU of 0.46 and shares a similar intraservice time. Compared to the specialty survey times, the RUC recommended a slight decrease (9 minutes) in preservice time for CPT code 29580, with the intraservice and immediate postservice times remaining unchanged.

For CPT code 29581, we considered a work RVU of 0.51 [we note that in the CY 2018 PFS proposed rule (82 FR 33991), this was cited as 0.50] by using the RUC-recommended work RVU increment between CPT codes 29580 and 29581 (+0.05), added to the work RVU we considered for CPT code 29580 (0.46), and crosswalking to CPT code 97597 (Debridement (*e.g.,* high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (*e.g.*, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less)), which has similar intraservice and total times to the RUC-recommended services times for CPT code 29581. We sought comment on whether a work RVU of 0.51 would improve relativity among the codes in this family.

For CY 2018, we proposed the RUC-recommended work RVUs for CPT codes 29580 and 29581 and sought comment on whether the alternative values we considered would be more appropriate.

Comment: In general, commenters were supportive of our proposal of the RUC-recommended work RVUs. Some expressed opposition to the alternative work RVUs.

Response: We will continue to consider alternative work RVUs as we propose the valuation of services for future notice and comment rulemaking.

Comment: Several commenters were supportive of the RUC-recommended PE inputs for these services.

Response: We disagree with the RUC-recommended PE inputs for these services. We proposed to refine the L037D clinical labor time for ''Provide pre-service education/obtain consent'' from 3 minutes to 2 minutes to conform to the standard for this clinical labor

activity. The RUC recommendation did not include a written justification for additional clinical labor time beyond the standard 2 minutes for this activity. As a result, we also proposed to refine the recommended equipment times for the exam table (EF023) and exam light (EQ168) to conform to changes in clinical labor time. Thus, we proposed to refine the equipment times for EF023 and EQ168 to 34 minutes for CPT code 29580 and to 36 minutes for CPT code 29581, to reflect the service period time associated with these codes. We continue to believe that the use of clinical labor standards provides greater consistency among codes that share the same clinical labor tasks and can improve relativity of values among codes.

After consideration of comments received, we are finalizing the work RVUs and direct PE inputs for these services as proposed.

(6) Resection Inferior Turbinate (CPT Code 30140)

CPT code 30140 (Submucous resection inferior turbinate, partial or complete, any method) was identified as potentially misvalued on a screen of Harvard-valued codes with utilization over 30,000 in CY 2014. During the review process, the RUC re-surveyed the code as a 0-day global period, based on the presence of a negative intensity value in the initial survey and highly variable postoperative office visits.

For CY 2018, we proposed the RUC-recommended work RVU of 3.00 for CPT code 30140 as a 0-day global code. We also considered a work RVU of 2.68 for CPT code 30140 and sought comment on changes in practice patterns since the code was previously reviewed, service times of comparable services, and whether a work RVU of 2.68 would better maintain relativity among similar codes. We noted that the RUC-recommended work RVU of 3.00 nearly doubles the derived intensity of the code as currently valued. We noted that the RUC recommendations referenced services that had similar service times to CPT code 30140 (CPT code 31240 (Nasal/sinus endoscopy, surgical; with concha bullosa resection), with a work RVU of 2.61; and CPT code 31295 (Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (*e.g.*, balloon dilation), transnasal or via canine fossa), with a work RVU of 2.70.

We noted that the initial survey for CPT code 30140 as a 90-day global resulted in a RUC-recommended work RVU of 3.57, while the second survey for the code as a 0-day global resulted in a RUC-recommended work RVU of 3.00, despite the removal of two postoperative office visits of CPT code 99212 and a half discharge visit of CPT code 99238. These removed postoperative visits have a total work RVU of 2.58, which is notably higher than the difference in the RUC-recommended work RVUs between the two surveys.

We also proposed to create equipment codes for three new equipment items based on invoices submitted with the RUC recommendations for CPT code 30140. We proposed to create three new equipment codes based on the invoices submitted for this code family: The 2mm reusable shaver blade (EQ383) at a price of $790, the microdebrider handpiece (EQ384) at a price of $4,760, and the microdebrider console (EQ385) at a price of $9,034.

Comment: Several commenters supported the proposed values for CPT code 30140 but disagreed with the alternative values.

Response: We continue to welcome information from all interested parties regarding valuation of services for consideration through our rulemaking process. We will continue to consider alternative work RVUs as we propose the valuation of services for future notice and comment rulemaking.

Comment: One commenter requested that CMS add a new supply named the ''turbinate reduction wand'' to the supply inputs associated with this procedure when performed in the physician office setting. The commenter stated that this device is designed to ablate, coagulate, and remove a core of tissue that provides the desired volumetric reduction of the anatomy, and supplied several invoices for use in pricing the new supply.

Response: We note that the suggested turbinate reduction wand has a price of nearly $200, which would add substantially to the costs of CPT code 30140. Before including such significant resource costs in the code, we believe that we should see input from the physician community such as the RUC. At present, we do not have any information to suggest that the use of this new supply is typical for CPT code 30140, and the RUC did not recommend the inclusion of this supply on either of the two occasions when this code was reviewed in CY 2017. For these reasons, we do not believe that it would be appropriate to add the turbinate reduction wand to CPT code 30140 at this time. We welcome the submission of additional information regarding this use of this supply from stakeholders.

After consideration of comments received, for CY 2018, we are finalizing the work RVUs and direct PE inputs for CPT code 30140 as proposed.

(7) Control Nasal Hemorrhage (CPT Codes 30901, 30903, 30905, and 30906)

In the CY 2018 PFS proposed rule, we proposed the RUC-recommended work RVU of 1.10 for CPT code 30901, 1.54 for CPT code 30903, 1.97 for CPT code 30905, and 2.45 for CPT code 30906. We also proposed the RUC-recommended direct PE inputs for CPT codes 30901, 30903, 30905, and 30906, with standard refinements to the equipment times to account for patient monitoring times. We noted that as part of its recommendation, the RUC informed us that the specialty societies presented evidence stating that the 1995 valuations for these services factored in excessive times, specifically to account for infection control procedures that were necessary at that time due to the prevalence of HIV/AIDS. The specialty societies also noted that increased availability and use of blood thinner medications compared to those available in 1995, has increased the difficulty and intensity of these procedures. We sought additional information regarding the presumption that the relative resource intensity of these services specifically would be affected by the commercial availability of additional blood thinner medications. We stated in the CY 2018 PFS proposed rule that we believe blood thinner medications were widely available before 1995 when these codes were last valued. We also sought comments on the prevalence of HIV/AIDS and whether the work related to infection control procedures would be relative across many PFS services or specifically related to nasal hemorrhage control procedures.

For CPT code 30901 (Control nasal hemorrhage, anterior, simple (limited cautery and/or packing) any method), we considered a work RVU of 1.00 (the 25th percentile survey result), crosswalking to CPT code 20606 (Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (*e.g.,* temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); with ultrasound guidance, with permanent recording and reporting), which has similar service times. The median survey total time (24 minutes) dropped by 2 minutes (from preservice time), to 24 minutes compared to the existing total time. The difference in total time reflected a small decrease in preservice time, with no change in intraservice time (10 minutes). Among codes with similar service times, we found only three codes that had a higher work RVU than the RUC-recommended value.

For CPT code 30903 (Control nasal hemorrhage, anterior, complex (extensive cautery and/or packing) any method), we considered a work RVU of 1.30 (the 25th percentile survey result), which would have been further supported by CPT codes 36584 and 51710, which have similar service times to the median survey results. The RUC recommended a decreased total time of 39 minutes compared to the existing total time (70 minutes), with intraservice time dropping from 30 to 15 minutes.

For CPT code 30905 (Control nasal hemorrhage, posterior, with posterior nasal packs and/or cautery, any method; initial), we considered a work RVU of 1.73, using the RUC-recommended work RVU increment between CPT codes 30903 and 30905 (0.43), added to the work RVU we considered for CPT code 30903 (1.30), and crosswalking to CPT code 45321 (Proctosigmoidoscopy, rigid; with decompression of volvulus), which has similar service times. The surveyed intraservice time dropped from 48 minutes to 20 minutes. The RUC recommendations indicated that surveyed service times for CPT code 30905 are longer than for CPT code 30903 since the service is performed to control an arterial posterior bleed. According to the specialty society, arterial posterior bleeds are more difficult to treat and require a more extensive procedure in comparison to services reported with CPT code 30903. We considered using the RUC-recommended work RVU increment between CPT codes 30903 and 30905 (0.43), added to the work RVU we considered for CPT code 30903 (1.30), resulting in a work RVU of 1.73. We sought comment on whether a work RVU of 1.73 would potentially affect relativity among the codes in this family.

For CPT code 30906 (Control nasal hemorrhage, posterior, with posterior nasal packs and/or cautery, any method; subsequent), we considered a work RVU of 2.21, using the RUC-recommended work RVU increment between CPT codes 30905 and 30906 (0.48), added to the work RVU we considered for CPT code 30905 (1.73), and crosswalking to services with similar service times (CPT codes 19281 (Placement of breast localization device(s) (*e.g.,* clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including mammographic guidance), 51727 (Simple Cystometrogram (CMG) (*e.g.*, spinal manometer); with urethral pressure profile studies (*i.e.*, urethral closure pressure profile), any technique), 49185 (Sclerotherapy of a fluid collection (*e.g.*, lymphocele, cyst, or seroma), percutaneous, including contrast injection(s), sclerosant injection(s), diagnostic study, imaging guidance (*e.g.*, ultrasound, fluoroscopy) and radiological supervision and interpretation when performed), and 62305 (Myelography via lumbar injection, including radiological supervision and interpretation; 2 or more regions (*e.g.*, lumbar/thoracic, cervical/thoracic, lumbar/cervical, lumbar thoracic/cervical)). The surveyed median intraservice time dropped from 60 minutes to 30 minutes. We sought comment on whether a work RVU of 2.21 would potentially improve relativity among the codes in this family.

Given the RUC's consensus, for CY 2018, we proposed the RUC-recommended work RVUs for each code in this family and sought comment on whether our alternative values would be more appropriate.

Comment: We received a few comments that specifically addressed our proposed values for this code family from professional specialty societies, including the RUC. Commenters expressed support for CMS' proposed values including the proposed direct PE inputs with standard refinements to equipment times.

Response: We appreciate the commenters' support and, after consideration of the comments received that specifically address the codes in this family, we are finalizing a work RVU of 1.10 for CPT code 30901, a work RVU of 1.54 for CPT code 30903, a work RVU of 1.97 for CPT code 30905, and a work RVU of 2.45 for CPT code 30906. We are also finalizing the direct PE inputs as proposed, with standard refinements to equipment times to account for patient monitoring times.

(8) Nasal Sinus Endoscopy (CPT Codes 31254, 31255, 31256, 31267, 31276, 31287, 31288, 31295, 31296, 31297, 31241, 31241, 31253, 31257, 31259, and 31298)

In October 2016, the CPT Editorial Panel created five new codes (CPT codes 31241, 31241, 31253, 31257, 31259 and 31298) and revised CPT codes 31238, 31254, 31255, 31276, 31287, 31288, 31296, and 31297. CPT codes 31253—31298 are newly bundled services representing services that are frequently reported together. CPT code 31241 represents a new service. The RUC reviewed this family of codes at its January 2017 meeting. For CY 2018, we proposed the RUC-recommended work RVUs for all 15 CPT codes in this family as follows: 4.27 for CPT code 31254, 5.75 for CPT code 31255, 3.11 for CPT code 31256, 4.68 for CPT code 31267, 6.75 for CPT code 31276, 3.50 for CPT code 31287, 4.10 for CPT code 31288, 2.70 for CPT code 31295, 3.10 for CPT code 31296, 2.44 for CPT code 31297, 8.00 for CPT code 31241, 9.00 for CPT code 31253, 8.00 for CPT code 31257, 8.48 for CPT code 31259, and 4.50 for CPT code 31298.

For CPT code 31296, we considered a work RVU of 2.82, supported by a crosswalk to CPT code 36901 (Intro cath dialysis circuit) with an intraservice time of 25 minutes and total time of 66 minutes, similar to the service times for CPT code 31296. We were concerned about the decrease in service time compared to the work RVU and sought comment on whether or not a work RVU of 2.82 might improve relativity with other PFS services.

For CPT code 31256, we considered a work RVU of 2.80, supported by a crosswalk to CPT code 43231 (Esophagoscopy, flexible, transoral; with endoscopic ultrasound examination), which has 30 minutes of intraservice time and 81 minutes of total time, similar to the RUC-recommended service times. We were concerned about the difference in total time between CPT code 31256 and the RUC-recommended crosswalk to CPT code 43247. CPT code 43247 has 30 minutes intraservice time and 58 minutes total time), and CPT code 31256 (30 minutes intraservice time and 83 minutes total time).

For CPT code 31254, we noted the RUC's explanation that this service is more intense than the functional endoscopic sinus surgery on the maxillary or sphenoid sinuses due to the risk of major complications such as injury to the eye muscles, bleeding into the eye or brain fluid leak and, consequently, that the RUC concluded that it should be valued higher than either CPT code 31256 or CPT code 31287. Since CPT code 31256 has the same total time (30 minutes) and intraservice time (30 minutes) as CPT code 31254, we considered whether the incremental difference recommended by the RUC between these two codes (work RVU of 1.16) would reflect the intensity of the service. We considered a work RVU of 2.80 for CPT code 31256, and also considered an alternative work RVU of 3.97 for CPT code 31254.

For CPT code 31287, we considered a work RVU of 3.19 based on the difference between the RUC-recommended work RVU for the maxillary sinus surgery (CPT code 31256) and the sphenoid sinus surgery (CPT code 31287) (difference = 0.28) added to the work RVU that we considered for the base code (CPT code 31256, a work RVU of 2.80). We noted that the magnitude of decreases in

service times is greater than those for the work RVU, which potentially could affect relativity among PFS services.

For CPT code 31255, we considered a work RVU of 5.30, based on a crosswalk to CPT codes 36475 (Endovenous rf 1st vein) and 36478 (Endovenous laser 1st vein) since both of these services have the same intraservice times, total times, and work RVUs. We noted that there are several CPT codes with similar total and intraservice times as CPT code 31255 that have lower work RVUs than the RUC's recommended work RVU of 5.75, such as CPT code 36246 (Ins cath abd/l-ext art 2nd), which has 45 minutes intraservice time, 96 minutes total time and a work RVU of 5.02

For CPT code 31276 (Nasal/sinus endoscopy, surgical; with frontal sinus exploration, including removal of tissue from frontal sinus, when performed), we considered a work RVU of 6.30, which is similar to other functional endoscopic surgeries. We noted that the services reported with CPT code 31276 are the most intense and complex of the functional endoscopic surgeries due to the risks of working in the narrow confines in the frontal recess. However, we had concerns regarding the RUC-recommended crosswalk to CPT code 52352 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with removal or manipulation of calculus (ureteral catheterization is included)), and sought comment on whether the RUC-recommended decrease in service times was appropriate since CPT code 52352 has 20 minutes more total time than CPT code 31276.

For CPT code 31241 (nasal/sinus endoscopy, surgical; with ligation of Sphenopalatine artery), we had concerns and sought comment regarding the accuracy and applicability of the surveys as the RUC indicated that the specialty society did not use the survey instrument that contained questions about the number and types of visits and that this service requires including a half day discharge day management as the patients typically stay overnight to be monitored for further bleeding. We sought comment on whether inclusion of a half day discharge day visit was typical for this service since services assigned 0-day global periods do not typically include discharge visits. We considered reducing the total time from 142 minutes to 123 minutes by removing the half day discharge. Using the alternative total time of 123 minutes, we found services with similar total and intraservice time (60 minutes) and total time (123 minutes).

We considered a work RVU of 7.30 for CPT code 31241, supported by a direct crosswalk to CPT code 36253 (Superselective catheter placement (one or more second order or higher renal artery branches) renal artery and any accessory renal artery(s) for renal angiography, including arterial puncture, catheterization, fluoroscopy, contrast injection(s), image postprocessing, permanent recording of images, and radiological supervision and interpretation, including pressure gradient measurements when performed, and flush aortogram when performed; unilateral), since CPT code 36253 has a similar total time compared to our alternative total time.

For CPT code 31257, we considered a work RVU of 7.30, based on a crosswalk to CPT code 36253 (Superselective catheter placement (one or more second order or higher renal artery branches) renal artery and any accessory renal artery(s) for renal angiography, including arterial puncture, catheterization, fluoroscopy, contrast injection(s), image postprocessing, permanent recording of images, and radiological supervision and interpretation, including pressure gradient measurements when performed, and flush aortogram when performed; unilateral). We had similar concerns regarding the service times for this service, including the cited reference codes, compared to the RUC-recommended work RVU. We sought comment on whether a work RVU of 7.30 for CPT code 31257 would improve consistency among the combined CPT codes in this family.

CPT code 31259 is a new code representing a combination of the services previously described by CPT codes 31255 and 31288. We noted the changes in overall service times compared to other codes in this family and other PFS services. We considered a work RVU of 7.85 for CPT code 31259, crosswalking to CPT code 93461 (R&l hrt art/ventricle angio), which has identical intraservice times. We sought comment on the effect that this alternative work RVU might have on consistency and rank order compared to the other bundled codes in this family.

CPT code 31298 represents a combination of CPT codes 31296 and 31297. We had concerns about the use of the RUC-recommended comparison codes, CPT codes 47532 and 58558, due to differences in both intraservice and total time compared to the service times for CPT code 31298. We considered a work RVU of 4.10 for CPT code 31298, crosswalking to CPT code 44406 (Colonoscopy w/ultrasound), which has similar service times.

In the CY 2018 PFS proposed rule, we proposed the RUC-recommended work RVUs for each code in this family and sought comment on our alternative values.

Comment: In general, commenters supported the work RVUs for existing CPT codes in this family as proposed. One commenter expressed concern about the proposed work RVUs for the newly bundled CPT codes: CPT code 31253, 31257, 31259, and 31298. The commenter encouraged CMS to adopt a payment rate for the newly bundled codes that more closely aligns with the payment if the individual codes are reported separately on the same claim. Valuing the newly bundled codes as the sum of the component codes would yield a work RVU of 12.50 for CPT 31253 instead of the proposed 9.00; a work RVU of 9.25 for CPT 31257 instead of the proposed 8.00; a work RVU of 9.85 for 31259 instead of the proposed 8.48; and a work RVU of 5.44 for CPT 31298 instead of the proposed 4.50.

Response: We believe that certain efficiencies occur when certain services are furnished together. From a payment perspective, those efficiencies are reflected in the multiple procedure payment reduction. Similarly, when services that used to be described by two separate codes are combined, those efficiencies are reflected in the work RVU for the combined code. Therefore, we are finalizing all work RVUs for the CPT codes in this family, including the newly combined services, as proposed.

Comment: One commenter noted that a few of the CPT codes have work RVUs that are decreasing by more than 20 percent and requested that CMS phase-in these rate reductions.

Response: Section 1848(c)(7) of the Act requires that, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2- year period. We note that the phase-in requirement does not apply to codes that are new or revised. Therefore, the CPT codes in this code family with work RVU reductions of greater than 20 percent are not subject to the phase-in requirement. Please see section II.F of the CY 2016 PFS final rule with comment period (80 FR 70930) for more information regarding the phase-in of significant RVU reductions. The document is available on the CMS Web site under downloads for the CY 2016 PFS final rule with comment period at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

Regarding the recommended direct PE inputs, we expressed concern about one of the supply items used in furnishing

services for several CPT codes in this family: ''sinus surgery balloon (maxillary, frontal, or sphenoid) kit'' (SA106). In the current recommendations, half of one kit (each kit has sufficient supply for two sinuses) is included in the PE inputs for CPT codes 31295, 31296, and 31297. The new CPT code 31298 has one full kit, reflecting a service consisting of two sinuses, according to the RUC's explanation. The price of the full kit (two sinuses) of this disposable supply is $2,599.06. Our analysis of 2016 Medicare claims data indicated that 48 percent of the time one of the three CPT codes (31295, 31296, and 31297) is billed, it is reported on a claim with either one or both of the other codes. Ten percent of the time one of the three CPT codes is billed, it is reported on a claim with both of the other two codes. Effectively, 10 percent of claims reporting these CPT codes are being paid for three sinuses. We sought comments on the number of units of this supply item that are used for each service. We welcomed suggestions about improved methodologies for identifying the quantity of this disposable supply used during these procedures and will continue to monitor utilization and reporting of these services.

Comment: We received several comments in response to our request for input about the number of units of supply item ''sinus surgery balloon (maxillary, frontal, or sphenoid) kit'' (SA106) that are appropriate for CPT codes 31295, 31296, 31297, and 31298. Commenters, including the RUC, noted that each kit includes one balloon, and each sinus requires 0.5 of a balloon, and that the current PE input of 0.5 of SA106 is appropriate for CPT 31295, 31296, and 31297. Commenters also noted that, since CPT code 31298 bundles CPT codes 31296 and 31297, an entire balloon kit is appropriate. The RUC also reiterated support for CMS to develop a standalone HCPCS supply code for the balloon kit.

Response: We are finalizing the PE input for supply item SA106 as proposed, which includes 0.5 kit for CPT codes 31295, 31296, and 31297, and one kit for CPT code 31298.

Comment: One commenter suggested that several PE inputs for CPT code 31254 are either missing, insufficient, or have an incorrect price. The commenter also requested that CMS develop nonfacility PE inputs for CPT code 31255.

Response: After reviewing the commenter's suggestions regarding supply items for CPT code 31254, we believe that the current supplies and prices, as developed by the RUC in concert with the specialty societies, account for the items that are typically involved in furnishing this service. We refer the commenter to the process by which additional information for consideration of prices for supply items can be provided to CMS through the annual rulemaking cycle, in particular through invoices. Regarding the request to establish nonfacility values for this code, we have historically proposed payment rates for specific settings that have been vetted through the RUC process. We also consider information on Medicare utilization that may indicate trends on where the service is being furnished to identify when it might be appropriate to value a code in the nonfacility setting. If stakeholders are interested in submitting information about PE inputs that reflect resource costs typical for a particular setting, we encourage collaboration with the RUC in addressing such inputs. We note that the valuation of a service under the PFS in particular settings does not address whether those services are medically reasonable and necessary in the case of individual patients, including being furnished in a setting appropriate to the patient's medical needs and condition. We are finalizing the PE inputs for CPT codes in this family as proposed.

In reviewing the RUC recommendations for this family of CPT codes, we noted that the CPT codes in this family are subject to the standard payment adjustment for multiple surgeries. In our analysis of the claims data, we noted that the average number of HCPCS codes in this family reported together on a claim line is approximately 2.89. In addition, about 15 percent of claims have two of the newly bundled CPT codes reported together on a claim line. We expressed concern about the frequency with which the nasal sinus endoscopy CPT codes in this family are billed together. We sought comments on whether we should consider the endobase code adjustments as a better approach to adjusting payment for these services instead of the current multiple procedure payment reduction. For additional information about the payment adjustment under the special rule for multiple endoscopic services, we refer readers to the Medicare Claims Processing Manual, Chapter 23 (available on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.html*.

Comment: There was no consensus among commenters about whether we should consider the endobase code adjustments as a better approach to adjusting payment for these services instead of the multiple procedure payment reduction. A few commenters stated their opposition, noting that in cases where multiple endoscopies are provided on the same date of service, this would result in the base procedure not being reimbursed, and that this would be grossly inappropriate because these are therapeutic procedures and each sinus represents very different work and risks. Other commenters supported the application of the payment reduction for multiple endoscopic procedures.

Response: We will consider these comments. We welcome feedback from stakeholders regarding these and other services for which a change in the indicator status designating the applicable type of multiple procedure payment reduction might be appropriate. We are finalizing our proposal to maintain the standard multiple procedure payment reduction for this group of nasal sinus endoscopy services.

To estimate utilization for new or newly bundled services in this group of complex codes, we used a different crosswalk to current services than was recommended by the RUC. We believe that the RUC did not sufficiently account for utilization changes that occur when several newly bundled CPT codes describe formerly separate services. We direct readers to the file called ''CY 2017 Analytic Crosswalk to CY 2018'' on the CMS Web site under downloads for the CY 2018 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

(9) Tracheostomy (CPT Codes 31600, 31601, 31603, 31605, and 31610)

CPT code 31600 was identified as part of a screen of high expenditure services with Medicare allowed charges of $10 million or more that had not been recently reviewed. CPT codes 31601, 31603, 31605, and 31610 were added and reviewed as part of the code family.

We proposed the RUC-recommended work RVUs for all five codes in this family. We proposed work RVUs of 5.56 for CPT code 31600, 8.00 for CPT code 31601, 6.00 for CPT code 31603, 6.45 for CPT code 31605, and 12.00 for CPT code 31610.

We considered a work RVU of 6.50 for CPT code 31601. We sought comment on the effect that this alternative value would have on relativity compared to other PFS services, especially since the survey data do not suggest an increase in the time required to perform the procedure.

We considered a work RVU of 4.77 for CPT code 31605, based on the survey 25th percentile from the combined survey total. We also considered an intraservice work time of 15 minutes, based on the median intraservice work time from the combined survey total for CPT code 31605. We sought comments on the methodology used to determine the RUC-recommended work RVU and intraservice work time. We were concerned that the number of respondents (20) was below the threshold typically required for submission of a survey, and the effect of using survey results only from physicians who had personal experience performing the procedure. CPT code 31605 has a lower intraservice and total time, but a higher work RVU than comparable codes under the PFS. We noted that the next highest 0-day global code with 20 minutes of intraservice time is CPT code 16035 (Escharotomy; initial incision) at a work RVU of 3.74. All other 0-day global codes with a work RVU of 6.45 or greater have at least 40 minutes of intraservice time.

We sought comment on the effect that an alternative work RVU of 4.77 would have on the relativity of this service compared to other services in this family of codes and compared to other PFS services, taking into account that CPT code 31605 describes a difficult and dangerous life-threatening emergency procedure.

We considered a work RVU of 6.50 for CPT code 31610 based on a direct crosswalk to CPT code 31601 (Incision of windpipe). We understand that the RUC considered the possibility of recommending this code be assigned a 0-day global period based on concerns about negative derived intensity. We shared the RUC's concerns with the current construction of CPT code 31610, particularly with the 242 minutes of work time included in the postoperative visits, which is an unusually large amount for a procedure with only 45 minutes of intraservice time. We did not identify any other comparable codes under the PFS with 45 minutes of intraservice time and more than 300 minutes of total time. We sought comment on whether the unusually high volume of physician work time included in the postoperative visits for CPT code 31610 contributed to the negative derived intensity reported by the survey data. Considering that the other codes in this family have 0-day global periods, we considered and sought comment on whether a 0-day global period should be assigned to CPT code 31610. Removal of the postoperative E/M visits from CPT code 31610 would result in an intraservice time of 45 minutes and a total time of 125 minutes, similar to CPT code 31601 with 45 minutes of intraservice time and 135 minutes of total time.

We proposed the RUC-recommended direct PE inputs for all five CPT codes in this family without refinements. As discussed earlier, we considered a 0-day global period for CPT code 31610, which would also have resulted in removal of the clinical labor associated with the postoperative E/M visits, along with the supplies and equipment utilized during those visits. While we remained concerned about the global period assigned to CPT code 31610 and the changes in service times reflected in the specialty surveys compared to the RUC-recommended work RVUs, for CY 2018, we proposed the RUC-recommended work RVUs and direct PE inputs for each code in this family and sought comment on our proposed and alternative values.

Comment: The commenters supported the proposed values for all five of the codes but disagreed with the alternative values.

Response: We appreciate the feedback from the commenters. We continue to welcome information from all interested parties regarding valuation of services for consideration through our rulemaking process.

After consideration of comments received, for CY 2018, we are finalizing the work RVUs, direct PE inputs, and global periods for the codes in the tracheostomy family as proposed.

(10) Bronchial Aspiration of Tracheobronchial Tree (CPT Codes 31645 and 31646)

CPT code 31645 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed with therapeutic aspiration of tracheobronchial tree, initial) was identified as potentially misvalued on a screen of Harvard-valued codes with utilization over 30,000 in CY 2014. CPT code 31646 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed with therapeutic aspiration of tracheobronchial tree, subsequent, same hospital stay) was added for review as part of the family of codes, and both were revised to reflect recent changes in how the services are typically performed. For CY 2018, we proposed the RUC-recommended work RVUs of 2.88 for CPT code 31645 and 2.78 for CPT code 31646.

We considered a work RVU of 2.72 for CPT code 31645, crosswalking to CPT code 45347 (Sigmoidoscopy, flexible; with placement of endoscopic stent). We had concerns regarding the decrease in intraservice and total time compared to the current values; we also believe that it is important to note how these related codes have been affected by the creation of separately billable codes for moderate sedation (see the CY 2017 PFS final rule (81 FR 80339)). The RUC recommended a work RVU for CPT code 31645 that is higher than the work RVU for CPT code 31622 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed), which is the base procedure for this broader group of codes. We agreed that CPT code 31645 should be valued at a higher work RVU than CPT code 31622; however, we sought comment on whether the work of moderate sedation was inadvertently included in the development of the recommended work RVU. We noted that as part of the CY 2017 PFS final rule (81 FR 80339), we finalized separate payment for moderate sedation. Following the creation of separately billable codes for moderate sedation, CPT code 31622 is currently valued at a work RVU of 2.53, not 2.78 as it was previously valued, and we did not believe it would be appropriate to continue to value CPT code 31645 as though moderate sedation was still an inherent part of the work of this service. As a result, we considered a direct crosswalk to CPT code 45347, which has the same intraservice time and 8 additional minutes of total time, at a work RVU of 2.72.

We considered a work RVU of 2.53 for CPT code 31646, crosswalking to CPT code 31622 (Dx bronchoscope/wash). The RUC recommendation for CPT code 31646 indicated that the code was comparable to CPT code 31622, since they share the same intraservice time and similar total time, and that the recommended work RVU of 2.78 for CPT code 31646 was equal to the work RVU of CPT code 31622 before the CY 2017 changes to reporting of moderate sedation. We agreed with the survey participants that these two codes are comparable to one another, but had concerns about valuation of CPT code 31646 using a cross reference to a code that included moderate sedation. We considered crosswalking CPT code 31646 using the current CY 2017 valuation for CPT code 31622 (a work RVU of 2.53).

For the direct PE inputs, we proposed to remove the oxygen gas (SD084) from CPT code 31645. This supply is included in the separately billable moderate sedation codes, and we proposed to remove the oxygen gas as recommended by the RUC's PE Subcommittee as part of the removal of

oxygen from non-moderate sedation post-procedure monitoring codes. We also proposed to remove the equipment time for the IV infusion pump (EQ032) from CPT code 31645. We did not agree that there would typically be a need for a separate infusion pump in CPT code 31645, as the infusion pump is contained in the separately reportable moderate sedation codes. We also proposed to remove the equipment time for the CO2 respiratory profile monitor (EQ004) and the mobile instrument table (EF027) from CPT code 31645. These equipment items are not contained in the current composition of the code, and there was no rationale provided in the RUC recommendations for their inclusion. As a result, we did not believe that their use would be typical for CPT code 31645.

We proposed to increase the equipment time for the flexible bronchoscopy fiberscope (ES017) for CPT code 31645 consistent with standard equipment times for scopes. We also proposed to increase the equipment time for the Gomco suction machine (EQ235) and the power table (EF031) consistent with standard equipment times for non-highly technical equipment. For CY 2018, we proposed the RUC-recommended work RVUs for both codes in this family and sought comment on whether we should finalize refined values consistent with the implementation of separately billable codes for moderate sedation.

Comment: Several commenters supported the proposed values for both of the codes but disagreed with the alternative values.

Response: We continue to welcome information from all interested parties regarding valuation of services for consideration through our rulemaking process. We will continue to consider alternative work RVUs as we propose the valuation of services for future notice and comment rulemaking.

Comment: One commenter disagreed with our proposal to remove the oxygen gas (SD084) and the equipment time for the CO2 respiratory profile monitor (EQ004) from CPT code 31645. The commenter stated that although the separately reported moderate sedation codes do include some oxygen, the new codes fail to include enough oxygen for the entire procedure, and there would be an unacceptable risk to the patient population if insufficient quantities of oxygen were allotted for this service. The commenter indicated that the use of these direct PE inputs was the standard of care for bronchoscopies.

Response: After reviewing the information supplied by the commenter, we agree that the removal of these two direct PE inputs from CPT code 31645 could create a risk for the patient population. Therefore, we are finalizing the inclusion of 175 liters of oxygen gas and 58 minutes of equipment time for the CO2 respiratory profile monitor for CPT code 31645.

After consideration of comments received, for CY 2018, we are finalizing the work RVUs and direct PE inputs for the codes in the bronchial aspiration of tracheobronchial tree family as proposed, with the exception of the proposed removal of the oxygen gas and CO2 respiratory profile monitor as detailed above.

(11) Cryoablation of Pulmonary Tumor (CPT Codes 32998 and 32994)

For CY 2018, the CPT Editorial Panel modified the descriptor for CPT code 32998 (Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; radiofrequency) to include imaging guidance. In addition, the panel deleted Category III CPT Code 0304T and replaced it with a new CPT code 32994, to describe ablation therapy for reduction of pulmonary tumor using cryoablation with imaging guidance. In the CY 2018 PFS proposed rule, we proposed the RUC-recommended work RVUs for CPT codes 32998 (a work RVU of 9.03) and 32994 (a work RVU of 9.03).

However, we expressed concerns about the descriptions of the codes and the recommended valuations assuming that imaging guidance is inherent to the procedure. Based on our analysis of claims data from 2014, existing CPT code 32998 is currently reported with one of the three imaging guidance codes (CPT codes 76940, 77013, or 77022) less than 50 percent of the time. We sought comment on whether there is additional information that would help explain why the codes are being bundled despite what is reflected in the Medicare claims data. We considered a work RVU of 7.69 for CPT code 32998, that included approximately one half the value of the imaging guidance in the new codes that describe the work of both the procedure and the image guidance (that is, the sum of the current work RVU for CPT code 32998 and one-half of the work RVU for CPT code 77013 (the imaging guidance code most frequently billed with CPT code 32998 according to 2014 claims data)). We applied the same general rationale regarding the use of imaging guidance for new CPT code 32994. Since the RUC recommended identical work RVUs for these codes, we also considered a work RVU of 7.69 for CPT code 32994.

For CPT codes 32998 and 32994, we proposed to use the RUC-recommended direct PE inputs with standard refinements and sought comment on our proposed values.

Comment: Commenters generally supported the work RVUs for these codes, as proposed. Some commenters expressed concerns about our analysis of utilization data related to the bundling of imaging guidance services with ablation therapy. In addition, commenters disagreed with our refinement to times for several equipment items.

Response: We continue to remain interested in ensuring that, when two services are combined into a single CPT code, that they are furnished together so frequently that the resulting resource valuation is not inadvertently overestimating resource costs.

After consideration of the public comments, we are finalizing the work RVUs as proposed. With regard to the PE inputs, we note that we applied the standard formulas for equipment times, and we continue to believe that these refinements are reasonable for these codes. An explanation of the standards and formulas for equipment related to direct PE inputs is in the CY 2014 PFS final rule with comment period (79 FR 67557). We are also finalizing the direct PE inputs with standard refinements for these services, as proposed.

(12) Artificial Heart System Procedures (CPT Codes 33927, 33929, and 33928)

For CY 2018, the CPT Editorial Panel deleted Category III CPT Codes 0051T through 0053T and created CPT codes 33927 (Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy), 33929 (Removal of a total replacement heart system (artificial heart) for heart transplantation), and 33928 (Removal and replacement of total replacement heart system (artificial heart)) to report artificial heart system procedures. We proposed the RUC-recommended work RVU of 49.00 for CPT code 33927, and proposed to assign contractor-priced status to CPT codes 33929 and 33928, as recommended by the RUC. We considered assigning contractor-priced status for CPT code 33927. We had concerns regarding the accuracy of the RUC-recommended work valuation for CPT code 33927, due to its low utilization and the resulting difficulties in finding enough practitioners with direct experience of the procedure for the specialty societies to survey. We sought comment on the sufficiency of the survey data, especially since new

technologies and those with lower utilization are typically contractor-priced. For CY 2018, we proposed the RUC-recommended work RVUs for CPT code 33927. We sought comment on this alternative pricing for this CPT code 33927. We did not propose any direct PE inputs, as we did not receive RUC-recommended PE information for CPT codes 33927, 33929, and 33928. These three codes will be placed on the RUC's new technology list and will be re-reviewed by the RUC in 3 years.

Comment: Several commenters supported the proposed values for CPT code 33927 but disagreed with the alternative values.

Response: We continue to welcome information from all interested parties regarding valuation of services for consideration through our rulemaking process. We will continue to consider alternative work RVUs as we propose the valuation of services for future notice and comment rulemaking.

After consideration of comments received for CY 2018, we are finalizing the work RVU of 49.00 for CPT code 33927 and finalizing contractor-priced status for CPT codes 33929 and 33928 as proposed.

(13) Endovascular Repair Procedures (CPT Codes 34701, 34702, 34703, 34704, 34705, 34706, 34707, 34708, 34709, 34710, 34711, 34712, 34713, 34812, 34714, 34820, 34833, 34834, 34715, and 34716)

The CPT/RUC joint workgroup on codes recommended in October 2015 to bundle endovascular abdominal aortic aneurysm repair (EVAR) codes together with radiologic supervision and interpretation codes, since these codes were typically reported together at least 50 percent of the time. The CPT Editorial Panel bundled these services together in September 2016, creating 16 new codes, revising four existing codes, and deleting 14 other codes related to endovascular repair procedures.

We proposed the RUC-recommended work RVUs for all 20 codes in this family. We proposed work RVUs of 23.71 for CPT code 34701, 36.00 for CPT code 34702, 26.52 for CPT code 34703, 45.00 for CPT code 34704, 29.58 for CPT code 34705, 45.00 for CPT code 34706, 22.28 for CPT code 34707, 36.50 for CPT code 34708, 6.50 for CPT code 34709, 15.00 for CPT code 34710, 6.00 for CPT code 34711, 12.00 for CPT code 34712, 2.50 for CPT code 34713, 4.13 for CPT code 34812, 5.25 for CPT code 34714, 7.00 for CPT code 34820, 8.16 for CPT code 34833, 2.65 for CPT code 34834, 6.00 for CPT code 34715, and 7.19 for CPT code 34716. We also proposed the RUC-recommended direct PE inputs without refinement for all 20 codes in the family.

We considered a work RVU of 32.00 for CPT code 34702 based on the survey 25th percentile, and further supported with a crosswalk to CPT code 48000 (Placement of drains, peripancreatic, for acute pancreatitis), which has the same intraservice time of 120 minutes and a work RVU of 31.95. When we compared the RUC-recommended work RVU to similar codes valued under the PFS, we were unable to find any 90-day global services with 120 minutes of intraservice time and approximately 677 minutes of total time that had a work RVU greater than 36.00.

We considered a work RVU of 40.00 for CPT code 34704 based on the survey 25th percentile, crosswalking to CPT code 33534 (Coronary artery bypass, using arterial graft(s); 2 coronary arterial grafts) which has a work RVU of 39.88. CPT code 33534 has 193 minutes of intraservice time, but a lower total time of 717 minutes. When we compared the RUC-recommended work RVU for CPT code 34704 to similar codes paid under the PFS, we were unable to find any 90-day global services with 180 minutes of intraservice time and approximately 737 minutes of total time that had a work RVU greater than 45.00.

We considered a work RVU of 40.00 for CPT code 34706 based on the survey 25th percentile. CPT code 34706 has nearly identical time values to CPT code 34704, with 2 fewer minutes of intraservice time and total time, and the RUC-recommended work RVU was the same for both of these codes. The survey respondents also believed that these two codes had a comparable amount of work, as the survey 25th percentile work RVU was 40.00 for both codes.

We considered a work RVU of 30.00 for CPT code 34708 based on the survey 25th percentile and sought comment on whether a work RVU of 30.00 would improve relativity among the codes in this family. CPT code 34708 has identical intraservice and total times as CPT code 34702. However, we noted that the RUC-recommended work RVU of 36.50 for CPT code 34708 is higher than the RUC-recommended work RVU of 36.00 for CPT code 34702. This is the inverse of the relationship between CPT codes 34707 and 34701, which describe the same procedures in a non-emergent state when a rupture does not take place. CPT code 34707 has a RUC-recommended work RVU of 22.28, while CPT code 34701 has a RUC-recommended work RVU of 23.71. We sought comment on whether the RUC-recommended work RVUs would create a rank order anomaly within the family by reversing the relationship between these paired codes when performed in an emergent state. We noted that if CPT codes 34708 and 34702 were valued at the survey 25th percentile, this potential rank order anomaly disappears; in this scenario, we considered valuing CPT code 34708 at a work RVU of 30.00 and CPT code 34702 at a work RVU of 32.00. We sought comment on whether these alternative work values would improve relativity with the RUC-recommended work RVUs for CPT code 34707 (22.28) and CPT code 34701 (23.71), with an increment of approximately 1.50 to 2.00 RVUs between the two code pairs.

For the eight remaining codes that describe endovascular access procedures, we considered assignment of a 0-day global period, instead of the RUC-recommended add-on (ZZZ) global period and subsequently adding back the preservice and immediate postservice work time, and increasing the work RVU of each code accordingly using a building block methodology. We noted that as add-on procedures, these eight codes would not be subject to the multiple procedure payment discount. We were concerned that the total payment for these services will be increasing in the aggregate based on changes in coding that alter MPPR adjustments, despite the information in the surveys that reflects a decrease in the intraservice time required to perform the procedures, and a decrease in their overall intensity as compared to the current values.

We considered a work RVU of 3.95 for CPT code 34713, based on the RUC-recommended work RVU of 2.50 plus an additional 1.45 work RVUs. This additional work results from the addition of 38 total minutes of preservice work time and 30 minutes of postservice work time based on a crosswalk to CPT code 37224 (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty) as valued by using the building block methodology. Using the same method, we considered a work RVU of:

- 6.48 for CPT code 34812 based on maintaining the current 75 minutes of preservice work time and the current 30 minutes of postservice work time, with a total work RVU of 2.35, added to the RUC-recommended work RVU of 4.13;
- 7.53 for CPT code 34714 with the addition of 75 minutes of preservice work time and 27 minutes of postservice work time to match CPT code 34833;
- 9.46 for CPT code 34820 based on maintaining the current 80 minutes of preservice work time and the current 30 minutes of postservice work time;

• 10.44 for CPT code 34833 based on maintaining the current 75 minutes of preservice work time and the current 27 minutes of postservice work time;
• 5.00 for CPT code 34834 based on maintaining the current 70 minutes of preservice work time and the current 35 minutes of postservice work time;
• 8.35 for CPT code 34715 with the addition of 70 minutes of preservice work time and 35 minutes of postservice work time to match CPT code 34834; and
• 9.47 for CPT code 34716 with the addition of 75 minutes of preservice work time and 27 minutes of postservice work time to match CPT code 34833.

We proposed the RUC-recommended work RVUs and direct PE inputs for each code in this family and sought comment on whether our alternative values would be more appropriate.

Comment: Several commenters supported the proposed values for all 20 of the codes but disagreed with the alternative values.

Response: We continue to welcome information from all interested parties regarding valuation of services for consideration through our rulemaking process. We will continue to consider alternative work RVUs as we propose the valuation of services for future notice and comment rulemaking.

After consideration of comments received, for CY 2018, we are finalizing the work RVUs and direct PE inputs for the codes in the endovascular repair procedures family as proposed.

(14) Selective Catheter Placement (CPT Codes 36215, 36216, 36217, and 36218)

CPT code 36215 was identified as potentially misvalued on a screen of Harvard-valued codes with utilization over 30,000 in CY 2014, as well as on a screen of high expenditure services across specialties with Medicare allowed charges of over $10 million. CPT codes 36216, 36217, and 36218 were added to the family to be reviewed together with CPT code 36215.

We proposed the RUC-recommended work RVUs for each code in this family. We proposed work RVUs of 4.17 for CPT code 36215, 5.27 for CPT code 36216, 6.29 for CPT code 36217, and 1.01 for CPT code 36218.

We also considered refinements to the intraservice work time for CPT code 36217 from 60 minutes to 50 minutes, consistent with the RUC's usual use of the survey median intraservice work time. We had concerns that the use of the recommended survey 75th percentile intraservice work time will not be clinically appropriate for this code, as the 75th percentile time was identical for CPT codes 36216 and 36217, and therefore, the use of this value would not preserve the incremental, linear consistency between the work RVU and the intraservice time within the family.

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Post-procedure doppler evaluation (extremity)'' activity from 3 minutes to 1 minute for CPT codes 36215, 36216, and 36217. We believed that 1 minute would be more typical for this task, as the practitioner would be able to quickly evaluate if there was an issue with the extremity because there would be visual signs of arterial insufficiency resulting from the procedure.

We proposed to remove the equipment time for the mobile instrument table (EF027) from CPT codes 36215, 36216, and 36217. We believed that the mobile instrument table would be used for moderate sedation, which was removed from these procedures in CY 2017 (see the CY 2017 PFS final rule (81 FR 80339). While we recognized that 180 minutes of post-procedure monitoring time remains in these codes during which the stretcher (EF018), IV infusion pump (EQ032), and 3-channel ECG (EQ011) would remain in use, we did not agree that the mobile instrument table would typically be in use during this period of monitoring. As a result, we proposed to remove this equipment time from these three codes.

While we remained concerned about the use of the survey 75th percentile intraservice work time for CPT code 36217, for CY 2018, we proposed the RUC-recommended work RVUs for each code in this family and sought comment on whether our alternative values would be more appropriate.

Comment: Commenters supported the proposed values for all four of the codes but disagreed with the alternative values. We did not receive any comments specifically requesting the use of the alternative values for this family of codes.

Response: We appreciate the feedback from the commenters. We continue to welcome information from all interested parties regarding valuation of services for consideration through our rulemaking process. We will continue to consider alternative work RVUs as we propose the valuation of services for future notice and comment rulemaking.

Comment: Several commenters disagreed with the CMS proposal to refine the clinical labor time for the ''Post-procedure doppler evaluation (extremity)'' activity from 3 minutes to 1 minute for CPT codes 36215, 36216, and 36217. Commenters stated that CMS picked another time under the impression that clinical staff should be able to perform this task more quickly and that this was not a reason to change the recommended clinical labor time.

Response: The response from the commenters did not provide any rationale as to why a clinical labor time of 3 minutes would be typical for this activity. We continue to believe that 1 minute would be more typical for this task, as the practitioner would be able to quickly evaluate if there was an issue with the extremity via visual signs of arterial insufficiency.

Comment: Several commenters disagreed with the proposal to remove equipment time for the mobile instrument table (EF027) from CPT codes 36215, 36216, and 36217. Commenters stated that the office still needed the instrument table during the postoperative period, outside of moderate sedation, to house all of the monitoring items.

Response: While we appreciate the concerns raised by the commenters, we disagree. Storage equipment is a form of indirect PE that is not individually allocable to services and therefore is not separately payable. Our methodology incorporates the costs of non-medical infrastructure, such as cabinets and counter space, as part of the office rent expenses contained as part of indirect PE. Because the mobile instrument table is analogous to storage equipment in this particular circumstance, we continue to believe that it would be classified as a form of indirect PE and would not typically be in use during this period of monitoring.

After consideration of comments received, for CY 2018, we are finalizing the work RVUs and direct PE inputs for the codes in the selective catheter placement family as proposed.

(15) Treatment of Incompetent Veins (CPT Codes 36470, 36471, 36482, 36483, 36465, and 36466)

In September 2016, the CPT Editorial Panel created four new codes to describe the treatment of incompetent veins, and revised existing CPT codes 36470 and 36471. These six codes were reviewed together as part of the same family of procedures. For CY 2018, we proposed the RUC-recommended work RVU for all six codes. We proposed work RVUs of 0.75 for CPT code 36470, 1.50 for CPT code 36471, 3.50 for CPT code 36482, 1.75 for CPT code 36483, 2.35 for CPT code 36465, and 3.00 for CPT code 36466.

We considered a work RVU of 4.38 for CPT code 36482, which would have been based on the RUC-recommended work RVU of 3.50 plus half of the RUC-recommended work RVU of CPT code

36483. We also considered assigning CPT code 36483 a status indicator of ''bundled.'' The services that would be reported using CPT codes 36482 and 36483 in CY 2018 are currently reported with unlisted CPT code 37799 (Unlisted procedure, vascular surgery). We had concerns about how frequently the current services include treatment of an initial vein (CPT code 36482) as compared to the treatment of initial and subsequent veins (CPT codes 36482 and 36483 together). We believed it may be more accurate to describe these services through the use of a single code, as in the rest of this code family, instead of a base code and add-on code pair. Under this potential scenario, we looked at the RUC-recommended crosswalk and noted that the add-on CPT code 36483 was estimated to be billed 50 percent of the time together with CPT code 36482. We therefore considered adding half of the RUC-recommended work RVU of CPT code 36483 (0.88) to the RUC-recommended work RVU of CPT code 36482 (3.50), which would result in a work RVU of 4.38.

We proposed to remove the 2 minutes of clinical labor for the ''Setup scope'' (CA015) activity and add the same 2 minutes of clinical labor for the ''Prepare room, equipment and supplies'' (CA013) activity for CPT codes 36482, 36465, and 36466. The RUC-recommended materials stated that these 2 minutes were a proxy for setting up the ultrasound machine, and we believe that this 2 minutes was more accurately described by the ''Prepare room, equipment and supplies'' (CA013) activity code, since there is no scope equipment utilized in these procedures. We proposed to maintain the Vascular Tech (L054A) clinical labor type for these 2 minutes. We also proposed to refine the clinical labor for the ''Check dressings, catheters, wounds'' (CA029) activity for CPT codes 36470, 36471, 36482, 36465, and 36466, consistent with the standard times for this clinical labor activity.

We proposed to remove the six individual 4x4 sterile gauze (SG055) supplies and replace them with a 4x4 sterile gauze pack of 10 (SG056) for CPT codes 36470, 36471, 36482, 36465, and 36466. The pack of 10 sterile gauze is cheaper than six individual pieces of sterile gauze, and we did not agree that it would be typical to pay a higher cost for fewer supplies. We also proposed to create three new supply codes in response to the invoices submitted for this family of codes. We proposed to establish a price of $1,495 for the Venaseal glue (SD323) supply, a price of $3,195 for the Varithena foam (SD324) supply, and a price of $40 for the Varithena admin pack (SA125) supply.

We proposed to adjust the equipment times for the surgical light (EF014), the power table (EF031), and the portable ultrasound unit (EQ250) for CPT codes 36482, 36465, and 36466, consistent with the standards for non-highly technical equipment and to reflect the changes in the clinical labor described in this section of the final rule.

While we remained concerned about the creation of a base code and add-on code pairing (CPT codes 36482 and 36483) out of services that are currently reported using an unlisted code, for CY 2018, we proposed the RUC-recommended work RVUs for each code in this family and sought comment on whether our alternative values would be more appropriate.

Comment: Several commenters supported the proposed values for all six of the codes but disagreed with the alternative values.

Response: We appreciate the feedback from the commenters.

Comment: One commenter stated that they agreed with the direct PE refinements as proposed.

Response: We appreciate the support from the commenter.

After consideration of comments received, for CY 2018, we are finalizing the work RVUs and direct PE inputs for the codes in the treatment of incompetent veins family as proposed.

(16) Therapeutic Apheresis (CPT Codes 36511, 36512, 36513, 36514, 36516, and 36522)

CPT code 36516 was nominated as potentially misvalued in the CY 2016 PFS proposed rule. The CPT Editorial Panel deleted CPT code 36515 and made revisions to CPT code 36516 to include immunoabsorption. CPT codes 36511, 36512, 36513, 36514, and 36522 were added to CPT code 36516 to be reviewed together as part of the therapeutic apheresis family.

For CY 2018, we proposed the RUC-recommended work RVUs for all six codes in the family. We proposed work RVUs of 2.00 for CPT code 36511, 2.00 for CPT 36512, 2.00 for CPT code 36513, 1.81 for CPT code 36514, 1.56 for CPT code 36516, and 1.75 for CPT code 36522.

We proposed to use the RUC-recommended direct PE inputs for these codes without refinement. We considered refining the clinical labor time for the ''Prepare room, equipment, supplies'' activity from 20 minutes to 10 minutes for CPT codes 36514 and 36522, and from 30 minutes to 10 minutes for CPT code 36516. We also considered refining the clinical labor for the ''Prepare and position patient/monitor patient/set up IV'' activity from 15 minutes to 10 minutes for these same three codes. In both cases, we considered maintaining the current clinical labor time for CPT codes 36514 and 36516, and adjusting the clinical labor time for CPT code 36522 to match the other two codes in the family. We had concerns about the lack of a rationale provided for these changes in clinical labor time, and whether these clinical labor tasks would typically require this additional time.

We proposed the RUC-recommended work RVUs and to use the RUC-recommended direct PE inputs for each code in this family and sought comment on whether our alternative values would be more appropriate. We also sought comment on whether these procedures were creating a new point of venous access or utilizing a previously placed access.

Comment: Several commenters supported the proposed values for all six of the codes but disagreed with the alternative values.

Response: We continue to welcome information from all interested parties regarding valuation of services for consideration through our rulemaking process. We will continue to consider alternative work RVUs as we propose the valuation of services for future notice and comment rulemaking.

Comment: Several commenters stated that a cell separator system (EQ084) was mistakenly left out of the RUC's recommendation for CPT code 36516. The commenters stated that this particular equipment item is critical for all of the therapeutic apheresis services and that CPT code 36516 uses a piece of equipment (the Liposorber system) that attaches to this missing equipment item. The commenters recommended adding this piece of equipment (EQ084) to CPT code 36516 with 324 minutes of use.

Response: We disagree with the commenters. Based on the information that we currently have available, we do not believe that the cell separator system (EQ084) was mistakenly left out of the RUC recommendation for CPT code 36516. We note that the RUC did not include the cell separator system in its recommendations for this procedure, and also made no mention of an error in the recommended direct PE inputs for CPT code 36516 in its comments on the CY 2018 PFS proposed rule. We are also confused by the statement from one commenter that the cell separator system is critical for all of the therapeutic apheresis services, since this equipment item is not included in the current direct PE inputs for CPT

code 36516, nor was it recommended for CPT code 36522 in the same family. We welcome additional feedback from stakeholders regarding whether the use of the cell separator system is typical in CPT code 36516.

Comment: Many commenters responded to the request for additional information regarding whether these procedures were creating a new point of venous access or utilizing a previously placed access point. Commenters agreed that both of the vignettes for these services, as well as the descriptions of work, stated that the typical patient has a previously placed venous access that is then utilized. While in some cases, a revision to the access site may need to be made, or initial access achieved, these cases were not representative of the typical patient scenario. There was widespread agreement from the commenters on the utilization of a previously placed access point in these services.

Response: We appreciate the feedback from the commenters in clarifying the clinical details surrounding the point of venous access.

After consideration of comments received, for CY 2018, we are finalizing the work RVUs and direct PE inputs for the codes in the therapeutic apheresis family as proposed.

(17) Insertion of Catheter (CPT Codes 36555, 36556, 36620, and 93503)

CPT code 36556 was identified as part of a screen of high expenditure services with Medicare allowed charges of $10 million or more that had not been recently reviewed. CPT codes 36555, 36620, and 93503 were added for review by the RUC as part of the code family. We proposed the RUC-recommended work RVUs for each code in this family. We proposed work RVUs of 1.93 for CPT code 36555, 1.75 for CPT code 36556, 1.00 for CPT code 36620, and 2.00 for CPT code 93503.

We proposed to remove the clinical labor time for the ''Monitor pt. following procedure'' activity and the equipment time for the 3-channel ECG (EQ011) for CPT code 36555. CPT code 36555 no longer includes moderate sedation as part of the procedure (see the CY 2017 PFS final rule (81 FR 80339). We proposed to remove the direct PE inputs related to moderate sedation from CPT code 36555 as they would now be included in the separately reported moderate sedation services. We also proposed to refine the equipment times for the exam table (EF023) and the exam light (EQ168) to reflect changes in the clinical labor time.

Comment: Several commenters requested that CMS not finalize its proposal to accept the RUC's recommendations for CPT codes 36555, 36556, 36620 and 93503 and instead finalize higher work RVUs that the specialty had provided to the RUC. The commenters stated that these work RVUs maintained relativity within the resource-based relative value scale (RBRVS) range of services and represented a more accurate valuation of these procedures. One commenter stated that the RUC-recommended work RVUs create a rank order anomaly in the intensity of the services in this family of codes.

Response: As we stated in the background of this code valuation section, we generally proposed RUC-recommended work RVUs for new, revised, and potentially misvalued codes for CY 2018. We believe that in the absence of other data regarding the appropriate valuation of these codes, the RUC-recommended work RVUs represent the most accurate valuation of the procedures. We continue to be open to reviewing additional and supplemental sources of data furnished by stakeholders. We encourage stakeholders to continue to provide such information for consideration in establishing work RVUs.

Comment: Several commenters disagreed with the proposal to remove the direct PE inputs related to moderate sedation from CPT code 36555. The commenters stated that any PE refinement necessary to address separate reporting of moderate sedation would have already taken place, so no further refinement to PE as it relates to this change should be necessary. Another commenter indicated agreement with the proposed direct PE refinements.

Response: We appreciate the support from the commenter for our proposed direct PE refinements. Regarding the other comments, we continue to believe that further refinements are needed to address the separate reporting of moderate sedation. CPT code 36555 does not currently contain any clinical labor for post procedure clinical labor monitoring related to moderate sedation; however, 7.5 minutes of monitoring time was added back into the procedure as part of the RUC-recommended direct PE inputs for CY 2018. Since this clinical labor for the monitoring time would be included in the separately reported moderate sedation code, we believe that it would be duplicative to include the same monitoring clinical labor time, or the equipment time for the 3-channel ECG, in CPT code 36555.

After consideration of comments received, for CY 2018, we are finalizing the work RVUs and direct PE inputs for the codes in the insertion of catheter family as proposed.

(18) Insertion of PICC Catheter (CPT Code 36569)

CPT code 36569 was identified as part of a screen of high expenditure services with Medicare allowed charges of $10 million or more that had not been recently reviewed. For CY 2018, we proposed the RUC-recommended work RVU of 1.70 for CPT code 36569.

We proposed to remove the equipment time for the exam table (EF023), as this equipment item is a component part of the radiographic-fluoroscopic room (EL014) included in CPT code 77001 (Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal). Because CPT code 36569 is typically billed together with CPT code 77001, we believed that including the additional equipment time for the exam table in CPT code 36569 would be duplicative.

Comment: Several commenters disagreed with the proposal to remove the equipment time for the exam table (EF023). Commenters stated that CMS' rationale for removing the exam table, that it is a component part of the radiographic-fluoroscopic room (EL014), was incorrect. Commenters pointed out that the radiographic-fluoroscopic room only includes a radiographic machine and camera, and requested that the exam table should be reinstated consistent with the RUC's recommendation.

Response: We appreciate the clarification regarding the contents of the radiographic-fluoroscopic room from the commenters. After reviewing the room's contents, we agree with the commenters that the radiographic-fluoroscopic room only includes a radiographic machine and camera. While we believe that the radiographic machine likely incorporates an exam table on which to place the patient, we concede that this is not specifically stated in the documentation for the radiographic-fluoroscopic room from the commenters. As a result, we are not finalizing our proposal to remove the equipment time for the exam table. We are restoring the exam table to CPT code 36569 at an equipment time of 32 minutes in accordance with our standard formula for non-highly technical equipment time.

After consideration of comments received, for CY 2018, we are finalizing the work RVUs and direct PE inputs for the codes for CPT code 36569 as proposed, with the exception of the

change for the exam table as detailed above.

(19) Bone Marrow Aspiration (CPT Codes 38220, 38221, 38222, and 20939)

CPT code 38221 was identified as part of a screen of high expenditure services with Medicare allowed charges of $10 million or more that had not been recently reviewed. The descriptors for CPT codes 38220 and 38221 were revised to reflect changes in practice patterns, and two new CPT codes (38222 and 20939) were created to more accurately describe new services that are now available. For CY 2018, we proposed the RUC-recommended work RVUs for each code in this family. We proposed a work RVU of 1.20 for CPT code 38220, 1.28 for CPT code 38221, 1.44 for CPT code 38222, and 1.16 for CPT code 20939.

We also received a recommendation from the RUC to change the global periods for CPT codes 38220, 38221, and 38222 from XXX global periods to 0-day global periods, even though these codes were surveyed under the XXX global period. We agreed with the recommendation that for these three particular codes, their services were more accurately described when assigned 0-day global periods as opposed to the XXX global status. Therefore, we proposed to assign a 0-day global period to all three codes in this family. We noted, however, that we believed that global period changes must be addressed on an individual basis, especially when the routine survey methodologies rely on assumptions regarding global periods for particular codes. Subsequently, we proposed to refine the preservice work time from 15 minutes of evaluation time to 9 minutes of evaluation time, 1 minute of positioning time, and 5 minutes of scrub, dress, and wait time. We proposed these refinements to the work times for these three codes to more closely align with the preservice times of other recently reviewed 0-day global procedures, such as CPT code 30903 (Control nasal hemorrhage, anterior, complex (extensive cautery and/or packing) any method). We also noted that given our proposal to value CPT code 38222, we proposed to eliminate payment using HCPCS code G0364 for CY 2018 since the changes to the set of CPT codes will now accurately describe the services currently reported by HCPCS code G0364. For CPT code 20939, we considered a work RVU of 1.00 based on a direct crosswalk to CPT codes 64494 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level) and 64495 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s)). CPT code 20939 is a global ZZZ add-on code for CPT code 38220, and we were concerned with maintaining relativity among PFS services, considering that an add-on code typically has significantly less intraservice time and total time compared to the base code. We considered an alternative crosswalk to CPT codes 64494 and 64495, which share the same intraservice and total time with CPT code 20939 and have work RVUs of 1.00.

We also proposed to refine the clinical labor for ''Lab Tech activities'' from 12 minutes to 9 minutes for CPT code 38220, from 7.5 minutes to 7 minutes for CPT code 38221, and from 12.5 minutes to 10 minutes for CPT code 38222. We maintained the current time value for the two existing codes, as we had no reason to believe that the typical duration has increased for these lab activities. We assigned 10 minutes for CPT code 38222 based on the statement in the RUC-recommended materials for the direct PE inputs that this activity takes 0.5 minutes longer than it does in the current version of CPT code 38220. We also proposed to remove the breakout lines for the lab activities. We believe that the breakout of activities into numerous subactivities generally tends to inflate the total time assigned to clinical labor activities and results in values that are not consistent with the analogous times for other PFS services.

We considered refining the clinical labor time for ''Provide preservice education/obtain consent'' for CPT codes 38220, 38221, and 38222 from 12 minutes to 6 minutes. We had concerns regarding whether 12 minutes would be typical for education and consent prior to these procedures, as much of the patient education takes place following the procedure, in the clinical labor activity described under the ''Check dressings & wound/home care instructions'' heading. We proposed the RUC-recommended work RVUs for each code in this family and sought comment on whether our alternative values would be more appropriate.

Comment: Several commenters agreed with the proposal to change the global period for CPT codes 38220, 38221, and 38222 from XXX global periods to 0-day global periods. These commenters also supported the proposed change to the preservice work times to more closely align with the preservice times of other recently reviewed 0-day global procedures.

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

Comment: Other commenters disagreed with the proposed change in global period. Commenters stated that maintaining these codes as XXX globals was consistent with the survey methodology used to generate the RUC-recommended work RVUs, as these codes were surveyed under the XXX global period. The commenters stated that these codes are billed less than 25 percent of the time with an E/M service, and that since an E/M service being performed on the same day is not typical, there was not a compelling reason to change the global period.

Response: We appreciate the additional responses from commenters requesting that the XXX global period should be retained for these three CPT codes. As these codes were surveyed and valued under XXX global status and the RUC has maintained that there is a need to resurvey when the global period changes, we will not finalize our proposal to change CPT codes 38220, 38221, and 38222 from XXX global periods to 0-day global periods. In the absence of compelling evidence that the 0-day global status would be more typical for these services, we believe that the current XXX global period should be maintained. We will also not finalize our related proposal to refine the preservice work time from 15 minutes of evaluation time to 9 minutes of evaluation time, 1 minute of positioning time, and 5 minutes of scrub, dress, and wait time. We welcome additional feedback from stakeholders regarding the global period that should be assigned to these codes.

Comment: Several commenters supported the proposed values for all four of the codes but disagreed with the alternative values.

Response: We continue to welcome information from all interested parties regarding valuation of services for consideration through our rulemaking process. We will continue to consider alternative work RVUs as we propose the valuation of services for future notice and comment rulemaking.

Comment: Several commenters disagreed with the proposal to refine the clinical labor for ''Lab Tech activities'' in CPT codes 38220, 38221, and 38222. Commenters stated that each CPT code is unique and the recommended clinical labor reflects the typical time of those activities associated with each service. Commenters also disagreed with the proposal to remove the breakout lines for the lab activities, stating that the

methodology at the time of review was to provide as much detail as possible and that just because these subactivities were fully displayed did not mean that they had been double counted. Several of the commenters supplied clinical information describing the activities that took place in additional detail.

Response: We appreciate the additional information supplied by the commenters. We agree with the commenters that each service is unique and must be valued on an individual basis. We also agree that the lab activities taking place in these services are important and that they must be performed. Our concern is that the individual accounting of clinical labor activities can lead to PE proliferation, and that this breakout of activities into numerous subactivities generally tends to inflate the total time assigned to clinical labor activities and results in values that are not consistent with the analogous times for other PFS services. In the case of these codes, we believe that maintaining the current clinical labor times as proposed will better serve the purposes of ensuring relativity. We will continue to look for additional information related to the clinical labor assigned to lab activities, and we welcome additional feedback from stakeholders.

After consideration of comments received, for CY 2018, we are finalizing the work RVUs and direct PE inputs for the codes in the bone marrow aspiration family as proposed. We are not finalizing the proposal to change CPT codes 38220, 38221, and 38222 from XXX global periods to 0-day global periods, and we are not finalizing the related proposal to refine the preservice work time from 15 minutes of evaluation time to 9 minutes of evaluation time, 1 minute of positioning time, and 5 minutes of scrub, dress, and wait time for these three codes.

(20) Esophagectomy (CPT Codes 43107, 43112, 43117, 43286, 43287, and 43288)

CPT codes 43286, 43287, and 43288 were created by the CPT Editorial Panel to report esophagectomy via laparoscopic and thoracoscopic approaches. CPT codes 43107, 43112, and 43117 were also reviewed as part of the family with the three new codes. CPT code 43112 was revised to clarify the nature of the service being performed. We proposed the RUC-recommended work RVUs for all six codes in the family. We proposed work RVUs of 52.05 for CPT code 43107, 62.00 for CPT code 43112, 57.50 for CPT code 43117, 55.00 for CPT code 43286, 63.00 for CPT code 43287, and 66.42 for CPT code 43288.

We also proposed the RUC-recommended work times for all six codes in this family. We considered removing 20 minutes from the preservice evaluation work time from all six of the codes in this family. We had concerns as to whether this additional evaluation time should be included for surgical procedures, due to the lack of evidence indicating that it takes longer to review outside imaging and lab reports for surgical services than for non-surgical services. We also considered refining the preservice positioning work time and the immediate postservice work time for all six of the codes in this family consistent with standard preservice and postservice work times allocated to other PFS services.

We had concerns about the presence of two separate surveys conducted for the three new CPT codes. We noted that CPT codes 43286, 43287, and 43288 were surveyed initially in January 2016, and then were surveyed again in October 2016 together with CPT codes 43107, 43112, and 43117 due to concerns about the description of the typical patient in the original vignette and a change in the codes on the reference service list (RSL). We noted that CPT codes 43286 and 43287 had the same median intraservice time on both surveys, while CPT code 43288 had a median intraservice time that was an hour longer on its second survey (420 minutes) as compared to its first survey (360 minutes). We also noted that the total survey time for CPT code 43286 decreased from 1,058 minutes in the first survey to 972 minutes in the second survey, while the median work RVU increased from 50.00 to 65.00. We did not understand how the survey median intraservice time could increase so significantly from the first survey to the second survey for CPT code 43288, or how the surveyed times for CPT code 43286 could be decreasing while the work RVU was simultaneously increasing by 15.00 work RVUs.

Based on our analysis, it appeared that the accompanying RSL was the main difference between the two surveys; the codes on the initial RSL had a median work RVU of 44.18, while the codes on the second RSL had a median work RVU of 59.64. This increase of 15.00 work RVUs between the two RSLs that accompanied the surveys appeared to account for the increase in the work RVUs for the three new codes. We were concerned that the second survey may have overestimated the work required to perform these procedures, as the 25th percentile work RVU of the second survey was higher than the median work RVU of the initial survey for all three codes, despite no change in the median intraservice work time for CPT codes 43286 and 43287.

Given these concerns, we considered a work RVU of 50.00 for CPT code 43286, a work RVU of 60.00 for CPT code 43287, and a work RVU of 61.00 for CPT code 43288, by using the survey median work RVU from the first survey for the three new codes. For CPT codes 43107 and 43117, we considered employing the intraservice time ratio between the laparoscopic version of the procedure represented by the new code and the open version of the same procedure represented by the existing code.

We considered a work RVU of 45.00 for CPT code 43107 based on the intraservice time ratio with CPT code 43286 and a work RVU of 55.00 for CPT code 43117 based on the intraservice time ratio with CPT code 43287. CPT code 43107 has 270 minutes of intraservice time as compared with 300 minutes of intraservice time for CPT code 43286, which produces a ratio of 0.9, and when multiplied by a work RVU of 50.00 (CPT code 43286), results in the proposed work RVU of 45.00. We considered using the same methodology for CPT codes 43117 and 43287.

Finally, we considered a work RVU of 58.94 for CPT code 43112 based on a direct crosswalk to CPT code 46744 (Repair of cloacal anomaly by anorectovaginoplasty and urethroplasty, sacroperineal approach). We noted that the intraservice time ratio when applied to CPT codes 43112 and 43288, the paired McKeown esophagectomy procedures, would have produced a potential work RVU of 52.29, creating a rank order anomaly within the family by establishing a higher work RVU for CPT code 43117 than CPT code 43112, and we were concerned with whether this was an appropriate valuation for the code.

We sought comment on whether the alternative work RVUs that we considered might reflect the relative difference in work more accurately between the six codes in the family. We noted, for example, that these valuations corrected the rank order anomaly between CPT codes 43112 and 43121 as noted in the RUC recommendations.

We proposed the RUC-recommended direct PE inputs for all six codes in the family without refinement. We considered changing the preservice clinical labor type for all six codes from an RN (L051) to an RN/LPN/MTA blend (L037D). We had concerns about whether the use of RN clinical labor would be typical for filling out referral forms or for scheduling space and equipment in the facility. We also

considered removing the additional clinical labor time for the ''Additional coordination between multiple specialties for complex procedures (*e.g.*, tests, meds, scheduling)'' activity, consistent with preservice standards for codes with 90-day global periods. We were concerned that this time would not typically be included in non-surgical procedures performed by other specialties even when additional coordination is required. We sought comment regarding the changes in the valuation between the two surveys, the preservice and immediate postservice work times, and the RN staffing type employed for routine preservice clinical labor.

Comment: Several commenters supported the proposed values for all six of the codes but disagreed with the alternative values.

Response: We continue to welcome information from all interested parties regarding valuation of services for consideration through our rulemaking process. We will continue to consider alternative work RVUs as we propose the valuation of services for future notice and comment rulemaking.

After consideration of comments received, for CY 2018, we are finalizing the work RVUs and direct PE inputs for the codes in the esophagectomy family as proposed.

(21) Transurethral Electrosurgical Resection of Prostate (CPT Code 52601)

CPT code 52601 appeared on a screen of potentially misvalued codes, which indicated that it was performed less than 50 percent of the time in the inpatient setting, yet included inpatient hospital E/M services within the global period. For CY 2018, we proposed the RUC-recommended work RVU of 13.16 for CPT code 52601 and proposed to use the RUC-recommended direct PE inputs without refinements.

We considered a work RVU of 12.29 for CPT code 52601 based on a direct crosswalk to CPT code 58541 (Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less), which is one of the reference codes. CPT code 58541 may potentially be a more accurate crosswalk for CPT code 52601 than the RUC-recommended direct crosswalk to CPT code 29828 (Arthroscopy, shoulder, surgical; biceps tenodesis). Although all three of these codes share the same intraservice time of 75 minutes, CPT code 58541 is a closer match in terms of the total time at only 10 minutes difference. CPT code 58541 also shares the same postoperative office visits as CPT code 52601, a pair of CPT code 99213 office visits, while CPT code 29828 also contains two CPT code 99212 office visits that are not present in the reviewed code.

We noted that if we were to use a reverse building block methodology for CPT code 52601 and subtract out the value of the E/M visits being removed, the proposed work RVU would be 11.21. We did not propose this work RVU; however, because as we noted in the CY 2017 PFS final rule (81 FR 80274), we agree that the per-minute intensity of work is not necessarily static over time or even necessarily during the course of a procedure. Instead, we utilize time ratios and building block methodologies to identify potential values that account for changes in time and compare these values to other PFS services for estimates of overall work. When the values we develop reflect a similar derived intensity, we agree that our values are the result of our assessment that the relative intensity of a given service has remained similar. For CPT code 52601, we were concerned about how the RUC-recommended derived intensity of the procedure could be increasing by 30 percent over the current derived intensity, while at the same time the typical site of service was changing from inpatient to outpatient status. In other words, if it was now typical for CPT code 52601 to be performed on an outpatient basis, then we would generally expect the intensity of the procedure to be decreasing, not increasing. We considered a work RVU of 12.29 for CPT code 52601 based on a direct crosswalk to CPT code 58541 (Lsh uterus 250 g or less), and sought comment on whether this alternative value might better reflect relativity.

Comment: Several commenters supported the proposed values for CPT code 52601 but disagreed with the alternative values.

Response: We appreciate the feedback from the commenters. We continue to welcome information from all interested parties regarding valuation of services for consideration through our rulemaking process.

After consideration of comments received, for CY 2018, we are finalizing the work RVUs and direct PE inputs for CPT code 52601 as proposed.

(22) Peri-Prostatic Implantation of Biodegradable Material (CPT Code 55874)

In October 2016, the CPT Editorial Panel deleted CPT Category III code 0438T and created a new CPT code 55874 (Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed). For CY 2018, we proposed the RUC-recommended work RVU of 3.03 for CPT code 55874.

In reviewing the RUC recommendations, we noted a decrease in preservice time (30 minutes) compared to the current value. In order to account for this change in time, we considered calculating the intraservice time ratio between the key reference code (CPT code 49411), which has an intraservice time of 40 minutes, and the RUC-recommended intraservice time (30 minutes) and multiplying that by the work RVU for CPT code 49411 (3.57), which would have resulted in a work RVU of 2.68. A work RVU of 2.68 would have been further supported by a bracket of two crosswalk codes, CPT code 65779 (Placement of amniotic membrane on the ocular surface; single layer, sutured), which has a work RVU of 2.50 and CPT code 43252 (Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy), which has a work RVU of 2.96. Compared with CPT code 55874, these codes have identical intraservice and similar total times. We sought comment on whether these alternative values should be considered, especially given the changes in time reflected in the survey data.

We received invoices with pricing information regarding two new supply items: ''endocavity balloon'' and ''biodegradeable material kit—periprostatic.'' The invoice for the endocavity balloon was $399.00 and the input price on the PE spreadsheet for this supply item was noted as such. We believed that the input price noted on the PE spreadsheet was an error, given that the invoice noted that the price of $399.00 was for a box of ten and the specialty society requested a single unit of this supply item. Therefore, we proposed to use this information to propose for supply item ''endocavity balloon'' a price of $39.90. The invoice for the ''biodegradeable material kit—periprostatic'' totaled $2,850.00. We proposed to use this information to propose for the supply item ''biodegradeable material kit—periprostatic'' a price of $2850.00. We also received an invoice with pricing information regarding the new equipment item ''endocavitary US probe'' which totaled $16,146.00. We proposed to use this information to propose for equipment item ''endocavitary US probe'', a per-minute price of $0.0639. We questioned, given an invoice price of $29,999.00 for this existing equipment item EQ250 (portable ultrasound unit), whether this equipment item includes probes. We sought public comments related to

whether equipment item EQ250 (portable ultrasound) includes probes.

Comment: In general, commenters were supportive of our proposal of the RUC-recommended work RVUs. Some commenters expressed opposition to the alternative work RVUs we considered.

Response: We are appreciative of the commenters' feedback. We continue to welcome information from all interested parties regarding valuation of services for consideration through our rulemaking process. We will continue to consider alternative work RVUs as we propose the valuation of services for future notice and comment rulemaking.

Comment: The RUC stated that CMS acknowledges that physician work intensity per minute is not typically linear and also that making reductions to RVUs in strict proportion to changes in time is inappropriate. The RUC further noted that for several comment periods they have laid out a compelling case to justify this position on work intensity per minute. They noted that they appreciate CMS's agreeing with the RUC's assertion that the usage of time ratios to reduce work RVUs is typically not appropriate, as often a change in the work time coincides with a change in the work intensity per minute.

Response: We do not agree with the commenter's characterization of our statements. We stated in the CY 2017 PFS final rule (81 FR 80273) that we are not implying that the decrease in time as reflected in survey values must necessarily equate to a one-to-one or linear decrease in newly valued work RVUs, given that intensity for any given procedure may change over several years or within the intraservice period. Nevertheless, 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 specifically increased or that the reduction in time is disproportionally from less intensive portions of the procedure, significant decreases in time should generally be reflected in decreases to work RVUs.

Comment: The RUC noted that they wanted to remind CMS of its and the RUC's longstanding position that treating all components of physician time as having identical intensity is incorrect, and inconsistently applying this treatment to only certain services under review creates inherent payment disparities in a payment system that is based on relative valuation. The commenter stated that when physician times are updated in the fee schedule, the ratio of intraservice time to total time, the number and level of bundled post-operative visits, the length of pre-service, and the length of immediate post-service time may all potentially change for the same service. These changing components of physician time result in the physician work intensity per minute often changing when physician time also changes, and the commenters recommended that CMS always account for these nuanced variables. The RUC highlighted that their recommendations now explicitly state when physician time has changed and address whether and to what magnitude these changes in time impact the work involved.

Response: We stated in the CY 2017 PFS final rule (81 FR 80275) that we understand that not all components of physician time have identical intensity and are mindful of this point when determining what the appropriate work RVU values should be. We agree that the nuanced variables involved in the changing components of physician time must be accounted for, and it is our goal to do so when determining the appropriate valuation. We appreciate when the RUC recommendations provide as much detailed information regarding the recommended valuations as possible, including thorough discussions regarding physician time changes and how the RUC believes such changes should or should not impact the work involved, and we consider that information when conducting our review of each code.

Comment: The RUC noted that its support of the proposed refinements for EF031, EQ250, EQ386, ER061, ER062, and L037D, was contingent on the assumption that the proposed PE refinements were because of the change in time for the clinical labor task, ''Obtain vital signs''.

Response: The proposed PE refinements for EF031, EQ250, EQ386, ER061, ER062, L037D, are a result of our proposal to refine the L037D clinical labor time for ''Obtain vital signs'' from 3 minutes to 5 minutes, to conform to the proposed standard for this clinical labor activity. As a result, we proposed to refine the equipment times for the power table (EF031) from 63 minute to 65 minutes and from 48 minutes to 50 minutes for the following: Portable ultrasound unit (EQ250), endocavitary US probe (EQ386), stepper stabilizer, template (for brachytherapy treatment) (ER061), and stirrups (for brachytherapy table) (ER062) to reflect the service period time associated with this code.

Comment: Several commenters, including the RUC, were supportive of our proposed price updates for the ''endocavity balloon'' (SD325), biodegradeable material kit—periprostatic'' (SA126), and ''endocavitary US probe'' (EQ386) and urged CMS to finalize the proposal.

Response: We appreciate the support from commenters.

After consideration of comments received, we are finalizing the following supply and equipment prices: SD325, at a price of $39.90; SA126, at a price of $2850.00; and EQ386, at a price of $16,146.00 (a per-minute price of $0.0639).

Comment: Several commenters, including the RUC, noted that ''portable ultrasound unit'' (EQ250), which has a cost of $29,999.00, does not include an intracavitary probe. These commenters further noted that the probe is necessary to perform this procedure and recommended that both the portable unit and the intracavitary probe be recognized as direct PE inputs for this service. One commenter included pricing information in its comment letter, noting that the probe should be added as an additional direct PE input at a cost of $20,700.

Response: While we appreciate the submission of this pricing information from the commenter, we are unable to consider this pricing information for the CY 2018 final rule without documentation of invoices. We request that commenters submit invoices for pricing updates and that the invoices contain clear documentation regarding the item in question: Its name, the CMS supply/equipment code that it references (if any), the unit quantity if the item is shipped in boxes or batches, and any other information relevant for pricing. To be considered for a given year's proposed rule, we generally need to receive invoices by February. In similar fashion, we generally need to receive invoices by the end of the comment period for the proposed rule in order to consider them for the supply and equipment pricing for the final rule for that calendar year. We note that both the ''endocavitary US probe'' (EQ386) and ''portable ultrasound unit'' (EQ250) are included in the PE inputs for this service, which are displayed in the CY 2018 PFS final rule direct PE input database, available on the CMS Web site under the downloads for the CY 2018 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

After consideration of comments received, we are finalizing the work RVUs and direct PE inputs for CPT code 55874 as proposed.

(23) Colporrhaphy With Cystourethroscopy (CPT Codes 57240, 57250, 57260 and 57265)

In October 2015, CPT code 57240 was identified by analysis of the Medicare data from 2011–2013 that indicated that services reported with CPT code 57240 were performed less than 50 percent of the time in the inpatient setting, yet include inpatient hospital E/M services within the global period. The RUC recommended that CPT codes 57240 (Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele), 57250 (Posterior colporrhaphy, repair of rectocele with or without perineorrhaphy), 57260 (Combined anteroposterior colporrhaphy), and 57265 (Combined anteroposterior colporrhaphy; with enterocele repair) be referred to the CPT Editorial Panel. In September 2016, the CPT Editorial Panel revised CPT codes 57240, 57260 and 57265 to preclude separate reporting of follow up cystourethroscopy after colporrhaphy (CPT code 52000).

For CY 2018, we proposed the RUC-recommended work RVUs for CPT code 57240 (a work RVU of 10.08), CPT code 57250 (a work RVU of 10.08), CPT code 57260 (a work RVU of 13.25), and CPT code 57265 (a work RVU of 15.00).

We note that there were changes in service times reflected in the specialty surveys compared to the RUC-recommended work RVUs for CPT code 57240. Specifically, we note that the RUC recommended a 48 minute decrease in total time, compared to the specialty survey total time of 259 minutes. The difference in total time reflected a decrease in preservice time (29 minutes) and inpatient visits (0.5 visits = 19 minutes). We considered a work RVU of 9.77 for CPT code 57240, crosswalking to CPT code 50590 (Lithotripsy, extracorporeal shock wave), which has similar service times. We sought comment on whether CPT code 57250 would be a relevant comparator for CPT code 57240, based on the described elements of each service and existing or surveyed service times, compared to CPT code 57240. We considered a work RVU of 11.47 for CPT code 57260 [we note that in the CY 2018 PFS proposed rule (82 FR 34000), this was cited as CPT code 57265], crosswalking to CPT code 47563 (Laparoscopy, surgical; cholecystectomy with cholangiography) with similar service times. We sought comment on how an alternative work RVU of 11.47 for CPT code 57260 [we note that in the CY 2018 PFS proposed rule (82 FR 34000), this was cited as CPT code 57260] would affect relativity among PFS services, and on whether CPT code 57265 [we note that in the CY 2018 PFS proposed rule (82 FR 34000), this was cited as CPT code 57260] is a relevant comparator for CPT code 57260 [we note that in the CY 2018 PFS proposed rule (82 FR 34000), this was cited as CPT code 57265], considering differences in the described procedures and service times.

We proposed the RUC-recommended direct PE inputs for CPT codes 57240, 57250, 57260 and 57265 without refinements.

Comment: In general, commenters were supportive of our proposal of the RUC-recommended work RVUs. We continue to welcome information from all interested parties regarding valuation of services for consideration through our rulemaking process. Some expressed opposition to the alternative work RVUs we considered.

Response: We will continue to consider alternative work RVUs as we propose the valuation of services for future notice and comment rulemaking.

After consideration of comments received, we are finalizing the work RVUs as proposed. We are finalizing the proposed direct PE inputs for CPT codes 57240, 57250, 57260 and 57265, without refinement.

(24) Injection of Anesthetic Agent (CPT Code 64418)

CPT code 64418 (Injection, anesthetic agent; suprascapular nerve) was identified by the AMA through their screen of Harvard-valued codes with utilization over 30,000. We proposed the RUC-recommended work RVU of 1.10 and RUC-recommended direct PE inputs without refinement.

Comment: We received one comment that expressed support for CMS' proposed value.

Response: We appreciate the commenter's support.

After consideration of the comment received that specifically addressed this code, for CY 2018, we are finalizing a work RVU of 1.10 and the proposed direct PE inputs without refinement for CPT code 64418.

(25) Nerve Repair With Nerve Allograft (CPT Codes 64910, 64911, 64912, and 64913)

The CPT Editorial Panel created two new Category I CPT codes (64912 and 64913) to report the repair of a nerve using a nerve allograft. CPT codes 64910 and 64911 were also reviewed as part of this code family. CPT codes 64912 and 64913 will be placed on the new technology list to be re-reviewed by the RUC in 3 years to ensure correct valuation and utilization assumptions.

For CY 2018, we proposed the RUC-recommended work RVUs for the following codes: A work RVU of 10.52 for CPT code 64910, a work RVU of 14.00 for CPT code 64911, a work RVU of 12.00 for CPT code 64912, and a work RVU of 3.00 for CPT code 64913.

We noted a decrease in preservice time (7 minutes) for CPT code 64910 and considered an alternate work RVU of 10.15, crosswalking to CPT code 15120 (Split-thickness autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1 percent of body area of infants and children (except 15050)), which has similar service times. We sought comments on whether an alternative work RVU of 10.15 for CPT code 64910 would better reflect relativity among PFS services with similar service times.

For CPT code 64911 (Nerve repair; with autogenous vein graft (includes harvest of vein graft), each nerve)), we considered a work RVU of 13.50, by crosswalking to CPT code 31591 (Laryngoplasty, medicalization, unilateral), which has similar service times and a work RVU of 13.56. We sought comments on whether a work RVU of 13.50 for CPT code 64911 would better reflect relativity among other PFS services with similar service times.

The new coding structure for these services increases granularity by including add-on codes that describe each strand of nerve repair. While we recognize that additional granularity may be important and useful for purposes of data collection, the advantages to Medicare for such granularity for purposes of payment are unclear, especially since we are unaware of a payment-related reason for such coding complexity. We considered proposing a bundled status to the new add-on codes and incorporating the relative resources in furnishing the add-on code (CPT code 64913) into the base code (CPT code 64912) based on the utilization assumptions that accompanied the RUC's recommendations. The RUC estimated that CPT code 64912 would have 750 Medicare allowed services in CY 2018, and that the corresponding add-on CPT code 64913 would have 150 Medicare allowed services in CY 2018. Therefore, the RUC estimated that CPT code 64912 will be billed without add-on CPT code 64913 for 80 percent (750/900) of the Medicare allowed services, and that CPT code 64912 will be billed with add-on CPT code time 64913 for 20 percent (150/900) of the Medicare allowed services in CY 2018. To account for the additional work involved in 20 percent of the allowed services, we added a

work RVU of 0.60 (20 percent of the work RVU of 3.00 for CPT code 64913) to the work RVU of 12.00 for CPT code 64912, to derive an alternative work RVU of 12.60 for CPT code 64912 and increased the intraservice time by 6 minutes to account for the bundling of services from CPT code 64913. The alternative work RVU of 12.60 would have been further supported by a crosswalk to CPT code 14301 (Adjacent tissue transfer or rearrangement, any area; defect 30.1 sq cm to 60.0 sq cm), which has similar intraservice and total times.

We proposed the RUC-recommended direct PE inputs for CPT codes 64910, 64911, 64912 and 64913 without refinements.

Comment: In general commenters were supportive of our proposal of the RUC-recommended work RVUs. Some expressed opposition to the alternative work RVUs.

Response: We will continue to consider alternative work RVUs as we propose the valuation of services for future notice and comment rulemaking.

Comment: Some commenters disagreed with our proposal to bundle CPT codes 64912 and 64913. Several commenters, including the RUC, noted that bundling the service would place a financial burden on the patients who do not require multiple strands because they would be charged 120 percent of what they should be charged. One commenter cited this as the payment-related reason to not bundle the services, and further noted that bundling would undermine the premise of coding and relative reimbursement. The RUC noted that CPT code 64913 is an add-on code for the additional work related to insertion of an additional nerve allograft for the same nerve. They stated that the additional work is not typically performed with the base code and therefore would not be appropriate to bundle into the work of the base code.

Response: We note that 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 physician fee schedule. We will continue to consider these options as we propose the valuation of services for future notice and comment rulemaking.

Comment: The RUC stated that it is atypical for CMS to question the coding structure of newly proposed services via rulemaking. In the future, they requested that CMS voice concerns regarding coding structure as part of the agency's participation in the CPT Editorial Panel review process.

Response: While we acknowledge that the discussion and consideration of different coding structures occurs during the CPT Editorial Panel review process, we also note that not all interested parties have the opportunity to participate in the CPT Editorial Panel review process, and not all relevant stakeholders are members of the CPT Editorial Panel. Additionally, we would like to reiterate that, while we appreciate that some commenters believe that CMS staff could offer useful perspectives by regularly attending and participating more fully in the CPT Editorial Panel review process, we do not believe that would be appropriate for many reasons, not least of which is that CMS staff participation in the CPT Editorial Panel review process cannot supplant our obligation to establish through notice and comment rulemaking what we determine to be appropriate coding structures for each reviewed code. Accordingly, we disagree with the commenter's suggestion that CMS staff should preemptively address the concerns of coding structures during the CPT Editorial Panel review process, instead of through notice and comment rulemaking. Formal notice and comment rulemaking allows all interested parties the opportunity to review our proposals and provide feedback, as well as to submit supplemental information about our proposals, and address any concerns or alternatives we have expressed in making our proposal.

Comment: A commenter questioned why CMS would be concerned with a code pair that is not typically reported for Medicare-aged patients, but instead is a service for younger patients that have better nerve healing capacity.

Response: As discussed in the CY 2017 PFS final rule (82 FR 80172), the statute requires us to establish, by regulation, each year's payment amounts for all physicians' services paid under the PFS. Although we prioritize high volume services when we routinely examine the valuation and coding for existing services under the misvalued code initiative, we also value low-volume services in accordance with the statute.

After consideration of comments received, we are finalizing the work RVUs for CPT codes 64910, 64911, 64912, and 64913 as proposed. We are also finalizing the proposed direct PE inputs for these codes, without refinement.

(26) Correction of Trichiasis (CPT Code 67820)

In CY 2016, CPT code 67820 was identified by the screen for high expenditure services across specialties with Medicare allowed charges of $10 million or more. The screen identified the top 20 codes by specialty in terms of allowed charges, excluding 10- and 90-day global services, anesthesia and E/M services and services reviewed since CY 2010. During the review process, the RUC re-surveyed the code and recommended a work RVU of 0.32, which we proposed in the CY 2018 PFS proposed rule.

The RUC also recommended 15 minutes of preservice time in the facility setting to complete preservice diagnostic and referral forms, coordinate pre-surgery services, schedule space and equipment in the facility, provide preservice education/obtain consent, and follow-up phone calls and prescriptions. We believed it to be atypical for a physician's staff to be performing these activities in a facility-setting with a procedure that has a 0-day global period. Therefore, we proposed removing the time associated with these activities.

We also note that in the course of refining the times associated with the clinical activities referenced above, we inadvertently reduced the time associated with the screening lane (EL006) from 11 minutes to 5 minutes.

Comment: Commenters stated that a default policy of allowing zero minutes of preservice time in the facility setting was inappropriate as ambulatory practices often expend staff time to coordinate with the facility in order to bring their patients in to perform procedures. Commenters also acknowledged that it may be atypical for epilation of eyelashes to require pre-surgery coordination, follow-up phone calls or prescriptions and that by removing these two activities, the total clinical staff preservice time would be more appropriate for the service.

Response: We appreciate the information provided by commenters regarding the preservice clinical activities and agree that certain activities are typical for this service. Therefore, for CY 2018, we will finalize a total of 9 minutes of preservice time which corresponds with coordinating pre-surgery services, scheduling space and equipment in the facility, and providing preservice education/obtain consent.

Comment: Commenters stated their disagreement with the reduction of time from 11 to 5 minutes for the screening lane (EL006), as the physician would be

treating the patient in the screening lane for all aspects of the procedure and therefore, it would be unavailable for any other use during the procedure.

Response: As we stated above, we inadvertently reduced the time of the screening lane and did not intend to make a proposal regarding this equipment item. Therefore, for CY 2018, we will finalize the RUC-recommended 11 minutes for the screening lane.

Comment: Another commenter expressed their support for the RUC process, but opposed the RUC-recommended work RVU of 0.32 for CPT code 67820. The commenter recommended CMS increase the work RVU to the 0.40 to align with 25th percentile of the survey.

Response: We believe the RUC's recommend valuation of 0.32 for CPT code 67820 is appropriate due to the overall reduction in total time and it having less intensity than its key reference code, CPT code 11900, Injection, intralesional; up to and including 7 lesions (work RVU = 0.52, intra time = 8 minutes). Therefore, after consideration of the comments, we will finalize the RUC-recommended work RVU of 0.32 for CPT code 67820 for CY 2018.

(27) CT Soft Tissue Neck (CPT Codes 70490, 70491, and 70492)

CPT codes 70490 and 70492 were identified through the high expenditure services across specialties with Medicare allowed charges of $10 million or more screen. CPT code 70491 was also included for review as part of this code family. For CY 2018, we proposed the RUC-recommended work RVUs of 1.28 for CPT code 70490, 1.38 for CPT code 70491, and 1.62 for CPT code 70492. For CPT code 70490, we considered a work RVU of 1.07 based on a crosswalk to CPT code 72125 (Computed tomography, cervical spine; without contrast material). CPT code 72125 is a non-contrast CT service on a similar anatomical area and has identical intraservice and total times to those recommended by the RUC for CPT code 70490. We also considered work RVUs of 1.17 for CPT code 70491 and 1.41 for CPT code 70492. We sought comment on how relativity among other CT services paid under the PFS would be affected by applying the alternative work RVUs described above for CPT codes in this family.

Comment: Commenters disagreed with our alternative values and supported our proposal to implement the RUC-recommended values.

Response: We appreciate the comments regarding our proposals.

After consideration of the public comments, we are finalizing the RUC-recommended work RVUs as proposed.

(28) Magnetic Resonance Angiography (MRA) Head (CPT Codes 70544, 70545, and 70546)

CPT code 70544 was identified by a screen of services across specialties with Medicare allowed charges of $10 million or more. Subsequently, CPT codes 70545 and 70546 were also reviewed as part of this code family. We proposed the RUC-recommended work RVUs of 1.20 for CPT code 70544, 1.20 for CPT code 70545, and 1.48 for CPT code 70546. We also proposed the following refinements to the RUC-recommended direct PE inputs. For the service period clinical labor activity ''Provide preservice education/obtain consent,'' we proposed 5 minutes for CPT code 70544, 7 minutes for CPT code 70545, and 7 minutes for CPT code 70546 so that the times for this activity are consistent with other magnetic resonance (MR) services performed without-contrast materials, with-contrast materials, and without-and-with contrast materials, respectively. For the clinical labor task ''Acquire images,'' we proposed using the RUC-recommended clinical time of 26 minutes for CPT code 70544. We considered proposing 20 minutes of clinical time to maintain the relativity among the three codes in this family and for consistency with other MRA and magnetic resonance imaging (MRI) codes, which do not typically assign more clinical labor time to this task for services without contrast material than for services with contrast material. We sought comment as to the appropriate time value for this clinical labor task. For the clinical labor task ''Technologist QCs images in PACS, checking all images, reformats, and dose page,'' we proposed to refine the clinical labor time from the RUC recommended 4 minutes to 3 minutes to comply with the standards.

Comment: A commenter disagreed with our proposed clinical labor time for the task ''Technologist QCs images in PACS, checking all images, reformats, and dose page,'' and stated that CMS had previously determined that the amount of clinical labor needed to check images in a PACS workstation may vary depending on the service, and that CMS would agree to times above the standard if a compelling rationale is presented.

Response: We believe that MRA services are analogous to MRI services in that they are most accurately considered procedures of intermediate complexity.

Comment: One commenter did not agree with our alternative value for the clinical labor task ''acquire images.''

Response: We appreciate the comment, and we are finalizing as proposed the RUC-recommended clinical labor time value for this task.

After consideration of the comments, we are finalizing these PE refinements as well as the RUC-recommended work RVUs, as proposed.

(29) Magnetic Resonance Angiography (MRA) Neck (CPT Codes 70547, 70548, and 70549)

CPT code 70549 was identified through a high expenditure screen. CPT codes 70547 and 70748 were also reviewed as part of this family of codes. We proposed the RUC-recommended work RVUs of 1.20 for CPT code 70547, 1.50 for CPT code 70548, and 1.80 for CPT code 70549. We also proposed several refinements to the RUC-recommended direct PE inputs for these services. For the service period clinical labor activity ''Provide preservice education/obtain consent,'' we proposed 5 minutes for CPT code 70547, 7 minutes for CPT code 70548, and 7 minutes for CPT code 70549 so that the times for this activity are consistent with other MR services performed without contrast material, with contrast material, and without-and with contrast material, respectively. For the intraservice clinical labor task acquire images, for CPT code 70547, we proposed to use the RUC-recommended 26 minutes. We considered applying 20 minutes to this clinical labor task, which would have maintained consistency with the 20 minutes recommended by the RUC for CPT code 70548 (the service that includes with-contrast material). We stated concern about the lack of evidence that a non-contrast MRA would require more clinical labor time than the with-contrast MRA service. We sought comment as to the appropriate time value for this clinical labor task. For the clinical labor task ''Technologist QCs images in PACS, checking all images, reformats, and dose page,'' we proposed to refine the clinical labor time from the RUC recommended 4 minutes to 3 minutes to comply with the standards.

Comment: A commenter did not agree with our alternative time value for the task ''acquire images.''

Response: We appreciate the comment, and we are finalizing the RUC-recommended time value for this clinical labor task as proposed.

Comment: A commenter disagreed with our proposed clinical labor time for the task ''Technologist QCs images in PACS, checking all images, reformats,

and dose page,'' stating that CMS had previously determined that the amount of clinical labor needed to check images in a PACS workstation may vary depending on the service, and that we will agree to times above the standard if a compelling rationale is presented.

Response: We believe that MRA services are analogous to MRI services in that they are most accurately considered procedures of intermediate complexity. Therefore, for CPT codes 70547, 70548, and 70549, we are finalizing these PE refinements as well as the RUC-recommended work RVUs, as proposed.

(30) CT Chest (CPT Codes 71250, 71260, and 71270)

CMS identified this code family through the high expenditures screen. We proposed the RUC-recommended work RVUs of 1.16 for CPT code 71250, 1.24 for CPT code 71260, and 1.38 for CPT code 71270. For CPT code 71250, we considered maintaining the CY 2017 work RVU of 1.02. We stated that we are concerned with the lack of evidence that the physician time or intensity of furnishing this service has changed since it was last valued. In addition, we noted that a comparison to other CT codes indicated that the RUC-recommended work values could be overvalued relative to other CT services and compared to similar, non-contrast CT studies such as CPT codes 72131 (Computed tomography, lumbar spine; without contrast material) and 73700 (Computed tomography, lower extremity; without contrast material), both of which have work RVUs of 1.00. For CPT code 71260, we considered proposing a work RVU of 1.10 by applying the RUC-recommended increment between CPT code 71250 and 71260 (0.08) to CPT code 71260. For CPT code 71270, we considered a work RVU of 1.24 by applying the RUC-recommended increment between CPT codes 71260 and 71270 (0.22) to CPT code 71270. In addition to maintaining relatively among the codes in this family, we considered further supporting these alternative values based on a comparison to other CT studies, such as with-contrast material CT studies, and without-and-with contrast CT studies. While noting our concerns, we proposed the RUC recommended work RVUs for CPT code 71250, 71260, and 71270 and sought comment on whether our alternative values would improve relativity.

Comment: Commenters supported the proposed values for these codes but disagreed with the alternative values.

Response: We appreciate the comments in support of our proposals.

After consideration of the public comments, we are finalizing the RUC-recommended values as proposed.

(31) MRI of Abdomen and Pelvis (CPT Codes 72195, 72196, 72197, 74181, 74182, and 74183)

CPT codes 74182 and 72196 were identified as part of the screen of high expenditure services across specialties with Medicare allowed charges of $10 million or more. CPT codes 74181, 74183, 72195, and 72197 were also reviewed as part of this code family. We proposed the RUC-recommended work RVUs of 1.46 for CPT code 72195, 1.73 for CPT code 72196, 2.20 for CPT code 72197, 1.46 for CPT code 74181, 1.73 for CPT code 74182, and 2.20 for CPT code 74183. While we proposed the RUC-recommended direct PE inputs, we considered 30 minutes for clinical labor task ''Acquire images'' for CPT codes 74181 and 74182, which we stated appeared to be more consistent with the codes in this family and more consistent with other MR codes. We also noted that for CPT codes 74181 and 74182, the clinical labor time for acquired images appears to have been developed through a consensus panel from the specialty society over 15 years ago. Given that these times are estimates based on expert panel consensus rather than survey data, we sought comment on whether using a structure that matches other MR code families would be more appropriate to value these clinical labor times.

Comment: A commenter stated that all clinical labor time inputs are based on an expert panel, and our expression of concern for this code family is thus inconsistent with our review of other services in current and past rulemaking.

Response: We appreciate the comment and we are finalizing the RUC-recommended work RVUs, as proposed.

(32) MRI Lower Extremity (CPT Codes 73718, 73719, and 73720)

CPT codes 73718 and 73720 were identified as part of the screen of high expenditure services, and CPT code 73719 was included for review as part of the code family. We proposed the RUC-recommended work RVUs of 1.35 for CPT code 73718, 1.62 for CPT code 73719, and 2.15 for CPT code 73720. We are also proposing the following refinements to the RUC-recommended direct PE inputs. For the service period clinical labor activity ''Provide preservice education/obtain consent,'' we proposed 5 minutes for CPT code 73718, 7 minutes for CPT code 73719, and 7 minutes for CPT code 73720. Likewise, for the service period task ''Prepare room, equipment, supplies,'' we proposed 3 minutes for CPT code 73718, 5 minutes for CPT code 73719, and 5 minutes for CPT code 73720. We proposed these changes to maintain consistency with other MR services without contrast materials, with contrast materials, and without-and-with contrast materials, respectively.

Comment: A commenter disagreed with our proposed PE refinements to the clinical labor activity ''Prepare room, equipment, supplies,'' stating that the RUC-recommended clinical labor time paralleled other recent MRI codes, including MRI brain and MRI face, and that MR involves strong magnetic fields and ensuring patient safety is important. More specifically, all objects in the room must be MRI compatible. MR exams involve the use of MR coils which vary based on the body part studied and are specifically selected to fit the patient. These coils must be prepared for the intended exam, positioned, and attached to the MR unit. In addition, the examinations involving the use of contrast require setup of the injector apparatus and preparation of the contrast material.

Response: We agree that the RUC-recommended clinical labor times for this activity appear consistent with those for the code family mentioned by the commenter. Therefore, we are not finalizing our proposed time values for this activity, and are instead finalizing the RUC-recommended values of 5 minutes, 7 minutes, and 7 minutes for CPT codes 73718, 73719, and 73720, respectively, to maintain consistency among similar services.

(33) Abdominal X-Ray (CPT Codes 74022, 74018, 74019, and 74021)

CPT codes 74000 (Radiologic examination, abdomen; single anteroposterior view) and 74022 (Radiologic examination, abdomen; complete acute abdomen series, including supine, erect, and/or decubitus views, single view chest) were identified via a high expenditure screen. The CPT Editorial Panel created CPT codes 7401874018, 7401974019, and 7402174021to replace CPT codes 74000, 74010, and 74020. The RUC suggested a utilization scenario that assumes that 25 percent of services currently reported with CPT code 74010 will be reported with CPT code 74019 and 75 percent will be reported with CPT code 74021; and 75 percent of services currently reported with CPT code 74020 will be reported with CPT code 74019 and 25 percent will be reported with CPT code 74021. In the CY 2018 PFS proposed rule, we stated that we did not identify evidence or a rationale for these assumptions. For

purposes of calculating the proposed RVUs, we used an even distribution of services previously reported as CPT codes 74010 and 74020 to CPT codes 740X2 and 740X3 instead of the RUC-recommended distribution because we thought that the services previously reported with codes 74010 and 74020 will be reported in equal volume between the code representing two views and the code representing three views, and we sought comment on information that would help us improve on this distribution for purposes of developing final RVUs, including rationale for the distribution reflected in the RUC's utilization crosswalk.

Comment: The RUC commented that its utilization assumptions are based on expert panel consensus, and said that its utilization assumptions will result in savings that would be reapplied to the Medicare conversion factor. The RUC also requested clarity regarding our utilization assumptions and their relationship to the work RVUs we proposed for this code family.

Response: We appreciate the RUC's input regarding utilization assumptions. We note that we are finalizing the RUC-recommended work RVUs as proposed, and our utilization assumptions do not determine the valuation of work RVUs, which will be incorporated into overall budget neutrality calculations.

(34) Angiography of Extremities (CPT Codes 75710 and 75716)

This code family was identified through the $10 million or more screen of high expenditure services. We proposed the RUC-recommended work RVUs of 1.75 for CPT code 75710 and 1.97 for CPT code 75716. We also proposed to use the RUC-recommended direct PE inputs for CPT codes 75710 and 75716, with the following refinements. For the clinical labor task ''Technologist QC's images in PACS, checking for all images, reformats, and dose page,'' we proposed refinements consistent with the standard clinical labor times for tasks associated with the PACS Workstation. We also proposed to refine the clinical labor by removing the 2 minutes associated with the task ''prepare room, equipment, and supplies.'' CPT codes 75710 and 75716, which represent radiological supervision and interpretation, are billed with codes that include activities such as needle placement and imaging, and the ''prepare room, equipment, supplies,'' activity will be accounted for with the codes that are billed with these interpretation codes.

Comment: A commenter disagreed with our proposed clinical labor time for the task ''Technologist QCs images in PACS, checking all images, reformats, and dose page,'' stating that CMS had previously determined that the amount of clinical labor needed to check images in a PACS workstation may vary depending on the service, and that we would agree to times above the standard if a compelling rationale is presented.

Response: We believe that MRA services are analogous to MRI services in that they are most accurately considered procedures of intermediate complexity.

After consideration of the comment we received, we are finalizing these PE refinements as well as the RUC-recommended work RVUs, as proposed.

(35) Ophthalmic Biometry (CPT Codes 76516, 76519, and 92136)

In the CY 2016 PFS final rule with comment period, CMS identified CPT codes 76519 and 92136 as potentially misvalued on the high expenditure screen. For CY 2018, we proposed the RUC-recommended work RVUs for each code in this family as follows: 0.40 for CPT code 76516, 0.54 for CPT code 76519, and 0.54 for CPT code 92136.

For CPT codes 76519 and 92136, the RUC recommended adding an additional 8 minutes of immediate postservice time for dictating the report of the procedure for the medical record, review and sign report, communicate results to the patient, discussing lens implant options for desired postoperative refractive result, and entering an order for the intraocular lens implant. We considered time and work values that would not include the additional 8 minutes of immediate postservice time in either of these codes, due to the concern that the additional time may not reflect the typical case. Were we to not include those 8 minutes, each of these procedures would have a total time of 14 minutes. We considered applying the total time ratio (decrease from 17 minutes to 14 minutes; ratio of 0.824) to the RUC-recommended work RVU of 0.54, which would have resulted in a work RVU of 0.44 for CPT codes 76519 and 92136. We sought comment on whether these alternative values would improve relativity.

Comment: Several commenters, including the RUC, stated the additional immediate postservice time for CPT codes 76519 and 92136 was appropriate due to the need for the provider to discuss the multiple lens options and refractive outcomes with the patient; as many of these medical options were not available when the code was last surveyed.

Response: We appreciate the feedback from the commenters regarding the relativity of our alternative value. After considering these comments, we are finalizing the RUC-recommended values of 0.54 RVUs for CPT codes 76519 and 92136, for CY 2018.

(36) Ultrasound of Extremity (CPT Codes 76881 and 76882)

The RUC identified CPT codes 76881 and 76882 for review only of PE inputs. For CPT code 76881, we proposed the RUC-recommended inputs with refinements. We proposed to remove 1 minute from the clinical labor task ''Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue,'' because this code does not include any equipment time for the PACS workstation proxy or professional PACS workstation. We noted that the RUC-recommended inputs shift the general ultrasound room from the PE inputs for CPT code 76881 to the PE inputs for CPT code 76882. We proposed to make this change, consistent with the RUC recommendations; however, we sought comment on whether a portable ultrasound unit would be a more accurate PE input for both codes, given that the dominant specialty for both of these services is podiatry, based on available 2016 Medicare claims data. As noted in the CY 2018 PFS proposed rule, we proposed that these codes would not be subject to the phase-in of significant RVU reductions given the significance of this shift of resource costs between codes in the same family and sought comment on this proposed application of the phase-in policy.

Comment: Many commenters disagreed with the RUC recommendations for the direct PE inputs, stating that the shift of PE from CPT code 76881 to CPT code 76882 is based on inaccurate assumptions regarding the typical equipment used in furnishing these services. These commenters noted that the equipment used to furnish the two procedures is identical. These commenters stated that the RUC-recommended direct PE inputs for CPT code 76881, which were developed based on the assumption that the dominant specialty furnishing the service is podiatry, do not reflect the equipment inputs utilized by rheumatologists such as an ultrasound room and PACS workstation.

Furthermore, these commenters stated that valuing CPT code 76882, which is the limited ultrasound procedure, at a higher price than CPT code 76881, which is the complete ultrasound procedure, represents a rank order anomaly. The RUC disagreed with our statement that podiatry is the dominant

specialty for both codes and re-affirmed its recommendation.

Response: Examination of 2016 claims indicates that the dominant specialty for both codes, when considering the volume of global and TC services in aggregate, is podiatry. Therefore, we are finalizing the RUC-recommended direct PE inputs with refinements for CPT code 76881 as proposed. For CPT code 76882, we are not finalizing our proposal to include an ultrasound room, and we are instead finalizing the RUC-recommended equipment, with the exception of the ultrasound room, which we are replacing with a portable ultrasound unit. This is based on the RUC's determination, as expressed through its recommendations for CY 2018, that a portable unit is the equipment type that is typical for podiatry, which is the dominant specialty furnishing CPT code 76882. We are thus applying the PE inputs that the RUC has determined are typical for the dominant specialty for both codes in order to maintain consistency and rank order.

Comment: A commenter requested that CMS reconsider our proposal not to subject these codes to the phase-in of significant RVU reductions.

Response: The significant RVU reductions that will result from the PE inputs that we are finalizing comprise a change in resource costs overall for the code family. This is in contrast to our proposal, which would have shifted costs within codes of the same family. Therefore, we are not finalizing our proposal to exempt these codes from the phase-in, and the reduction in the PE for CPT code 76881 will thus be limited to 19 percent for the first year. This transition period will allow us to obtain more stakeholder input on the appropriate PE inputs and specialty assumptions for these services, and we expect to consider this input for future rulemaking.

Comment: A commenter disagreed with our decision to remove from CPT code 76881 the one minute of clinical labor assigned to the task ''Exam document scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue,'' stating that regardless of whether the service includes a PACS workstation, there is still documentation to be entered.

Response: The task of entering documentation, when not applied to a code that includes a PACS workstation as an equipment item, is most appropriately considered indirect PE; therefore, we are finalizing this refinement as proposed.

(37) Flow Cytometry Codes (CPT Codes 88184 and 88185)

The flow cytometry interpretation family of codes is split into a pair of codes used to describe the technical component of flow cytometry (CPT codes 88184 and 88185) that do not have a work component, and a trio of codes (CPT codes 88187, 88188, and 88189) that do not have direct PE inputs, as they are professional component only services. CPT codes 88184 and 88185 were reviewed by the RUC in April 2014, and their CMS-refined values were included in the CY 2016 PFS final rule with comment period. These codes were reviewed again at the January 2016 RUC meeting, and new recommendations were submitted to CMS as part of the CY 2017 PFS rulemaking cycle. In the CY 2017 PFS final rule (81 FR 80325), we finalized all of the direct PE inputs for CPT codes 88184 and 88185, as proposed, except for the proposed refinement to the dye sublimation printer.

As discussed in the potentially misvalued services section of this final rule (section II.E), we have received conflicting information about the direct PE inputs for CPT codes 88184 (Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker) and 88185 (Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; each additional marker). Therefore, in the CY 2018 PFS proposed rule, we proposed these codes as potentially misvalued so that they can be reviewed again because some stakeholders have suggested the clinical labor and supplies that were previously finalized are no longer accurate. In response to the CY 2018 PFS proposed rule, several commenters urged CMS to use the RUC's recommendations for CY 2017 in developing final PE RVUs for these services instead of recommending additional review under the misvalued code initiative. Based on this suggestion from the commenters, which appears to reflect a broad consensus, we have re-examined the CY 2017 RUC-recommended direct PE inputs for these services, in light of the specific comments. In the paragraphs below, we summarize the direct PE inputs that we are changing based on these comments.

Comment: Several commenters urged CMS to use the RUC-recommended 15 minutes for the clinical labor activity ''Instrument start-up, quality control functions, calibration, centrifugation, maintaining specimen tracking, logs and labeling.'' from CY 2017 for this clinical labor activity. Commenters stated that the CMS comparison to CPT code 88182 was not appropriate, as that code uses older/simpler technology, and that the more robust testing described in these codes requires a higher level of skill, experience, and continuing education in the laboratory staff than in CPT code 88182.

Response: After reviewing this additional information, we agree with the commenters that 15 minutes would be typical for this task. We are finalizing a clinical labor time of 15 minutes for the ''Instrument start-up, quality control functions . . .'' clinical labor activity for CPT code 88184.

Comment: Several commenters stated that the RUC-recommended time of 10 minutes for ''Load specimen into flow cytometer, run specimen, monitor data acquisition, and data modeling, and unload flow cytometer'' activity for CPT code 88184 reflects the typical case. Commenters stated that the time it takes for data capture, data modeling, data acquisition, and computational analysis is significantly longer for CPT code 88184 than for CPT code 88182, since additional colors result in more complicated profiles which are more difficult and time consuming to evaluate.

Response: After reviewing this additional information, we agree with the commenters that 10 minutes would be typical for this task. We were persuaded by the additional information that the commenters supplied regarding the need for extra clinical labor time in CPT code 88184 as compared to CPT code 88182 due to the additional colors used in flow cytometry. Therefore, we are finalizing a clinical labor time of 10 minutes for the ''Load specimen into flow cytometer . . .'' clinical labor activity for CPT code 88184.

Comment: Several commenters objected to the finalized supply quantity of 1 for the flow cytometry antibody (SL186) in CPT codes 88184 and 88185. Commenters stated that although it is standard practice to use a single antibody multiple times during the analysis, each antibody or marker can only be billed once per analysis. According to commenters, multiple uses of such antibodies are not reportable or billable, but are critical to the overall analysis and interpretation of results and are part of the total cost for each procedure performed. A commenter stated that for a typical immunophenotyping panel, it takes 38 units of different antibody reagents to identify 24 distinct cell surface markers across 10–12 separately analyzed tubes, and therefore a ratio of 1.6 units of antibody reagent for each reportable and billable surface marker is required, not

the 1:1 ratio in the finalized CY 2017 values. All of the commenters requested using the CY 2017 RUC recommendation of 1.6 supply quantity for this input.

Response: We appreciate the additional information supplied by the commenters regarding the flow cytometry antibody (SL186) in CPT codes 88184 and 88185, and in particular the extensive data provided to explain why the supply quantity of 1.6 would be typical for these procedures. After reviewing this additional information, we agree with the commenters and we are finalizing a supply quantity of 1.6 for the flow cytometry antibody in these two CPT codes.

Comment: Several commenters disagreed with the finalized equipment time for the dye sublimation printer (ED031). One commenter stated that printing is not performed all at one time, with 25–30 pages of information and data printed over a 5-minute time span. One commenter indicated that this time cannot be linked directly to one particular clinical labor task line, and the printer cannot be used for any other task during these 5 minutes even while it is not actively printing, and urged CMS to adopt the RUC-recommended 5 minutes of equipment time. Another commenter stated that this process takes usually 10 minutes for their most technically advanced personnel.

Response: We note that in the CY 2017 PFS final rule, due to the presentation of new information detailing how the equipment time for the printer was disassociated from any clinical labor tasks, we increased the finalized equipment time to the RUC-recommended 5 minutes for CPT code 88184 and 2 minutes for CPT code 88185. Regarding the request to increase the equipment time for the dye sublimation printer to 10 minutes, we have no data to indicate that this amount of equipment time would be typical. The information that we received from commenters during the CY 2017 rule cycle, which was again echoed by additional commenters in this rule cycle, indicated that 5 minutes was the typical length of time required to print the 25–30 pages of materials used in this service. The commenter who disagreed and suggested 10 minutes of equipment time included time for the pathologist to review the printed materials, and we do not agree that the printer would typically need to remain in use while the pathologist conducted this review. We continue to believe that the RUC-recommended equipment times for the dye sublimation printer would be typical for these services.

After consideration of the comments received as part of the CY 2018 rule cycle, we are updating the direct PE inputs finalized in CY 2017 for CPT codes 88184 and 88185 with the changes detailed above.

(38) Pathology Consultation During Surgery (CPT Codes 88333 and 88334)

CPT codes 88333 and 88334 were surveyed for both work and PE for the CY 2018 rule cycle. We proposed the RUC-recommended work RVU of 1.20 for CPT code 88333 and the RUC-recommended work RVU of 0.73 for CPT code 88334. For the direct PE inputs, we proposed to remove the clinical labor for the ''Prepare room. Filter and replenish stains and supplies (including setting up grossing station with colored stains)'' activity from CPT code 88333. This clinical labor is not currently included in the direct PE inputs for CPT code 88333, and we believed that this is a form of indirect PE that is not individually allocable to a particular patient for a particular service. While we agreed that replenishing stains and supplies is a necessary task, under the established methodology, we believed that it is more appropriately classified as indirect PE.

We proposed to refine the clinical labor time for ''Clean room/equipment following procedure'' activity for CPT code 88333, consistent with the standard clinical labor time assigned for room cleaning when used by laboratory services. We sought comments related to the equipment time assigned to the ''grossing station w-heavy duty disposal'' (EP015) for CPT codes 88333 and 88334. Although the recommended equipment time of 10 minutes maintains the current equipment time assigned to the grossing station, and we had no reason to believe that this time is incorrect, it was unclear to us how this equipment time was derived.

Comment: Several commenters stated that the RUC recommended that CPT code 88334 should have a ZZZ global period rather than a XXX global period because it is an add-on code and does not include any preservice or postservice work time. These commenters requested the assignment of a ZZZ global period for CPT code 88334.

Response: We appreciate the identification of this issue with the global period for CPT code 88334 from the commenters. Due to a technical error, a global period of XXX was incorrectly assigned to this code in the proposed rule. We are finalizing a global period of ZZZ for CPT code 88334 as the RUC recommended.

Comment: Several commenters disagreed with the proposal to remove the clinical labor for the ''Prepare room. Filter and replenish stains and supplies (including setting up grossing station with colored stains)'' activity from CPT code 88333. One commenter stated that this was not a form of indirect PE as the clinical labor task was attributable to a specific patient and constituted a necessary function of directly providing patients with important lab services. Another commenter stated that this was not a form of indirect PE because it was akin to a number of recognized direct PE activity codes such as Prepare room, equipment and supplies (CA013) and Provide education/obtain consent (CA011). The commenter stated that to classify these PE activities as indirect expenses would be unintentionally biased against pathology and laboratory services, due to their unique status as a medical specialty in which many procedures can be performed in batches, serving multiple patients simultaneously.

Response: We continue to believe that many of the activities described by the clinical labor task ''Prepare room. Filter and replenish stains and supplies (including setting up grossing station with colored stains)'' constitute forms of indirect PE. The fact that many clinical labor tasks associated with pathology and laboratory services cannot be allocated to individual patients is the reason why they are classified as indirect PE under our methodology. While some of these issues may be unique to pathology and laboratory services, in many other non-lab cases there are also supplies or clinical labor tasks that are not allocable to individual services that we have assigned to indirect PE. However, we agree with the commenters that some of the clinical labor described in this task is analogous to the clinical labor described in non-laboratory direct PE activity codes such as Prepare room, equipment and supplies (CA013). Since 2 minutes is the standard time allocated for the CA013 clinical labor activity code in non-laboratory services, we will assign 2 minutes for room preparation and equipment setup for CPT code 88333. We continue to believe that the replenishing of stains and supplies constitutes a form of indirect PE, and we do not agree that clinical labor time should be allocated for this task.

Comment: Several commenters disagreed with the proposal to refine the clinical labor time for ''Clean room/equipment following procedure'' activity for CPT code 88333 from 5

minutes to 1 minute, consistent with the standard clinical labor time assigned for room cleaning when used by laboratory services. Commenters stated that they were aware of the existence of this specific standard, but indicated that they looked to the typical patient scenario as well as similar services to arrive at a time estimate. The recommended time of 5 minutes included tasks performed when the add-on CPT code 88334 was also provided.

Response: We continue to believe that the standard clinical labor time of 1 minute for room and equipment cleaning in laboratory services should be applied to CPT code 88333, as the commenters did not supply a rationale as to why this time would not be typical. The RUC's recommendations for this clinical labor task stated that cleaning the grossing area was attributable to the first code only (CPT code 88333), and if there is additional clinical labor required when CPT code 88334 is performed, we believe that it should be included in the direct PE inputs for that service.

Comment: Several commenters responded to CMS' request for information regarding the derivation of the recommended equipment time for the ''grossing station w-heavy duty disposal'' (EP015). Commenters stated that the time assigned to the EP015 grossing station w-heavy duty disposal is derived from a combination of the total clinical labor time for the service and the physician time of reviewing the patient case at the same grossing station.

Response: We appreciate the additional information from the commenters regarding the equipment time. As we stated in the proposed rule, we have no reason to believe that the recommended equipment time is incorrect, it was simply unclear to us how this equipment time was derived.

After consideration of comments received, for CY 2018, we are finalizing the work RVUs and direct PE inputs for the codes in the pathology consultation during surgery family as proposed, with the exception of the refinement to the ''Prepare room. Filter and replenish stains and supplies (including setting up grossing station with colored stains)'' clinical labor time as detailed above. We are also finalizing an add-on global period (ZZZ) for CPT code 88334 as the RUC recommended.

(39) Radiation Therapy Planning (CPT Codes 77261, 77262, and 77263)

CPT code 77263 was identified through a screen of high expenditure services across specialties. CPT codes 77261 and 77262 were included for review. For CY 2018, we proposed the RUC-recommended work RVUs of 1.30 for CPT code 77261, 2.00 for CPT code 77262, and 3.14 for CPT code 77263. However, we stated that we had concerns regarding the RUC-recommended work RVUs given the decreases in service times as recommended by the RUC and reflected in the survey data compared to the current values. For CPT code 77263, we considered a work RVU of 2.60 based on a crosswalk to CPT code 96111 (Developmental testing, (includes assessment of motor, language, social, adaptive, and/or cognitive functioning by standardized developmental instruments) with interpretation and report), which has an identical intraservice time, and similar total time to the RUC-recommended time values for CPT code 77263. We expressed concern that despite a 15 minute decrease in intraservice time, the RUC did not recommend a work RVU decrease. We noted that the majority of the utilization among the codes in this family would be reported with CPT code 77263. Therefore, we considered using a work RVU of 2.60 for CPT code 77263 as a base for alternative valuations for CPT codes 77261 and 77262 by applying the ratio of the crosswalk work RVU of CPT code 96111 (Developmental test extend) to the RUC-recommended work RVU of CPT code 77263 (that is, 2.60/3.14 = 0.83) to the RUC-recommended work RVU for CPT code 77261 (that is, $0.83 \times 1.30 = 1.08$) and CPT code 77262 (that is, $0.83 \times 2.0 = 1.66$), which would have resulted in work RVUs of 1.08 for CPT code 77261 and 1.66 for CPT code 77262. We sought comments on whether the alternative valuation would be more appropriate for these codes.

Comment: Some commenters disagreed with our considered alternative values, and urged us to adopt the RUC-recommendations as proposed.

Response: We appreciate the feedback from commenters on our proposal and our alternative values.

After consideration of the comments, we are finalizing the RUC-recommended work RVUs as proposed.

(40) Tumor Immunohistochemistry (CPT Codes 88360 and 88361)

CPT codes 88360 and 88361 appeared on a high expenditure services screen across specialties with Medicare allowed charges of over $10 million. We proposed the RUC-recommended work RVU of 0.85 for CPT code 88360 and the RUC-recommended work RVU of 0.95 for CPT code 88361.

We proposed to refine the clinical labor time for the ''Enter patient data, computational prep for antibody testing, generate and apply bar codes to slides, and enter data for automated slide stainer'' activity for both codes, consistent with the standard time for this clinical labor activity across different pathology services. For CPT code 88361, we also proposed to remove the 1 minute of clinical labor time from the ''Performing instrument calibration, instrument qc and start up and shutdown'' and the ''Gate areas to be counted by the machine'' activities. These clinical labor activities do not appear in other recently reviewed computer-assisted pathology codes. We believe that these clinical labor activities would not be typical for CPT code 88361 and are already included in the allocation of indirect PE, consistent with our established methodology.

We proposed to remove the clinical labor time for ''Clean room/equipment following procedure'' for CPT codes 88360 and 88361, as we believed that this clinical labor is duplicative of the 4 minutes of clinical labor assigned to ''Clean equipment and work station in histology lab''. We also proposed to remove the clinical labor time for the ''Verify results and complete work load recording logs'' and the ''Recycle xylene from tissue processor and stainer'' activities for CPT codes 88360 and 88361. As we stated in previous rules, such as in the CY 2017 PFS final rule (81 FR 80319), we believed these clinical labor activities were already included in the allocation of indirect PE, consistent with our established methodology.

We proposed to refine the equipment time for the ''Benchmark ULTRA auto slide prep & E-Bar Label system'' (EP112) from 18 minutes to 16 minutes for both codes. The RUC-recommended equipment time of 18 minutes was an increase of 3 minutes from the current EP112 equipment time to incorporate the equipment time of the ''E-Bar II Barcode Slide Label System'' (EP113), which the recommended materials have clarified is part of the EP112 equipment item. We proposed to add 1 minute over the current value of 15 minutes to the EP112 equipment time to reach the aforementioned 16 minutes, as we believed that this would be more typical for the slide labeling taking place.

For CPT code 88361, we proposed to maintain the current price of $195,000.00 for the DNA image analyzer (EP001) equipment, as the submitted invoice contained a series of unrelated items that have been crossed out, making it difficult to determine the cost of the equipment. We considered refining the equipment time for the DNA image analyzer from 30 minutes to 5 minutes. The equipment literature for

the DNA image analyzer states that the machine can run 50 slides per hour, and CPT code 88361 only requires 3 slides per procedure. This works out to 3.6 minutes of equipment usage (3 slides divided by 50 slides per hour multiplied by 60 minutes in an hour), to which we considered adding 1 minute for preparing the slides. The resulting figure of 4.6 minutes would then round up to 5 minutes, which we considered as the potential equipment time for EP001 assigned to CPT code 88361. We sought comments on additional pricing information for the EP001 DNA image analyzer equipment, specifically, invoices solely for this equipment containing a rationale for each component part, as well as the appropriate equipment time typically required for use in CPT code 88361.

Comment: Several commenters disagreed with our proposal to refine the clinical labor time for the ''Enter patient data, computational prep for antibody testing, generate and apply bar codes to slides, and enter data for automated slide stainer'' activity for both codes from 5 minutes to 1 minute. One commenter stated that this clinical labor task was unique to immunohistochemistry services and was significantly more complicated than performance of a hematoxylin and eosin stained section in the traditional histology laboratory. Another commenter stated that CMS did not finalize a standardized time for this particular clinical labor activity in the CY 2017 PFS final rule, and expressed concern with the reliance on standardized pathology clinical labor tasks and times. The commenter stated that it would be inappropriate to finalize this particular refinement since there had not been an opportunity for stakeholders to comment on the establishment of this standard.

Response: As we stated in the CY 2017 PFS final rule (81 FR 80324), we agree with the commenters that entering patient data into information systems is an important task, and we agree that it would take more than zero minutes to perform. However, we continue to believe that this is correctly categorized as indirect PE, and therefore, we do not recognize the entry of patient data as a direct PE input, and we do not consider this task as typically performed by clinical labor on a per-service basis.

We also agree with the commenter that we did not finalize a standard clinical labor time for this particular clinical labor task. However, we believe that the clinical labor described here under ''generate and apply bar codes to slides'' is broadly analogous to the clinical labor task ''Complete workload recording logs. Collate slides and paperwork. Deliver to pathologist'' in CPT codes 88321, 88323, and 88325, which were addressed in the CY 2017 PFS final rule (81 FR 80325–80326) and were finalized with 1 minute of clinical labor time. Although we agree that the unique nature of pathology and laboratory services can make comparisons across codes more difficult than in other services, we believe the comparison of similar clinical labor activities across different services is important to maintaining the relativity of the direct PE inputs. Since we have typically allocated 1 minute to the labeling of slides in other recently reviewed laboratory services, and we have no reason to believe that CPT codes 88360 and 88361 would not be typical, we are finalizing a clinical labor time of 1 minute for this activity.

Comment: Several commenters disagreed with the proposal to remove the 1 minute of clinical labor time from the ''Performing instrument calibration, instrument qc and start up and shutdown'' and the ''Gate areas to be counted by the machine'' activities from CPT code 88361. Commenters stated that the fact that these activities do not appear in other recently reviewed pathology CPT codes should have no bearing on CPT code 88361, as not all pathology services are identical in terms of the individual components involved in their execution and many are unique. Commenters stated that accurate calibration and quality control are key to accurately measuring the cells and this clinical labor should be recognized.

Response: We agree with the commenter that there are distinctions between individual services, and that no two services are identical. We also believe that comparisons across similar services have an important role in allowing for greater transparency and consistency, as well as maintaining the relativity of the direct PE inputs. We are concerned that too much individual accounting of clinical labor activities, such as with these two tasks, can lead to PE proliferation, and that this breakout of activities into numerous subactivities generally tends to inflate the total time assigned to clinical labor activities and results in values that are not consistent with the analogous times for other PFS services. The fact that these clinical labor activities do not appear in other recently reviewed computer-assisted pathology codes is noteworthy since it suggests that these tasks were previously subsumed under other clinical labor activities, rather than being broken out into individual clinical labor tasks. Instead of listing ''Performing instrument calibration, instrument qc and start up and shutdown'' and ''Load slides on automatic image analyzer'' as separate clinical labor tasks, we believe that these activities have historically been grouped together under more general headings related to preparation. In other words, we believe that the additional recommended clinical labor time in this case derives from the separate listing of these activities as individual tasks rather than representing a change in practice patterns. We also continue to believe that these clinical labor activities would not be typical for CPT code 88361 and are already included in the allocation of indirect PE, consistent with our established methodology.

Comment: Several commenters disagreed with our proposal to remove the clinical labor time for ''Clean room/equipment following procedure'' for CPT codes 88360 and 88361. Commenters stated that the histology laboratory prepares the tissue for sectioning by embedding the tissue into blocks while the immunohistochemistry laboratory is typically in a separate and distinct work area. Since these procedures require both of these work areas to be cleaned, the commenters requested the restoration of this clinical labor time.

Response: After reviewing this new information, we agree with the commenters that this clinical labor is not duplicative of the 4 minutes of clinical labor assigned to ''Clean equipment and work station in histology lab''. We are finalizing the restoration of this 1 minute of clinical labor time, as recommended.

Comment: Several commenters disagreed with the proposal to remove the clinical labor time for the ''Verify results and complete work load recording logs'' and the ''Recycle xylene from tissue processor and stainer'' activities for CPT codes 88360 and 88361. Commenters stated that the time associated with these tasks was a direct expense, not an indirect cost input, and was allocable to a specific patient. One commenter indicated that 1 minute was necessary for these tasks in these services. Another commenter stated that while completion of the work load reporting logs might be an indirect expense, the quality control of results is performed for each and every case, and it should be reported separately as a direct expense.

Response: We appreciate the support from the commenter who agreed that completion of work load recording logs was a form of indirect PE. We continue to believe that both of these clinical labor activities are already included in the allocation of indirect PE consistent

with our established methodology. Other non-laboratory services conduct similar administrative activities, such as filling out electronic health records and recycling supplies, without receiving clinical labor time for individual services.

Comment: Several commenters disagreed with the proposal to refine the equipment time for the ''Benchmark ULTRA auto slide prep & E-Bar Label system'' (EP112) from 18 minutes to 16 minutes for both codes. Commenters stated that this appeared to be an arithmetic error made when equipment items EP112 and EP113 were combined, and that there was a need to add back minutes that had been removed when EP113 was deleted. The commenters urged CMS to adopt the RUC-recommended EP112 for CPT codes 88360 and 88361, along with CPT codes 88341, 88342, and 88344.

Response: Our proposed value of 16 minutes was not based on an arithmetic error, as we proposed to add 1 minute over the current value of 15 minutes to the EP112 equipment time because we believed that 1 minute would be more typical than 3 minutes for the slide labeling taking place in CPT codes 88360 and 88361. However, after consideration of the additional evidence supplied by the commenters, we agree that there should be 3 additional minutes of EP112 equipment time in these codes as recommended. We were persuaded by the commenters that slide labeling would indeed take the full 3 minutes of additional time previously assigned to EP113, rather than the 1 minute that we proposed to assign for this task. We are finalizing this change to the equipment time for CPT codes 88360 and 88361, along with a correction to the total equipment time reclassified as EP112 for the other three codes mentioned by commenters, as described in Table 11.

TABLE 11—BENCHMARK ULTRA AUTO SLIDE PREP & E-BAR LABEL SYSTEM (EP112) EQUIPMENT TIME

CPT code	Current EP112 minutes	Current EP113 minutes	Total equipment time reclassified as EP112
88341	15	1	16
88342	15	3	18
88344	30	3	33
88360	15	3	18
88361	15	3	18

Comment: Several commenters disagreed with the alternative proposal to refine the equipment time for the DNA image analyzer (EP001) from 30 minutes to 5 minutes. Commenters stated that although the product literature provides information for 20x and 40x (50 slides/hr.) however, this is just the initial step in the analytical process of obtaining an image of the tissue stained for the appropriate antigen. The commenters stated that it was the additional steps of analysis that resulted in the RUC recommending 30 minutes of equipment time, and listed a series of tasks performed by the histotechnologist involving the EP001 equipment. Commenters stated that 30 minutes of equipment time is appropriate for the DNA image analyzer. Commenters also supplied new invoices to address CMS' concerns with the pricing of the EP001 equipment, and requested a name change from ''DNA image analyzer'' to ''DNA/digital image analyzer.''

Response: We appreciate the additional information supplied by the commenters regarding the use of the EP001 equipment.

After consideration of the comments, we are finalizing our proposed equipment time of 30 minutes instead of the alternative equipment time. We are finalizing a price of $248,946.30 for this equipment, based on the submitted price of $258,042.30 minus the price of the user training ($6,800.00), the instructor-led online training ($646.00) and the shipping and handling costs ($1,650.00). These costs are allocated through the indirect allocation under the established PE methodology. We are also finalizing the name change to the EP001 equipment, as requested by the commenters.

Comment: One commenter recommended a series of clinical labor times that were higher than the RUC's recommendations. The commenter stated that these were the average times required to perform the clinical labor tasks based on their internal time studies.

Response: We are supportive of the submission of additional data that can aid in the process of determining the resources that are typically used to furnish these services. However, because we did not receive data on these specific time studies from the commenter to support these increases above the RUC recommendations, we are not incorporating these changes to clinical labor into the tumor immunohistochemistry codes at this time. We urge interested stakeholders to consider submitting robust data for these and other services.

After consideration of comments received, for CY 2018, we are finalizing the work RVUs for the codes in the tumor immunohistochemistry family as proposed. We are finalizing the direct PE inputs for these codes, as proposed, along with the refinements detailed above in response to the comments.

(41) Cardiac Electrophysiology Device Monitoring Services (CPT Codes 93279, 93281, 93282, 93283, 93284, 93285, 93286, 93287, 93288, 93289, 93290, 93291, 93292, 93293, 93294, 93295, 93296, 93297, 93298, and 93299)

As part of the CY 2016 PFS final rule with comment period (80 FR 70914), several services in this family (reported with CPT codes 93288, 93293, 93294, 93295, and 93296) were identified as potentially misvalued through the high expenditure by specialty screen. Seven of the 21 services in this family involve remote monitoring of cardiovascular devices, and two of these services (reported with CPT codes 93296 and 93299) are valued for PE only. In the CY 2018 PFS proposed rule, we proposed the RUC-recommended work RVUs for the 19 CPT codes in this family that are valued with physician work as follows: 0.65 for CPT code 93279, 0.77 for CPT code 93280, 0.85 for CPT code 93281, 0.85 for CPT code 93282, 1.15 for CPT code 93283, 1.25 for CPT code 93284, 0.52 for CPT code 93285, 0.30 for CPT code 93286, 0.45 for CPT code 93287, 0.43 for CPT code 93288, 0.75 for CPT code 93289, 0.43 for CPT code 93290, 0.37 for CPT code 93291, 0.43 for CPT code 93292, 0.31 for CPT code 93293, 0.60 for CPT code 93294, 0.74 for CPT code 93295, 0.52 for CPT code 93297, and 0.52 for CPT code 93298.

For CPT code 93293, we considered a work RVU of 0.91 (25th percentile survey result) and sought comment on

whether this alternative work RVU would better maintain relativity between single and dual lead pacemaker systems and cardioverter defibrillator services. We considered reducing the work RVU for CPT code 93282 by 0.11 work RVUs and sought comments on whether this alternative value would better reflect relativity between the single and dual lead systems that exist within pacemaker services and within cardioverter defibrillator services. We also noted that there is a difference of 0.10 work RVUs between the RUC-recommended values for CPT codes 93289 and 93282. Therefore, we considered a proportionate reduction for CPT code 93289 to a work RVU of 0.69. For CPT code 93283, we considered a work RVU of 0.91, consistent with the 25th percentile from the survey results, and sought comment on whether this value would improve relativity.

As noted in this section of the final rule, several of the CPT codes (99392, 99294, 99295, 99297, and 99298) reviewed by the RUC in January 2017 involve remote monitoring services for cardiac devices. We agreed with the RUC that these services are difficult to value considering that the monitoring duration (number of days between 30 and 90) and the average number of transmissions vary. We also noted that these codes were surveyed twice, and in both cases the intraservice and total times were considered by the specialty societies to be inconsistent with existing times. The RUC explained that it extrapolated total and intraservice time data for these codes and warned against making comparisons. Without additional information about the methods and sources used for extrapolation, however, we had no basis for assuming the imputed values are of higher quality and/or accuracy than those from the survey. We did not agree, therefore, that survey results should not be used as a point of comparison in the context of other factors, particularly when they are used to support other considerations.

Although we proposed the RUC-recommended work RVUs for each of these CPT codes, we considered alternative values. The RUC recommended a work RVU of 0.31 for CPT code 93293, which is 0.01 work RVUs lower than the existing work RVU for this code. We have concerns that the amount of the reduction in the work RVU recommended by the RUC may not be consistent with the decrease in total time of 7 minutes. We considered an alternative crosswalk for CPT code 93293 (Pm phone r-strip device eval) (5 minutes intraservice time and 13 minutes total time) to CPT code 94726 (Pulm funct tst plethysmograp), which has 5 minutes intraservice time and 15 minutes total time and a work RVU of 0.26. We sought comments on our proposed and alternative valuations for this code.

For CPT code 93294, we considered a work RVU of 0.55, crosswalking from CPT code 76706 (Us abdl aorta screen aaa), and sought comments on whether it would better align with the RUC-recommended service times. We were concerned that a work RVU of 0.60 may not account for the difference between existing service times and the RUC-recommended service times. Similarly, the RUC recommended a work RVU for CPT code 93294 of 0.60, which is 0.05 work RVUs less than the existing work RVU. The total time for furnishing services reported with CPT code 93294 decreased by 10 minutes, however, and we believe this reduction in time may not be appropriately reflected by a decrease of 0.05 work RVUs. Compared to services with similar total and intraservice times, we identified CPT code 76706 (Us abdl aorta screen aaa) as a potentially more appropriate crosswalk. CPT code 76706 has identical intraservice and total service times as CPT code 93294, with a work RVU of 0.55. We sought comments on whether our alternative value would better reflect the time and intensity involved in furnishing this service.

For CPT code 93295, we considered a work RVU of 0.69, crosswalking to CPT code 76586, which has identical intraservice and total times compared to CPT code 93295. We considered using a work RVU of 0.69 to maintain the differential between CPT code 93295 and the work RVU we considered for the previous code in this family (a work RVU of 0.11 for CPT code 93295). We were concerned about the decrease in service time compared to the work RVU. We noted that the existing intraservice time is 22.5 minutes, compared to the RUC-recommended intraservice time of 10 minutes. We sought comments on whether our alternative value would better reflect the time and intensity involved in furnishing this service.

For CPT code 93298, the RUC recommended a work RVU of 0.52, which is unchanged from the current work RVU for this code. We were concerned about that recommendation given the reduction in both intraservice and total time for this service. The intraservice time decreased from 24 to 7 minutes, while total time decreased from 44 to 17 minutes. We acknowledged that the current times for this CPT code and others in this family are extrapolations. However, without additional information about the extrapolation of data from survey results, we question whether the survey results should be excluded from consideration altogether. We considered a work RVU of 0.37 for CPT code 93297, crosswalking to CPT code 96446 (Chemotx admn prtl cavity). We also considered a work RVU of 0.37 for CPT code 93298 based on a crosswalk to CPT code 96446, since the RUC indicated that the work RVUs for CPT codes 93297 and 93298 should be the same. We sought comment on our proposed valuation and whether our alternative valuation would be more appropriate for this code.

We proposed the RUC-recommended direct PE inputs with the following refinements. We proposed to remove 2 minutes for ''review charts'' from CPT codes 93279, 93281, 93282, 93283, 93284, 93285, 93286, 93287, 93288, 93289, 93290, 93291, and 93292 to maintain relativity since it is not typically incorporated for similar PFS codes. We also proposed removing 2 minutes for ''complete diagnostic forms, lab & X-ray requisitions'' for the labor category ''med tech/asst'' (L026A) for these services because we believe the same activity is being performed by labor category RN/LPN/MTA (L037D). We sought comments regarding whether this row was included in error. For the same group of CPT codes, we also proposed standard refinements for the time for equipment items EF023 and EQ198.

We proposed to use the RUC-recommended direct PE inputs and times for all other CPT codes in this family (CPT codes 93293, 93294, 93295, 93296, 93297, 93298, and 93299) without refinement.

Comment: We received several comments requesting that CMS retain the contractor priced status of the PE-only CPT code 93299. In general, commenters opposed to the change were concerned that the amount of payment proposed for this code was too low to adequately reimburse practitioners.

Response: After reviewing the range of current prices established by MACs, we agree with concerns that the proposed rate of 0.77 RVUs corresponds to a low reimbursement relative to the range of payments across localities and states. We concur that there is no need, at this time, to establish a national rate, and we defer to individual MACs to set a reimbursement rate for this CPT code that reflects local populations, supply costs, and practice patterns. For these reasons, we are not finalizing our proposal with respect to CPT code 93299, and this code will remain contractor-priced.

Comment: We received a comment specifically regarding the proposed decrease in work RVUs for CPT code 93295 from 1.29 to 0.74. The commenter maintained that the decrease in work RVUs is inconsistent with the time requirements and focus on patient care required for ongoing review of monitoring reports over a 90-day period. The commenter further noted that the reduction in work RVUs for this code is inconsistent with a shift in paradigm from an office-based patient care model to comprehensive care.

Response: We appreciate the commenters' concerns about the RUC-recommended decrease in work RVUs for this code. However, we note that the survey conducted by the specialty societies as part of the RUC process describes a time period of up to 90 days for this code. For this code, as with many others, these surveys are the best data we have about the time and intensity of work for a particular CPT code, as well as the labor time, supplies, and equipment required in furnishing the service. After consideration of the public comments, we are finalizing a work RVU of 0.74 for CPT code 93295, as proposed. We are also finalizing work RVUs for the remainder of the CPT codes in this family as proposed.

(42) Transthoracic Echocardiography (TTE) (CPT Codes 93306, 93307, and 93308)

In the CY 2016 PFS final rule with comment period (80 FR 70914), CMS identified CPT code 93306 through the high expenditures screen. Subsequently, the RUC reviewed CPT codes 93307 and 93308, in addition to CPT code 93306, as part of this family of codes that describe transthoracic echocardiograms. In the CY 2018 PFS proposed rule, we proposed the RUC-recommended work RVUs for CPT codes 93306 (a work RVU of 1.50), 93307 (a work RVU of 0.92), and 93308 (a work RVU of 0.53), and proposed the RUC-recommended direct PE inputs for CPT codes 93306, 93307, and 93308 without refinement.

For CPT code 93306 (Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler echocardiography), we considered maintaining the CY 2017 work RVU of 1.30. The surveyed total time for this code dropped slightly due to changes in the immediate postservice time. The median preservice and intraservice time remained unchanged.

For CPT code 93307 (Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, without spectral or color Doppler echocardiography), we considered a work RVU of 0.80, crosswalking to services with similar service times (CPT codes 93880 (Duplex scan of Extracranial arteries; complete bilateral study), 93925 (Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study), 93930 (Duplex scan of upper extremity arteries or arterial bypass grafts; complete bilateral study), 93976 (Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; limited study), and 93978 (Duplex scan of aorta, inferior vena cava, iliac vasculature or bypass grafts; complete study)). The surveyed total time dropped 3 minutes (from the intraservice time) compared to the existing service times for this code.

For CPT code 93308 (Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, follow-up or limited study), we considered a work RVU of 0.43, crosswalking to CPT code 93292 (Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; wearable defibrillator system) based on similar service times. The surveyed total time dropped by 5 minutes (from the intraservice time) compared to the existing service times for this code.

For CY 2018, we proposed the RUC-recommended work RVUs for CPT codes 93306, 93307, and 93308 and sought comments on whether our alternative values would have better reflected the time and intensity of these services.

Comment: A few commenters addressed the codes in this family including the RUC. Commenters expressed support for CMS' proposed values.

Response: We appreciate the commenter's support.

After consideration of the comments received that specifically addressed this code family, for CY 2018, we are finalizing a work RVU of 1.50 for CPT code 93306, a work RVU of 0.92 for CPT code 93307, and a work RVU of 0.53 for CPT code 93308, as proposed. We are also finalizing the proposed direct PE inputs without refinement for all codes in this family.

(43) Stress Transthoracic Echocardiography (TTE) Complete (CPT Codes 93350 and 93351)

CPT code 93351 was identified as potentially misvalued and the RUC reviewed CPT code 93350 as part of the same code family. In the CY 2018 PFS proposed rule, we proposed the RUC-recommended work RVUs for CPT codes 93350 (a work RVU of 1.46) and 93351 (a work RVU of 1.75).

We proposed the following refinements to the RUC-recommended direct PE inputs for CPT codes 93350 and 93351. For both codes, we applied the standard formula in developing the minutes for equipment item ED053 (professional PACS workstation), which results in 18 minutes for CPT code 93350 and 25 minutes for CPT code 93351. We also proposed standard clinical labor times for providing preservice education/obtaining consent. We did not propose to include clinical labor time for the task setup scope since there is no scope used in the procedure and we did not agree with the RUC's statement that this replicates 5 minutes in CPT code 93015 when the RN prepares patients for 10-lead ECG. We found that there was no corresponding time of 5 minutes for setup scope in the PE inputs for CPT code 93015. We proposed refinements to the equipment time for ED050 (PACS workstation proxy) for CPT code 93351, consistent with our standard equipment times for PACS Workstation Proxy.

Comment: Commenters generally supported our proposed work RVUs for CPT codes 93350 and 93351, which are remaining unchanged from CY 2017.

Response: We appreciate the feedback from stakeholders and we are finalizing work RVUs for these two codes, as proposed.

Comment: Several commenters, including the RUC, disagreed with our proposed refinements to PE inputs, particularly with regard to changes in the equipment time to conform to established policies for non-highly technical equipment and PACS workstations.

Response: We note that these refinements are in accordance with the standards and formulas for equipment related to direct PE inputs as described in the CY 2015 PFS final rule with comment period (79 FR 67557). Therefore, we are finalizing the PE inputs and refinements for CPT 93350 and 93351 as proposed.

(44) Peripheral Artery Disease (PAD) Rehabilitation (CPT Code 93668)

We have issued a national coverage determination (NCD) for Medicare

coverage of supervised exercise therapy (SET) for the treatment of peripheral artery disease (PAD). Information regarding the NCD can be found on the CMS Web site at *https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=287*. CPT code 93668, currently assigned PROCSTAT N (noncovered service by Medicare), will be payable before the end of CY 2017, retroactive to the effective date of the NCD to implement payment under the NCD.

For CY 2018, we proposed to make payment for Medicare-covered SET for the treatment of PAD, consistent with the NCD, reported with CPT code 93668. For CPT code 93668, we proposed to use the most recent RUC-recommended work and direct PE inputs. We are also sought comment on the coding structure and valuation assumptions. Since the RUC has not reviewed CPT code 93668 since 2001, we sought comments on the direct PE inputs assigned to the code, which appear in the direct PE input database. We also noted that CPT code 93668 is a PE-only code and does not include physician work.

CPT prefatory language states that CPT code 93668 may be separately reported with appropriate E/M services, including office and/or outpatient services (CPT codes 99201 through 99215), initial hospital care (CPT codes 99221 through 99223), subsequent hospital care (CPT codes 99231 through 99233), and critical care services (CPT codes 99291 through 99292). Our understanding of CPT's prefatory language is that these E/M codes may only be billed when review or exam of the patient is medically indicated and must conform to all existing E/M documentation requirements. E/M visit codes should not be billed to account for supervision of SET for the treatment of PAD by a physician or other qualified healthcare practitioner. We sought comments on whether to develop professional coding to reflect the supervision of clinical staff, and on the potential overlap with 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 any distinctions between time spent by clinical staff for CPT code 99211 and time spent by clinical staff for CPT code 93668.

Comment: Commenters were supportive of CMS' proposal to make CPT code 93668 active for CY 2018 and payable before the end of CY 2017, retroactive to the effective date of the NCD, to facilitate separate payment for SET. The RUC responded to CMS' request for comment on the coding structure and the valuation assumptions by stating that it intends to work with the specialty societies through the CPT Editorial Panel and the RUC process to evaluate both. The RUC recommended maintaining current PE inputs until they provide recommendations for CY 2019.

Response: We will be maintaining the current PE inputs until we receive a new recommendation from the RUC.

Comment: One commenter stated that advanced practice providers, such as nurse practitioners, clinical nurse specialists, or physician assistants, should be able to refer patients for SET. This commenter noted that these practitioners are often relied up to provide referrals and education for patients.

Response: Under the conditions of the NCD, beneficiaries must have a face-to-face visit with the physician responsible for the overall PAD treatment to obtain a referral for SET.

After consideration of these public comments, we are finalizing the RUC-recommended values for CPT code 93668, as proposed.

(45) INR Monitoring (CPT Codes 93792 and 93793)

In October 2015, AMA staff assembled a list of all services with total Medicare utilization of 10,000 or more that have increased by at least 100 percent from 2008 through 2013, and these services were identified on that list. The RUC recommended that HCPCS codes G0248, G0249 and G0250, which describe related INR monitoring services, be referred to the CPT Editorial Panel to create Category I codes to describe these services.

For CY 2018, the CPT Editorial Panel is deleting CPT codes 99363 and 99364 and creating new CPT codes 93792 (Patient/caregiver training for initiation of home INR monitoring under the direction of a physician or other qualified health care professional, including face-to-face, use and care of the INR monitor, obtaining blood sample, instructions for reporting home INR test results, and documentation of patient's/caregiver's ability to perform testing and report results) and 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). CPT code 93792 is a technical component-only code. With the creation of CPT codes 93792 and 93793, the RUC recommended that CMS delete HCPCS codes G0248, G0249 and G0250.

For CPT code 93793, we proposed the RUC-recommended work RVU of 0.18. Because HCPCS codes G0248, G0249 and G0250 are used to report related services under a Medicare National Coverage Determination, we did not propose to delete the G-codes.

In reviewing the recommended PE inputs for these services, we obtained updated invoices for prices for particular items. We proposed to use the invoices to update the price of the supply ''INR test strip'' (SJ055). We obtained publically available pricing information from two vendors. The pricing from one vendor indicated the price for a box of 24 of supply item SJ055 item (INR test strip) is $150.00, which equated to a unit price of $6.25. Pricing from a second vendor indicated the price of a box of 48 of the supply item SJ055 to be $233.00, which equated to a unit price of $5.06. The average price of these two unit prices is $5.66.

Therefore, we proposed to re-price SJ055 from $21.86 to $5.66 for CPT code 93792. We sought public comments on current pricing for the INR test strip supply.

Comment: In general, commenters were supportive of our proposal of the RUC-recommended work RVUs.

Response: We appreciate the commenters' feedback. We continue to welcome information from all interested parties regarding valuation of services for consideration through our rulemaking process.

Comment: The RUC noted that it agreed with CMS' proposal to update the price of the thirteen supplies and one equipment item listed on Table 14: CY 2018 Proposed Rule Invoices Received for Existing Direct PE Inputs of the CY 2018 proposed rule (82 FR 34078).

Response: We thank the RUC for its support and note that the re-price of supply item SJ055 was included in Table 14: CY 2018 Proposed Invoices Received for Existing Direct PE Inputs of the CY 2018 proposed rule (82 FR 34078).

Comment: A commenter disagreed with our proposed re-pricing of SJ055, noting that it would result in an RVU reduction of almost 50 percent for HCPCS codes G0248 and G0249, which would adversely impact access to these services.

This commenter discussed ''home-use'' vs ''professional-use only'' INR test strips, noting that the method CMS used to re-price SJ055 was incorrect because

the pricing information was based on two vendors who were selling ''professional-use only'' strips in units of 24 and 48. The commenter provided publicly available pricing information and recommended that we re-price the INR test strip to $20.31 per unit, inclusive of $1.85 per unit for shipping.

Response: In reviewing the publicly available pricing information provided by the commenter, the price for a box of 6 INR test strips was noted at $110.79, which equated to $18.46 per test strip. We note that the product did not make a distinction of ''home-use'' or ''professional-use only''. Furthermore, this was the same product we used to propose to re-price the INR test strip, but in a smaller quantity. Because we believe it is reasonable to assume that an efficient practice would be more likely to purchase the same supply in a larger quantity in order to take advantage of a significantly lower unit price for that supply, we are not including this price in our valuation of the INR test strip.

Furthermore, given that beneficiaries are generally responsible for paying cost-sharing, the re-price of $20.31 recommended by the commenter would increase beneficiary cost-sharing. Also, as discussed in the CY 2017 PFS final rule (81 FR 80525), after reviewing the public comments in response to the CY 1998 PFS proposed rule, we finalized in Phase I significant revisions with respect to the scope of the volume or value standard. We revised our interpretation of the ''volume or value'' standard for purposes of section 1877 of the Act to permit, among other things, payments based on a unit of service, provided that the unit-based payment is fair market value and does not vary over time (66 FR 876 through 879).

Comment: Several commenters noted that the RVUs used to support the ongoing provision of INR Test Materials/Equipment (that is, G0249) are based on the patient producing 4 test results and not the IDTF simply providing 4 test strips. These commenters recommended the inclusion of 6 to 7 or more test strips for this service. One commenter noted that in order to produce 4 test results, IDTFs must provide a sealed vial of 6 test strips and that two additional strips are used to allow patients to re-confirm critical out of range (or aberrant) test results before their physician alters therapy.

Response: The commenter did not provide, nor were we able to find, documentation to support the requirement for a sealed vial of 6 test strips.

After consideration of the comments received, we will finalize the re-price of SJ055 as proposed, and increase the number of INR test strips by two as recommended by commenters.

Comment: One commenter noted that the supply ''INR test strip'' (SJ055) is categorized as ''Pharmacy, Non-Rx'' but should be more accurately categorized as ''Pharmacy, Rx''.

Response: Historically, this supply item has been categorized as ''Pharmacy, Non-Rx''. We note that the internal use of this categorization does not have an impact on how this supply is priced under the PFS.

After consideration of the comments received, we will finalize the re-price of SJ055 as proposed, but will increase the number of INR test strips by two, as recommended by commenters. We will also increase the number of lancets and alcohol swab-pads by two each, which we believe are typically used to furnish this service. For CPT code 93793, we are finalizing the RUC-recommended work RVU of 0.18 for CY 2018, as proposed.

(46) Pulmonary Diagnostic Tests (CPT Codes 94621, 94617, and 94618)

CPT code 94620 was identified as part of a screen of high expenditure services with Medicare allowed charges of $10 million or more that had not been recently reviewed. CPT code 94621 was added to the family for review. The CPT Editorial Panel deleted CPT code 94620 and split it into two new codes, CPT codes 94617 and 94618, to describe two different tests commonly performed for evaluation of dyspnea. We proposed the RUC-recommended work RVUs of 1.42 for CPT code 94621, 0.70 for CPT code 94617, and 0.48 for CPT code 94618.

We proposed to refine the clinical labor time for the ''Provide preservice education/obtain consent'' activity from 10 minutes to 5 minutes for CPT code 94621, which is the current time assigned for this task. While we agree that CPT code 94621 requires additional time above the standard for this clinical labor activity, we do not believe that double the current time would be typical for this procedure. We also proposed to refine the clinical labor time for the ''Prepare and position patient/monitor patient/set up IV'' activity from 5 minutes to 3 minutes for the same code. The standard time for this activity is 2 minutes, and we proposed a value of 3 minutes to reflect 1 minute of additional preparation time above the standard. We believed that additional clinical labor time used for preparation would be included under the 10 minutes assigned to the ''Prepare room, equipment, supplies'' activity for this code.

We proposed to refine the clinical labor time for the ''Complete diagnostic forms, lab & X-ray requisitions'' activity, consistent with the standard clinical labor time for this activity. We also proposed to refine the equipment times for CPT codes 94621 and 94617 to account for 1:4 patient monitoring time, and to refine the equipment times for CPT code 94618 consistent with standards for non-highly technical equipment.

We considered refining the clinical labor time for the ''pre exercise ECG, VC, Min Vent. Calculation'' activity from 27 minutes to 15 minutes for CPT code 94621. We considered proposing this value of 15 minutes based on assigning 5 minutes apiece for the ECG, the MVV, and the spirometry. We believed that each of these three components of this clinical labor activity would typically take no longer than 5 minutes based on a comparison to the use of these tasks in other CPT codes. We also considered refining the clinical labor time for the ''Clinical staff performs procedure'' activity from 55 minutes to 35 minutes for CPT code 94617 and from 14 minutes to 12 minutes for CPT code 94621. The RUC-recommended materials for the PE inputs state that this clinical labor task consists of performing 5 spirometries at 9 minutes each plus 10 minutes of exercise time for CPT code 94617; we believed that the spirometries typically take 5 minutes each, which would reduce this activity from 55 minutes to 35 minutes. For CPT code 94621, we considered maintaining the current value of 12 minutes due to a lack of justification for increasing the time to 14 minutes.

While we remained concerned about the intraservice period clinical labor times, for CY 2018, we proposed the RUC-recommended work RVUs for each code in this family and sought comment on whether our alternative clinical labor times would better reflect the work and times for these services.

Comment: The commenters supported the proposed values for all three of the codes but disagreed with the alternative values.

Response: We continue to welcome information from all interested parties regarding valuation of services for consideration through our rulemaking process. We will continue to consider alternative work RVUs as we propose the valuation of services for future notice and comment rulemaking.

Comment: Several commenters disagreed with the proposal to refine the clinical labor time for the ''Provide preservice education/obtain consent'' activity from 10 minutes to 5 minutes

for CPT code 94621. Commenters stated that the explanation to the patient involves a back and forth discussion that is important for obtaining an accurate test for the patient, and this education cannot be rushed. The commenters indicated that sufficient time for informed consent is also important since exercising to maximal capacity does have risks, including death, and testing may include additional invasive procedures which require additional and adequate explanation to the patient.

Response: We agree that there is an important need for preservice education and that this service requires additional clinical labor time beyond the standard. However, the standard time for this clinical labor activity is 3 minutes, and CPT code 94621 is currently receiving additional time beyond the standard with 5 minutes of allocated clinical labor time. We continue to believe that increasing the clinical labor time for preservice education above the current valuation would not be typical for this procedure.

Comment: Several commenters disagreed with the proposal to refine the clinical labor time for the ''Prepare and position patient/monitor patient/set up IV'' activity from 5 minutes to 3 minutes for the same code. Commenters stated that any breakdown in monitoring or IV access during the test itself adversely impacted the ability to interpret the test due to a lack of full and continuous data, and could also impact the validity of the test if the patient exercise were interrupted for any reason. Commenters explained that it takes more than the standard time to set up patient with 10 ECG leads and a blood pressure cuff, fit the patient with a face mask ensuring tight seal, and position on the bicycle ergometer.

Response: After reviewing this additional information, we agree with the commenters that 5 minutes would be typical to conduct the positioning as described. We are finalizing a clinical labor time of 5 minutes for the ''Prepare and position patient/monitor patient/set up IV'' clinical labor activity for CPT code 94621.

Comment: Several commenters disagreed with the proposal to refine the clinical labor time for the ''Complete diagnostic forms, lab & X-ray requisitions'' activity to 3 minutes, consistent with the standard clinical labor time for this activity. Commenters stated that the technician had to summarize over 40 pages of data and compile reports for physician to interpret, including ECG and spirometries.

Response: We continue to believe that 3 minutes would be typical for three codes, consistent with the standard clinical labor time for this activity. We did not receive any information from the commenters to suggest that the standard clinical labor time would not be typical for these services.

Comment: Several commenters disagreed with the proposed refinements to the equipment time for these three codes. Commenters stated that CMS proposed the use of a 1:4 patient monitoring time rather than the RUC recommended 1:1 time. Commenters explained that patients recover in the testing room, not a separate room, while technologists are cleaning equipment, and therefore the equipment time could not be a 1:4 ratio because the typical procedure environment allowed only one patient in one room.

Response: We believe that the specific refinement comment used for the equipment time in CPT codes 94621 and 94617 (Refined equipment time to conform to established policies for equipment with 4x monitoring time) may have been misinterpreted by the commenters. This specific comment was intended to convey only that the equipment times were adjusted in accordance with our standard equipment time formulas. In the specific context of CPT codes 94621 and 94617, this refinement comment indicated that we did not include the clinical labor time for ''Complete diagnostic forms, lab & X-ray requisitions'' into the equipment times for these two codes, as this clinical labor activity is not part of our standard equipment formula and we do not believe that equipment such as the pulse oximeter would typically be in use while completing forms. Aside from the removal of this single clinical labor activity's time, the proposed equipment time formula for these two codes was the same as the RUC-recommended equipment time formula. We were not conveying a clinical judgment about the use of 1:4 patient monitoring time as opposed to 1:1 patient monitoring time for these services. However, we do note that the RUC's recommendations for CPT codes 94621 and 94617 include the clinical labor activity ''Monitor pt. following procedure/check tubes, monitors, drains, multitasking 1:4'', which led us to believe that 1:4 patient monitoring time was in use for these services. If we were to adopt 1:1 patient monitoring time for these services, we note that this would reduce the equipment times for CPT code 94621 by 22 minutes and for CPT code 94617 by 6 minutes. After consideration of the comments, we are finalizing the 1:4 patient monitoring time.

After consideration of comments received, for CY 2018, we are finalizing the work RVUs for the codes in the pulmonary diagnostic tests family as proposed. We are finalizing the direct PE inputs for these codes as proposed along with the refinements detailed above in response to the comments.

(47) Percutaneous Allergy Skin Tests (CPT Code 95004)

In the CY 2016 PFS proposed rule (80 FR 41706), CPT code 95004 was identified through the high expenditures screen as potentially misvalued. The RUC suggested in its comments on the CY 2016 PFS proposed rule (80 FR 41706), that CPT code 95004 should be removed from the list of potentially misvalued codes because it has a work RVU of 0.01 and that it would serve little purpose to survey physician work for this code. The RUC and CMS previously determined that there is physician work involved in providing this service since the physician must interpret the test and prepare a report. In the CY 2016 PFS final rule with comment period (80 FR 70913), CMS reiterated an interest in the review of work and PE for this service.

We note that our interest in stakeholder review of a particular code should not be considered a directive for survey under the RUC process. We intend to more clearly state our interests in the future, so that under similar circumstances, such effort need not be undertaken based on a mistaken impression. To reiterate, we believed that whether or not a code should be surveyed in response to our interest in receiving recommendations regarding the work RVUs should be at the discretion of the RUC and the specialty societies. In many cases, we have used recommendations developed through means other than surveys in developing RVUs. For example, for many PFS services, the direct PE inputs are the primary drivers of overall RVUs and Medicare payment. In most of these cases, the recommended inputs are not derived from survey data. In some cases, especially for resource-intensive and highly technical services, we have expressed some concern about the lack of survey or other broad-based data that we have relied on in developing rates across the PFS for many years.

For CY 2018, we proposed the RUC-recommended work RVU of 0.01 for CPT code 95004.

Regarding direct PE inputs, we proposed to refine the equipment times for the ''exam table'' (EF023) and the ''mayo stand'' (EF015) to 79 minutes

each to account for clinical 1:4 patient monitoring time. We received invoices with new pricing information for two supplies: SH101 ''negative control, allergy test'' ($5.17) and SH102 ''positive control, allergy test'' ($26.12). Using this information, we proposed a price of $0.03 per test for supply item SH101 and a price of $0.13 per test for supply item SH102.

Comment: In general, commenters were supportive of our proposal of the RUC-recommended work RVUs.

Response: We will continue to consider alternative work RVUs as we propose the valuation of services for future notice and comment rulemaking. We appreciate the commenter's feedback.

Comment: Several commenters noted that they would expect that CMS will phase in reductions for this service.

Response: The payment reductions for CPT code 95004 are subject to the phase-in. We note that the CY 2018 PFS Final Rule List of Codes Subject to Phase-in is available on the CMS Web site under the downloads section of the CY 2018 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-;Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. 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).

After consideration of the comments received, we are finalizing the work RVUs and PE inputs for CPT code 95004, as proposed.

(48) Continuous Glucose Monitoring (CPT Codes 95250, 95251, and 95249)

CPT codes 95250 (Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording) and 95251 (Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report) are used to report the technical and professional component for continuous glucose monitoring. In April 2013, CPT code 95251 was identified through the high volume growth services screen and subsequently this code family was reviewed at the RUC's October 2016 meeting.

For CY 2018, we proposed the RUC-recommended work RVU of 0.70 for CPT code 95251. However, we were concerned and sought comments on whether the 2 minutes of physician preservice time was necessary. Since CPT code 95251 is typically billed with an E/M service on the same day, we believed the 2 minutes of preservice time may be duplicative. Furthermore, we sought comment on whether it would be typical for the physician to spend 2 minutes to obtain the CGM reports for review since we believed the report would typically be obtained by clinical staff on behalf of the physician.

For the direct PE inputs, the RUC submitted 19 invoices to update the price of the medical supply item ''glucose monitoring (interstitial) sensor'' (SD114) for CPT code 95250. We proposed to use these invoice prices for the glucose monitoring (interstitial) sensor (SD114), with an average cost of $53.08. Therefore, we proposed to use the average price of $53.08 for this supply item.

As part of our review of this service, we obtained publicly available pricing information for the CGM system (EQ125). We reviewed the information provided in a study titled, ''The cost-effectiveness of continuous glucose monitoring in type 1 diabetes,'' (Huang, SE., O'Grady, M., Basu, A. et al., *Diabetes Care.* June 2010), which indicated the price of CGM technology (without sensors) from 3 different vendors, reflective of full retail prices with no insurer discounts, to be $600.00, $1119.00, and $1250.00, which equated to an average cost of $1016.00 for the CGM system. In addition, we obtained publicly available pricing information for two vendors. This information indicated the price of a CGM system to be $1061.90 and $1279.17, which equated to an average cost of $1170.54. For CY 2018, we proposed to price supply items SD114 at $53.08 and EQ125 at $1170.54. We sought comments on current pricing for equipment item ''continuous glucose monitoring system'' (EQ125).

Comment: In general, commenters were supportive of our proposal of the RUC-recommended work RVUs. Some expressed opposition to the alternative work RVUs.

Response: We will continue to consider alternative work RVUs as we propose the valuation of services for future notice and comment rulemaking.

Comment: The RUC noted that the CPT Editorial Panel indicated that the new PE-only CPT code 95249 (Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording), along with CPT codes 95250 and 95251 (with editorial revisions), will appear in the 2018 CPT coding manual. The RUC requested an exemption to CMS's policy to propose values in the proposed rule for all RUC recommendations that we receive by the February 10th deadline each year, and asked that we include CPT code 95249 in the CY 2018 PFS final rule. The RUC recommendations for CPT codes 95250 and 95251 were affirmed without change at the April 2017 RUC meeting. At this same meeting, the RUC developed recommendations for the direct PE inputs for the newly approved CPT code 95249, a PE-only code that is a part of the code family that includes CPT codes 95250 and 95251. The RUC used the direct PE inputs from CPT code 95250 to derive the PE inputs for CPT code 95249 by removing PE inputs that were not applicable to CPT code 95249. Several other commenters also recommended inclusion of CPT code 95249 in the CY 2018 final rule.

Response: We recognize that the CPT Editorial Panel created CPT code 95249, which is part of the family of services described by CPT codes 95250 and 95251, in order to accommodate the different ways in which this service can be furnished and billed. While we continue to believe that the process we established through rulemaking where we propose values in the PFS proposed rule and finalize values in the PFS final rule is suitable for the vast majority of services that we price on the PFS, we believe there is merit to the RUC's request so that we can ensure relativity within this code family.

Comment: The RUC noted that it agreed with CMS' proposal to update the price of the 13 supplies and one equipment item listed on Table 14: CY 2018 Proposed Rule Invoices Received for Existing Direct PE Inputs of the CY 2018 proposed rule (82 FR 34078).

Response: We appreciate the commenter's feedback.

After consideration of the comments received, we are finalizing the work RVUs and PE inputs for CPT codes 95250 and 95251, as proposed. We are also finalizing the PE inputs for CPT code 95249 and will include this code in the CY2018 Medicare Physician Fee Schedule.

(49) Parent, Caregiver-Focused Health Risk Assessment (CPT Codes 96160 and 96161)

In the CY 2017 PFS final rule (81 FR 80330), we discussed that in October 2015, the CPT Editorial Panel created two new PE-only codes, CPT code 96160 (Administration of patient focused health risk assessment instrument (*e.g.,* health hazard

appraisal) with scoring and documentation, per standardized instrument) and CPT code 96161 (Administration of caregiver-focused health risk assessment instrument (*e.g.,* depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument). We assigned an active payment status to both codes for CY 2017 and finalized use of the RUC recommended values for these codes. We also assigned an add-on code status to both of these services. As add-on codes, CPT codes 96160 and 96161 describe additional resource components of a broader service furnished to the patient that are not accounted for in the valuation of the base code. The RUC submitted updated recommendations for the direct PE inputs for CPT codes 96160 and 96161 after reviewing new specialty society surveys. The RUC recommended 7 total minutes of clinical staff time, and we proposed to adopt this number of minutes in valuing the services. The PE worksheet included several distinct tasks with minutes for each; however, in keeping with the standardization of clinical labor tasks, we proposed to designate all 7 minutes under ''administration, scoring, and documenting results of completed standardized instrument'' rather than dividing the minutes into the four categories as shown in the RUC recommendations.

Comment: One commenter noted that they appreciate CMS' review of these services and agreed with the refinement to aggregate the four clinical activities into one direct PE input.

Response: We appreciate the comment.

After consideration of the public comment, we are finalizing the direct PE inputs for CPT codes 96160 and 96161, as proposed.

(50) Chemotherapy Administration (CPT Codes 96401, 96402, 96409, and 96411)

In the CY 2016 PFS proposed rule, CPT codes 96401 (Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic), 96402 (Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic), 96409 (Chemotherapy administration; intravenous, push technique, single or initial substance/drug), and 96411 (Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)) were identified through the high expenditure services screen across specialties with Medicare allowed charges of over $10 million.

For CY 2018, we proposed the RUC-recommended work RVUs of 0.21 for CPT code 96401, 0.19 for CPT code 96402, 0.24 for CPT code 96409, and 0.20 for CPT code 96411.

For CPT code 96402, we proposed the RUC-recommended equipment times with refinements for the biohazard hood (EP016) and exam table (EF023) from 31 minutes to 34 minutes to reflect the service period time associated with this code. We proposed the RUC-recommended direct PE inputs for CPT codes 96401, 96409, and 96411 without refinements.

Comment: In general, commenters were supportive of our proposal of the RUC-recommended work RVUs and RUC-recommended PE inputs for these services. One commenter noted that maintaining the recommended physician work RVUs will promote fair and adequate reimbursement and protect patient access.

Response: We appreciate the commenter's feedback.

Comment: One commenter noted that there are no acuity adjustments for chemotherapy or infusion services. The commenter further noted that CMS could enact site-of-service neutrality for payment of these codes in addition to adding acuity adjustment modifiers to reflect more intensive care given to some patients.

Response: We refer readers to section II.G. of this final rule for more information on site neutrality regarding payment rates under the Medicare physician fee schedule for nonexcepted items and services furnished by nonexcepted off-campus provider-based departments of a hospital. With regard to acuity adjustments for chemotherapy or infusion services, we will consider whether to propose such adjustments in future notice and comment rulemaking.

Comment: Several commenters supported our proposed equipment times for the biohazard hood and the exam table to reflect the service period time associated with CPT code 96402. One commenter noted support for our proposal of the RUC-recommended PE inputs for the other three services in this code family.

Response: We appreciate the comments. We note that the PE inputs for these services are displayed in the CY 2018 PFS final rule direct PE input database, available on the CMS Web site under the downloads for the CY 2018 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Comment: Several commenters expressed concern with our proposed reductions in payment for many drug administration codes. Commenters stated that the payment for CPT code 96402 would be reduced by almost 12 percent and that these reductions could harm access to care, especially in rural settings, and they urged CMS not to implement them. Furthermore, they noted that if CMS implemented the proposed payment reductions, that it would be essential to monitor patient access to care.

Response: We share the concern of the commenters in maintaining access to care for Medicare beneficiaries. We continue to carefully consider the impact that our valuation of these services will have on beneficiary access to care. We note that we believe that improved payment accuracy under the PFS generally facilitates access to reasonable and necessary physicians' services. The statute requires us to establish payments under the PFS based on national uniform RVUs that account for the relative resources used in furnishing a service. We proposed the RUC-recommended PE inputs for this family of services, which were based on the expertise of the RUC. We believe that the RUC recommendations appropriately reflect the resource costs of furnishing the services and thus would result in appropriate valuation of these services.

Comment: One commenter noted the importance of ensuring that chemotherapy treatments are funded and allowed to continue in order to sustain life.

Response: We are appreciative of the commenter's perspective and share the commenter's concern in maintaining access to care for Medicare beneficiaries. We did not make any proposals and are not finalizing any policies to limit Medicare coverage of these services. These services will be payable under the PFS for CY 2018.

Comment: One commenter noted that it was aware that CMS is researching how to minimize payment differentials between hospital-based infusion centers and practice infusion centers. The commenter also noted that the coding nomenclature used for both chemotherapy and infusion services do not have acuity adjustments. Another commenter noted that the RVU supervision credit is only given for practice-based infusion centers and not when the service is provided in the facility, where many of these complicated infusions take place. They noted that RVU supervision of these chemotherapy and infusion services

should be usable by both providers and facility providers.

Response: For more information on how CMS is researching how to minimize payment differentials between hospital-based infusion centers and practice infusion centers, we refer readers to section II.G of this final rule for more information on payment rates under the Medicare physician fee schedule for nonexcepted items and services furnished by nonexcepted off-campus provider-based departments of a hospital.

After consideration of comments received, we are finalizing the work RVUs and PE inputs for CPT codes 96401, 96402, 96409, and 96411, as proposed.

(51) Photochemotherapy (CPT Code 96910)

CPT code 96910 appeared on a high expenditure services screen across specialties with Medicare allowed charges of over $10 million. It is a PE-only code that does not have a work RVU.

We proposed to refine the clinical labor time for the ''Provide preservice education/obtain consent'' activity from 3 minutes to 1 minute for CPT code 96910. We believed that 1 minute would be typical for patient education, as CPT code 96910 is a repeat procedure where there would not be a need to obtain consent again. We also proposed to remove the 2 minutes of clinical labor for the ''Complete diagnostic forms, lab & X-ray requisitions'' activity, as this item is considered indirect PE under our established methodology. We proposed to create a new supply code (SB054) for the sauna suit, and proposed to price at $9.99 based on the submitted invoice. Finally, we also proposed to adjust the equipment times to reflect changes in the clinical labor for CPT code 96910.

We proposed the RUC-recommended clinical labor time of 15 minutes for the ''Prepare and position patient/monitor patient/set up IV'' activity, the RUC-recommended clinical labor time of 16 minutes for the ''Monitor patient during procedure'' activity, and the RUC-recommended clinical labor time of 15 minutes for the ''Clean room/equipment by physician staff'' activity, but we sought additional information regarding the rationale for these values. Given the lack of explanation, we considered using the current clinical labor time of 7 minutes for the ''Prepare and position patient/monitor patient/set up IV'' activity, the current clinical labor time of 4 minutes for the ''Monitor patient during procedure'' activity, and the current clinical labor time of 10 minutes for the ''Clean room/equipment by physician staff'' activity. We sought comment on whether maintaining the current values would improve relativity.

We considered removing the ''Single Patient Discard Bag, 400 ml'' (SD236) supply and replacing it with the ''biohazard specimen transport bag'' (SM008). We were concerned about whether the single patient discard bag is the appropriate size for storing the sauna suit used in this procedure, and whether use of a biohazard specimen transport bag would be typical. We sought comments on our proposed and alternative values for these direct PE inputs.

Comment: Several commenters supported the proposed values for CPT code 96910 but disagreed with the alternative values.

Response: We continue to welcome information from all interested parties regarding valuation of services for consideration through our rulemaking process.

Comment: One commenter disagreed with the proposal to refine the clinical labor time for the ''Provide preservice education/obtain consent'' activity from 3 minutes to 1 minute. The commenter stated that the preservice education needed for this procedure takes longer due to the nature of the procedure, as the staff needs to provide very specific instructions to insure the safety and comfort of the patients while they are in the ultraviolet treatment unit receiving treatment.

Response: After reviewing this additional information, we agree with the commenter that 3 minutes would be typical to conduct the preservice education as described. Therefore, we are finalizing a clinical labor time of 3 minutes for the ''Provide preservice education/obtain consent'' clinical labor activity for CPT code 96910.

Comment: One commenter disagreed with the proposal to remove the 2 minutes of clinical labor time for the ''Complete diagnostic forms, lab & X-ray requisitions'' activity. The commenter stated that the subjective, objective, assessment, and plan notes needs to be completed for each patient.

Response: We agree with the commenter that these diagnostic forms need to be filled out for each patient. However, this activity is considered indirect PE under our established methodology and is included in the administrative costs of the service. Filling out forms or restocking shelves are necessary tasks, but they are not individually allocable to a service and therefore fall under the category of indirect PE.

Comment: One commenter disagreed with the proposal to adjust the equipment times to reflect changes in the clinical labor. The commenter did not provide a rationale for this disagreement, other than restating its opposition to the removal of the clinical labor time and the other proposed refinements.

Response: Over the past decade, the increasing standardization of clinical labor tasks has resulted in greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. We currently utilize a series of standard formulas for equipment time, which are calculated based on the clinical labor activities in which the equipment would typically be in use. When the clinical labor for a procedure is altered in response to a proposal, we will typically alter the equipment time for that procedure as well to reflect the changes in clinical labor time, assuming of course that the equipment in question would typically be utilized during that clinical labor activity. We proposed to decrease the equipment time for CPT code 96910 in accordance with the changes in the proposed clinical labor time, and we have no reason to believe that the standard equipment time formulas would be inapplicable for this service. We also note that as a result of the increase in the clinical labor time for the ''Obtain vital signs'' activity from 3 minutes to 5 minutes, the final equipment time for everything other than the phototherapy UVB measuring device (EQ203) is 67 minutes, the same equipment time contained in the RUC's recommendations.

After consideration of comments received, we are finalizing the direct PE inputs for CPT code 96910 as proposed, with the exception of the change to the ''Provide preservice education/obtain consent'' clinical labor activity, as detailed above.

(52) Photodynamic Therapy (CPT Codes 96567, 96573, and 96574)

CPT code 96567 was identified as potentially misvalued through a CMS screen for codes with high expenditures. This code describes a service furnished by clinical staff and does not include physician work. For CY 2018, the CPT Editorial Panel created two new codes, CPT codes 96573 and 96574, to describe photodynamic therapy by external application of light to destroy premalignant skin lesions, including the physician work involved in furnishing the service. CPT codes 96567, 96573, and 96574 were reviewed during the RUC's January 2017 meeting.

For CY 2018, we proposed the RUC-recommended work RVUs for CPT

codes 96573 (a work RVU of 0.48) and 96574 (a work RVU of 1.01).

We proposed the RUC-recommended PE inputs with refinements due to inconsistencies between the stated description of clinical activities and the submitted spreadsheets. First, we proposed to add assist physician clinical staff time to CPT codes 96573 (10 minutes) and 96574 (16 minutes), which is equivalent to the physician intraservice times for these services. For both CPT codes 96573 and 96574, we proposed a reduction from 35 minutes to 17 minutes for clinical activity in the postservice time, consistent with the description of clinical work in the summary of recommendations, which states that the patient receives activation of the affected area with the BLU–U Photodynamic Therapy Illuminator for approximately 17 minutes. For CPT codes 96573 and 96574, we proposed to refine equipment formulas for two items: Power table (EF031) and LumaCare external light with probe set (EQ169), consistent with standards for nonhighly technical equipment. An explanation of the standards and formulas for equipment related to direct PE inputs is in the CY 2014 PFS final rule with comment period (79 FR 67557).

Comment: Several commenters, including the RUC, disagreed with our proposal to change the RUC-recommended clinical labor times for CPT 96573 and 96574 due to inconsistencies between the stated description of clinical activities and the submitted spreadsheets. Commenters also noted that Table 11 in the CY 2018 PFS proposed rule did not reflect these changes.

Response: We appreciate commenters' attention to this discrepancy. In the proposed rule, we wrote that we proposed this change, but as commenters pointed out, the proposed refinements were reflected in the data presented in Table 11. We are finalizing the RUC recommended PE clinical labor times for these two CPT codes. We are finalizing our proposal to refine equipment formulas for EF031 and EQ169 for these two CPT codes, in accordance with formula standards.

We identified several vendors with publically available prices for supply item LMX 4 percent cream (SH092) for significantly less than the existing $1.60 per gram. Based on our research of vendors, we proposed to set the price of supply item SH092 to $0.78 per gram. Other CPT codes affected by the proposed change in the price of supply item LMX 4 percent cream (SH092) would be: CPT code 46607 (Anoscopy; with high-resolution magnification (HRA) (*e.g.*, colposcope, operating microscope) and chemical agent enhancement, with biopsy, single or multiple), CPT code 17000 (Destruction (*e.g.*, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (*e.g.*, actinic keratoses); first lesion), CPT code 17003 (Destruction (*e.g.,* laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (*e.g.*, actinic keratoses); second through 14 lesions, each (List separately in addition to code for first lesion)), and CPT code 17004 (Destruction (*e.g.*, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (*e.g.*, actinic keratoses), 15 or more lesions)).

In addition, the RUC forwarded an invoice for a new supply item, safety goggles, at $6.00 and requested three goggles each for CPT codes 96573 and 96574. Because we did not have a basis for distinguishing the requested new goggles from the existing UV-blocking goggles, we considered this invoice to be an additional price point for SJ027 rather than an entirely new item. We proposed a price of $4.10 for supply item SJ027 (the average of the two prices for this supply item ($2.30 + $6.00)/2 = $4.10)). Other CPT codes affected by the proposed change in the price of supply item UV-blocking goggles (SJ027) are: CPT code 36522 (Photopheresis, extracorporeal), CPT code 96910 (Photochemotherapy; tar and ultraviolet B (Goeckerman treatment) or petrolatum and ultraviolet B), CPT code 96912 (Photochemotherapy; psoralens and ultraviolet A (PUVA)), and CPT code 96913 (Photochemotherapy (Goeckerman and/or PUVA) for severe photoresponsive dermatoses requiring at least 4–8 hours of care under direct supervision of the physician (includes application of medication and dressings)), CPT code 96920 (Laser treatment for inflammatory skin disease (psoriasis); total area less than 250 sq cm), CPT code 96921 (Laser treatment for inflammatory skin disease (psoriasis); 250 sq cm to 500 sq cm), and CPT code 96922 (Laser treatment for inflammatory skin disease (psoriasis); over 500 sq cm). We sought comments on our proposed PE refinements, including our proposed supply item prices.

Comment: Commenters generally supported our proposed work RVUs for CPT codes 96573 and 96574. Two commenters disagreed with our proposal to accept the RUC's recommended PE inputs for the existing CPT code 96567. They stated that the staff and equipment times for CPT codes 96567 should mirror the times in CPT code 96573, with the addition of 10 minutes for staff to apply the photosensitizing agent. As currently proposed, the commenters noted that staff times for CPT code 96567 are inadequate to perform the service.

Response: Based on support from commenters on our proposed work RVUs for CPT codes 96573 and 96574, we are finalizing those values as proposed. We thank commenters for their comments regarding clinical labor inputs for CPT code 96567. The RUC provides recommendations regarding clinical labor that are developed through a collaborative process with specialty societies. The RUC did not, in its comment letter, modify recommendations for this CPT code. The RUC has a process for identifying potentially missing clinical labor time, and we encourage commenters to work in concert with the RUC to resolve those concerns.

Comment: One commenter questioned whether the CPT Editorial Panel should have used the same code number as an existing service, rather than a new one, to describe the revised service for CPT code 96567.

Response: In certain circumstances, we may find it necessary to deviate from the CPT Editorial Panel's decisions. However, we note that CMS does not direct the CPT Editorial Panel and we encourage the commenter to follow the panel's established process for reviewing CPT codes and descriptors.

Comment: A few commenters questioned our proposal to refine equipment times to confirm to standard formulas. In particular, they maintained that the equipment time for the power table should not be refined because the patient has to stay on the table during the illumination period and the room is not available for other patients' use.

Response: We agree that the power table may be required throughout the illumination period, and we would consider the recommendation if there were additional information explaining why equipment time for the power table included the entire service time plus 3 additional hours. However, the total time for the power table formula of 230 minutes and 232 minutes for CPT codes 96573 and 96574, respectively, was not consistent with the narrative accompanying the recommendation. In the narrative for both CPT codes, illumination of the affected area is approximately 17 minutes with no specific amount of time for incubation provided. In the absence of additional information explaining why the times are needed, we are finalizing our

proposed refinement for this and two other equipment items.

Comment: We received several comments about our proposal to reduce the price for supply item LMX 4 percent cream (SH092) from $1.60 to $0.78. We also received comments about our proposal to blend the prices of two types of goggles, SJ027 and SD326.

Response: We discuss these supply items and prices in detail in section II.B of this final rule.

(53) Physical Medicine and Rehabilitation (PM&R) (CPT Codes 97012, 97016, 97018, 97022, 97032, 97033, 97034, 97035, 97110, 97112, 97113, 97116, 97140, 97530, 97533, 97535, 97537, 97542, and HCPCS Code G0283)

In our CY 2015 PFS final rule with comment period (79 FR 67576) and CY 2016 PFS final rule with comment period (80 FR 70917), we identified a total of ten codes through the high expenditure by specialty screen for services primarily furnished by physical and occupational therapists: CPT codes 97032, 97035, 97110, 97112, 97113, 97116, 97140, 97530, 97535, and HCPCS code G0283. An additional nine codes in this PM&R family were identified for review by the physical therapy (PT) and occupational therapy (OT) specialty societies: CPT codes 97012, 97016, 97018, 97022, 97033, 97034, 97533, 97537, and 97542. Many of these code values had not been reviewed since they were established in 1994, 1995 or 1998.

After review during its January 2017 meeting, the HCPAC submitted recommendations to CMS for all 19 codes. While the HCPAC included recommendations for CPT code 97014, we note that this is a code we have not recognized for PFS payment since 2002 when we implemented our wound care electrical stimulation policies. For payment under the PFS, instead of CPT code 97014, we recognize HCPCS code G0281 for wound care electrical stimulation and HCPCS code G0283 for all other electrical stimulation scenarios, when covered. For CY 2018, we proposed the HCPAC recommendations for CPT code 97014, HCPCS code G0283, and HCPCS code G0281.

CMS considers all 19 codes as ''always therapy'' which means they are always considered to be furnished under a physical therapy (PT), occupational therapy (OT), or speech-language pathology (SLP) plan of care regardless of who furnishes them and the payment amounts are counted towards the appropriate statutory therapy cap—either the therapy cap for PT and SLP services combined, or the single therapy cap for OT services. These ''always therapy'' codes are also subject to the therapy MPPR.

For CY 2018, we proposed the HCPAC's recommended work RVUs for CPT codes 97012, 97016, 97018, 97022, 97032, 97033, 97034, 97035, 97110, 97112, 97113, 97116, 97140, 97530, 97533, 97535, 97537, 97542, and G0283 (97014).

For supervised modality services reported with CPT codes 97012, 97016, 97018, and 97022, and HCPCS code G0283 (97014), we considered maintaining the current values for these codes rather than the HCPAC recommendations. We note that the work times recommended by the HCPAC reflect use of the survey data even though the HCPAC explained in its recommendations that the survey results were not deemed credible because of a lack of evidence to support higher work RVUs of each survey's 25th percentile or median values. We note total time decreases among these codes ranging from 1 to 8 minutes.

While we proposed the HCPAC-recommended work RVUs and work times for each code in this family, we sought comments on whether maintaining the current times, given the HCPAC's lack of confidence in the survey data, would better reflect the work times for these services.

We proposed to maintain the existing CY 2017 PE inputs for all 19 codes. We noted that section 1848(b)(7) of the Act requires a 50 percent therapy MPPR instead of the 25 percent therapy MPPR established during CY 2011 PFS rulemaking. One of the primary rationales for the MPPR policy developed through the rulemaking process was that the direct PE inputs for these services did not fully recognize the redundant inputs when these services were furnished together, or in multiple units. After reviewing the recommended direct PE inputs, it was evident that they were developed based on an acknowledgement of the efficiencies of services typically furnished together as well as codes billed in multiple units. Given this assessment, we believed that were we to use the recommended inputs to develop the PE RVUs, the 50 percent MPPR on the PE for these services, as required by current law, would functionally duplicate the payment adjustments to account for efficiencies that had already been addressed through code-level valuation. Therefore, for CY 2018, we proposed to retain the existing CY 2017 PE inputs for these services and sought comments on whether there is an alternative approach that would avoid duplicative downward payment adjustments while still allowing for the direct PE inputs to be updated to better reflect current practice.

We noted that we believed that the always therapy codes subject to the therapy MPPR on PE are unique from other therapeutic and diagnostic procedure codes paid under the PFS and subject to MPPRs. For example, unlike most surgical services, these ''always therapy'' codes are typically billed either with other therapy codes or in multiple units, or both. Generally, MPPRs are used when codes are often, but not typically, furnished with other particular codes. When full sets of related codes are almost all typically billed with other codes, or billed in multiple units, coding and valuation have changed to reflect these practices. For example, new codes have been introduced to describe combined services or some related services are described by add-on codes. In other cases, the MPPR is considered in the valuation for individual services.

The following is a summary of public comments received on our proposal to accept the HCPAC-recommended work RVUs for all 19 PM&R codes and the request for comment for the supervised modality codes—CPT codes 97012, 97016, 97018, and 97022, and HCPCS code G0283 (97014)—to alternatively not accept the work times:

Comment: We received many comments all of which were in support of our proposal to accept the HCPAC-recommended work RVUs for the 19 PM&R codes that includes an increase in work RVUs for six of the codes. The majority of commenters disagreed with the alternative we considered to retain the current work times associated with the five supervised modality services, while one commenter agreed. The HCPAC and other commenters disagreed and asked us to maintain the proposed recommendations in this final rule because they noted that the survey's 25th percentile time for each of these codes more accurately reflects the time necessary to perform the service and takes into account efficiencies based on the typical number of services reported per session. One commenter asked us to keep the current time values for the supervised modality services reported with CPT codes 97012, 97016, 97018, and 97022, and HCPCS code G0283 (97014) and not accept the HCPAC's proposed time values and offered several clinical scenarios for some of the supervised modality services they believe demonstrate the need for maintaining the current time values for these services.

Response: We appreciate the many commenters who supported our

proposal to accept the work RVU recommendations we received from the HCPAC for the 19 PM&R codes. While we appreciate the various comments we received on our alternative consideration to retain the times associated with the work RVUs for the supervised modality codes, we are finalizing our proposal to accept the work RVUs, including the times, for all 19 PM&R codes.

The following is a summary of the public comments received as to whether there is an alternative approach to our proposal to retain the CY 2017 direct PE inputs for always therapy codes that would avoid duplicative downward payment adjustments while still allowing for the direct PE inputs to be updated to better reflect current practice and our responses:

Comment: Many commenters agreed with our proposal to maintain the existing 2017 PE inputs for all 19 PM&R codes. A number of these commenters noted the importance of the PE values that reflect the costs of maintaining a therapy practice (such as renting office space, buying supplies and equipment, and staff salary/benefits). Some of these commenters thanked CMS for recognizing that if the recommended inputs to develop the PE RVUs were adopted, the 50 percent MPPR on the PE for these services would duplicate the payment adjustments to account for efficiencies that had already been addressed through the code-level valuation process.

Several other commenters, including the HCPAC, urged us to implement the recommended direct PE inputs. In its comment, the HCPAC assured CMS that the RUC PE Subcommittee understood the 50 percent MPPR and took it into account, in addition to the efficiencies of services billed together, when reviewing the direct PE inputs for these services. The HCPAC noted in its comment letter that the PE inputs were reviewed with the understanding that as a result of the MPPR, a 50 percent reduction is in place for the second and subsequent reporting of a physical medicine and rehabilitation service on the same date of service. The HCPAC comment letter clarified that the PE Subcommittee's recommendations apply to the 22 codes that are subject to the therapy MPPR—the 19 codes in this PM&R section and the three codes for orthotic and prosthetic management services (discussed in the below section).

Response: We are persuaded by the HCPAC's reassurance that the PE Subcommittee took the 50 percent MPPR into consideration during its deliberative process and that the forwarded recommendations reflect the therapy MPPR policy, in addition to the efficiencies of services billed together. Therefore, we will not finalize our proposal to maintain the existing direct PE inputs for therapy codes; instead, we will accept the HCPAC recommendations for the direct PE inputs for the 19 PM&R codes in this section and the three codes discussed in a subsequent section for services related to orthotics and prosthetics management and/or training.

After consideration of comments received, we are finalizing the HCPAC-recommended work RVUs, including the times, for all 19 PM&R codes as proposed. We are also finalizing to accept the HCPAC recommendations for the direct PE inputs for all 19 codes.

(54) Cognitive Function Intervention (CPT Code 97127)

We received HCPAC recommendations for new CPT code 97127 that describes services currently reported under CPT code 97532 (Development of cognitive skills to improve attention, memory, problem solving (includes compensatory training), direct (one-on-one) patient contact, each 15 minutes). CPT code 97532 is scheduled to be deleted for CY 2018 and replaced by CPT code 97127.

The existing code is reported per 15 minutes and the new code is reported once. Under current coding, Medicare utilization for these services is heterogeneous and indicates that practitioners of different disciplines incur significantly different resource costs (especially in time) when furnishing these services to Medicare beneficiaries. As described by both the existing and new code, the service might be appropriately furnished both by therapists under the outpatient therapy (OPT) services benefit (includes physical therapy (PT), occupational therapy (OT) or speech-language pathology (SLP)); and outside the therapy benefit by physicians, certain NPPs, and psychologists. As an OPT service, it can (1) be billed by physicians, certain NPPs, or private practice therapists including physical therapists (PT–PPs), occupational therapists (OT–PPs) and speech-language pathologists (SLP–PPs) in private practice, or (2) be billed by institutional providers (for example, skilled nursing facilities, rehabilitation agencies, outpatient hospitals, etc.) when furnished by therapists working for the institutional providers.

According to the HCPAC, professional claims data indicate that CPT code 97532 was most often billed in 4 units. The HCPAC recommended a work RVU of 1.50 for CPT code 97127, which is only 3.4 times greater than the work RVU for the predecessor code (0.44). Assuming professional billing patterns remain the same, the recommended coding and valuation could result in a significant reduction in overall Medicare payment under the PFS.

However, our analysis of the claims data indicates that the number of units typically reported for the current code suggests a significant difference in the amount of time spent with the patient, depending on which discipline (and implicitly under which benefit) bills Medicare for services described by this single code.

Based on our review of claims data by specialty, SLP–PPs, OT–PPs and PT–PPs furnishing the same services under the OPT benefit would receive overall payment increases due simply to the change in coding because they typically bill for fewer than 4 units, while overall payment for clinical psychologists furnishing therapeutic interventions for cognitive function would decrease because they typically bill in units of four or more.

We sought additional information regarding the potential impact of this coding and payment change prior to proposing its use under the PFS. For CY 2018, we proposed to maintain the current coding and valuation for these cognitive function services. If the CPT Editorial Panel deletes the existing CPT code for CY 2018, we would effectuate this proposal through use of a new a HCPCS code G-code, G0515, which would maintain the descriptor and values from existing CPT code 97532. Under this proposal, new CPT code 97127 would be given a procedure status of ''I'' (Invalid for Medicare).

We also noted that this change in coding and payment could have significant impact for payment to Medicare institutions for OPT services. Under section 1834(k) of the Act, when reported by Medicare institutional providers, OPT services are paid at PFS non-facility payment rates. Institutional claims data for CPT code 97532 when furnished by the three therapist disciplines show a much higher utilization overall than that for professional claims, but significantly fewer 15 minute units reported. This suggests that outpatient therapy professionals generally spend significantly less time with patients in the institutional setting. Use of the new CPT code could, therefore, result in significant additional expenditure to the Medicare program, as well as other payers, including Medicaid programs, based on the change in coding alone.

The following is a summary of the public comments received on additional information regarding the potential impact of this coding and payment change prior to its use under the PFS and our responses:

Comment: The HCPAC and other commenters—after considering CMS concerns and an independent review and analysis conducted by the speech-language pathology specialty of Medicare Part B facility-based claims (using the Medicare 5% Limited Data Set (LDS)) that confirmed the same variable billing patterns and higher utilization of CPT code 97532—generally agreed with our proposal to create HCPCS code G0515 instead of recognizing CPT code 97127 in the short term and encouraged us to work with stakeholders, including the AMA, on a more permanent coding solution. These same commenters had expressed concern that CMS did not use the data in the same way as the HCPAC and RUC to determine the typical units billed, and that moving forward, they would be interested to work with CMS to identify exceptional procedure codes such as this one where the more commonly used database may be misleading.

Response: We agree that the untimed CPT code 97127 designed to replace the 15-minute timed CPT code 97532 represents an ''exceptional'' procedure code, primarily because it would be covered and paid by Medicare under two separate benefits—one for medical services and the other for OPT services. It is this uniqueness that prompted us to examine the differing billing patterns of the various practitioners furnishing these cognitive therapy services as well as the overall utilization in all the settings it is reported. Because CPT code 97127 would have been reported by institutional providers of OPT services and typical units in a same-day billing file is not available, our review required us to look at the average units reported by each therapy discipline. We appreciate the work of the SLP and psychology specialties in completing the HCPAC survey process for CPT code 97127, and we thank the HCPAC and the specialty societies for recognizing our necessity to develop HCPCS code G0515 to report these cognitive therapy services.

Comment: One commenter expressed concern that our proposal to create HCPCS code G0515 instead of adopting CPT code 97127 would result in confusion for providers that would have two different codes to report for cognitive therapy services: One for Medicare and another for private payers. The commenter requested that we use CPT code 97127, perhaps with modifiers to account for billing pattern differences, unless CMS commits to extensive outreach services to the provider community.

Response: If we were to adopt the new coding and higher payment for CPT code 97127, instead of creating HCPCS code G0515 to maintain current coding and valuation for these services as we proposed, we acknowledge that the institutional providers of OPT services such as those represented by this commenter would benefit the most from the untimed nature of CPT code 97127, assuming current billing patterns and resource use, since therapists in these settings typically furnish these services in fewer units. We note that private payers have the option to adopt our G-codes for reporting purposes. In addition, the coding we proposed for HCPCS code G0515 is identical to that which Medicare providers have used in the past for these cognitive therapy services. As with all new therapy codes, we will address changes to the 2018 therapy code list made in this CY 2018 PFS final rule in an upcoming Change Request (CR) for the 2018 Annual Update to the Therapy Code List, CR 10303, which will be available on the 2017 Transmittals Web page at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017-Transmittals.html*.

Comment: The HCPAC and other commenters pointed out that the description of HCPCS code GXXX1 listed in Table 10: Proposed CY 2018 Work RVUs for New, Revised and Potentially Misvalued Codes of the proposed rule, (82 FR 34021) does not reflect CMS' intent to maintain the descriptor for CPT code 97532.

Response: We thank the commenters for notifying us about the incorrect descriptor for GXXX1 that we inadvertently included in Table 10 of the CY 2018 PFS proposed rule (82 FR 34021). The correct descriptor for GXXX1/G0515 in that table should have been the same as that for the prior CPT code 97532 that we defined and included in our discussion as: Development of cognitive skills to improve attention, memory, problem solving (includes compensatory training), direct (one-on-one) patient contact, each 15 minutes.

Comment: The HCPAC and other commenters expressed concern about CMS' refinement of PE inputs for CPT code 97127, contending that the agency lacked a rationale for the refinements shown in Table 11—CY 2018 Proposed Codes with Direct PE Input Recommendations with Refinements. These commenters encouraged CMS to either use the existing PE inputs in CPT code 97532 for HCPCS code G0515 or more closely mirror the PE refinements that were forwarded by the HCPAC for CPT code 97127 to those for CPT code 97532. The commenters noted that any changes that result in significant deviations from current PE inputs should not be implemented absent another review of cognitive therapy services through the HCPAC valuation process.

Response: We thank the commenters for informing us that Table 11 contained PE input refinements for CPT code 97127. Their inclusion in Table 11 was inadvertent given that we proposed to retain the same valuation of CPT code 97532 for HCPCS code G0515 and not to recognize CPT code 97127 for Medicare purposes.

Comment: One commenter asked us to provide greater insight as to what we believe would comprise an effective permanent coding solution that permits sufficient coverage of and fair payment for these cognitive therapy services when furnished to outpatients in both the professional office and facility-based settings.

Response: CMS' typical role is to review the codes forwarded to us from the RUC and HCPAC and to agree or disagree with those valuations. Through the review and analysis necessary for valuation purposes, we have at times found it necessary due to Medicare programmatic concerns to create our own G-code instead of recognizing the code sent to us, as we did in the case of the untimed code, CPT code 97127. This code, which represents services that are utilized and reported under two separate benefits—medical services and outpatient therapy services—the latter of which can be billed by facility-based providers on institutional claims when furnished by qualified therapists, or on professional claims by therapists in private practice, physicians, or certain NPPs (NPs, PAs, CNSs)—presents an unusual coding challenge. Other than what has been already discussed in this rulemaking process, we do not believe we are in a position to provide additional insight to a permanent code that the HCPAC has not yet forwarded to us.

After consideration of the public comments, we are finalizing our proposal to create HCPCS code G0515 to mirror the coding and valuation of existing CPT code 97532, instead of adopting CPT code 97127. We will assign CPT code 97127 a status indicator of ''I'' to indicate that it is ''Invalid'' for Medicare policy and payment purposes.

We have designated HCPCS code G0515 a as ''sometimes therapy'' code,

which means that an appropriate therapy modifier—GN, GO or GP, to reflect that it is under an SLP, OT, or PT plan of care—is always required when this service is furnished by therapists; and, when it is furnished by or incident to physicians and NPP when the services are integral to an SLP, OT, or PT plan of care. Accordingly, HCPCS code G0515 is sometimes appropriately reported by physicians, NPPs, and psychologists without a therapy modifier when it is appropriately furnished outside an SLP, OT, or PT plan of care. When furnished by psychologists, the services of HCPCS code G0515 are never considered therapy services and may not be reported with a GN, GO, or GP therapy modifier.

(55) Management and/or Training: Orthotics and Prosthetics (CPT Codes 97760, 97761, and 977X1)

For CY 2018, the CPT Editorial Panel revised the set of codes that comprise the CPT manual's PM&R subsection for orthotic management and prosthetic management at its September 2016 meeting. According to the CPT Editorial Panel, these revisions were made at the request of the specialty societies representing physical and occupational therapists to differentiate between the initial and subsequent encounters and to describe the ongoing management and/or training that is involved in subsequent encounters. These changes include:

- Revising the code descriptors by adding the term ''initial encounter'' to CPT code 97760 (Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes), and CPT code 97761 (Prosthetic(s) training, upper and/or lower extremity(ies), initial prosthetic(s) encounter, each 15 minutes);
- Creating a new CPT code 977X1 (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); and
- Deleting CPT code 97762 (checkout for orthotic/prosthetic use, established patient, each 15 minutes).

Intended for the management and/or training of patients with orthotics and/or prosthetics, CPT codes 97760 and 97761 were previously used to report both the initial and subsequent encounters, that, when furnished under the Medicare outpatient therapy services benefit, included services occurring during the same PT or OT episode of care. CPT code 97762 was used to separately report the assessment and fitting (including any adjustments) of an orthotic or prosthetic for an established patient when these services were not bundled into another code or service. For CY 2018, CPT codes 97760 and 97761 are intended to be reported only for the initial encounter, and CPT code 977X1 is intended to be reported for all other orthotic and/or prosthetic services for an established patient that occur on a ''subsequent encounter'' or a different date of service from that of the initial encounter service.

The HCPAC submitted work and PE recommendations for CPT codes 97760, 97761, and 977X1 from their January 2017 meeting. For CY 2018, we proposed the HCPAC-recommended work RVU of 0.50 for CPT code 97760, a work RVU of 0.50 for CPT code 97761, and a work RVU of 0.48 for CPT code 977X1. We noted that for budget neutrality purposes, the HCPAC recommendations also included utilization crosswalks for each of the three codes that were each assigned a one-to-one crosswalk to the utilization of the prior codes: All the prior services of CPT codes 97760 and 97761 were each crosswalked to the same newly revised codes; and, all the utilization from CPT code 97762 was crosswalked to the new CPT code 977X1.

For CPT code 977X1, we considered a work RVU of 0.33, crosswalking to CPT code 92508 (Speech/hearing therapy), which has a similar total therapist time (22 minutes). We were concerned and sought comments on the HCPAC one-to-one utilization crosswalk recommendations for all three codes in this family since the utilization assumptions are potentially flawed when viewed in the context of the new CPT code descriptors. For instance, for CPT code 977X1, the new descriptor indicates that the services inherent to CPT code 97762 (over 14,000 in 2015), as well as the new services for subsequent encounters previously reported via CPT codes 97760 and 97761 will also be encompassed, although it is difficult to estimate the number of additional services the latter represents. We were concerned that the HCPAC's valuation is inconsistent with the submitted information regarding how services will be reported under the new coding. We sought comments on our proposed and alternative values for CPT code 977X1. We were also interested in receiving comments from stakeholders and clinicians with expertise in furnishing these orthotic management and/or prosthetics training services about the utilization and types of services that would be furnished under the new CPT coding structure, particularly those of the newly created CPT code 977X1 and how these services differ from the services reported with the predecessor CPT code 97762.

We proposed to maintain the current PE inputs for CPT codes 97760, 97761, and 977X1, as we discussed in our proposals for the PM&R codes discussed above; the same therapy MPPR applies. We proposed the current direct PE inputs for CPT code 97762 and for new CPT code 977X1, though we sought comment as to whether or not a different crosswalk or other adjustment would be appropriate given the change in code descriptor.

The following is a summary of the public comments received as to whether or not a different crosswalk or other adjustment would be appropriate for CPT code 97763 given the change in code descriptor and our responses:

Comment: Many commenters supported of our proposal to adopt the HCPAC recommendations for revised work RVUs for CPT codes 97760 and 97761, and the proposed work RVU of newly created CPT code 977X1/97763. A few commenters also expressed support for the revised CPT descriptors of codes 97760 and 97761 to include the term ''initial encounter'', which they believe will eliminate billing confusion; and, also that the addition of the term ''subsequent encounter'' to the descriptor of CPT code 97763, because, the commenters stated it clarifies when this code is used—that, for the same patient, the provider would only report CPT code 97763 on the second or other subsequent visit after previously reporting an initial encounter for orthotic and/or prosthetic training and management using either CPT code 97760 or 97761. Other commenters informed us that they support the revised descriptors because they better align with the descriptions used within the ICD–10 system. One commenter noted that the new descriptors designation of subsequent or initial services will contribute confusion to the coding process for these services.

Response: We appreciate the support of the many commenters for our proposal to accept the work RVU values for these orthotic and/or prosthetic management and training services.

Comment: In response to our alternative work valuation of 0.33 RVUs for CPT code 97763, several commenters disagreed, stating that the suggested crosswalk to CPT code 92508 is inappropriate, that the work involved in delivering the orthotic/prosthetic subsequent encounter service is very similar to that furnished in the initial encounter, as substantiated through the

HCPAC survey process. One commenter that does not support the 0.33 work RVU, told us they agree with our crosswalk of CPT code 92508 for purposes of therapist time (17 minutes), given that we were limited for comparable crosswalks since the 97000 series of codes was under review. Another commenter noted that our alternative value was too low and that we should adopt the higher value based on their belief that many ''orthotics and prosthetics require increasingly complex and critical subsequent encounter adjustments based on changes in the status of a patient. These services often require a great deal of time and expertise on the part of the therapist.'' In addition, the commenter noted that some orthotic devices are dynamic in nature and need regular adjustments to ensure that the fit is correct and that orthotics and prosthetics management and training technology has evolved since the last valuation of these codes, meaning more specialized expertise is needed by a therapist.

Response: We thank the commenters for their input. We continue to believe that the proposed value most accurately captures the work involved in this service. As a result, we are finalizing our proposed value for CY 2018.

Comment. One commenter supported ''CMS' proposal to eliminate code 97762'' but did not support the adoption of CPT code 97763 in its place because in their view it eliminates the evaluation component of CPT code 97760 that was previously used to report subsequent encounters for orthotic management services. This commenter believes that the new CPT codes descriptors complicate coding through the unnecessary designation of subsequent or initial services. This commenter also noted this to mean that all other encounters are subsequent encounters to this initial fabrication—which they believe is typically billed using a HCPCS L-code; that the new CPT code 97763 is redundant because it is used at a subsequent encounter from the one during which the orthosis was fabricated, and that CPT code 97760 is the only code needed to bill correctly for both the evaluation of fit and use, subsequent modifications and additional training or repairs revealed during reassessment of the orthosis. Regardless of the specific encounter during which these orthotic management services are billed, the commenter noted that the level of work is the same—supporting the increased work RVUs of code 97760.

Response: We thank the commenter for the information provided on their coding concerns and their support for the work RVU of CPT code 97760. We note that while CMS proposes and finalizes the valuation of these services, it is the CPT Editorial Panel that revises CPT descriptors as well as adds and deletes CPT codes.

Comment. Several commenters expressed concern that the HCPAC one-to-one utilization crosswalk recommendations for all three codes in this family are potentially flawed when viewed in the context of the new CPT code descriptors. One commenter stated that they anticipate there will be a redistribution in coding between CPT codes 97760 and 97761 to 977X1/97763 based on the assumption that the majority of patients have more than 1 billing session for an orthosis or prosthesis; therefore, the commenter estimated some volume of services previously billed under CPT codes 97760 and 97761 will be billed under CPT code 977X1. Another commenter noted the code descriptor revisions, particularly the addition of ''initial encounter'' to CPT code 97760, could be interpreted to include that encounter in which the therapist billed for the fabrication of the orthotic using an HCPCS L-code, and could result in a shift to CPT code 97763.

Response: We appreciate the feedback that these commenters provided on the utilization crosswalk recommendations from the HCPAC, and note that these concerns echo some of the concerns that we raised in the CY 2018 PFS proposed rule. After consideration of the public comments, we are finalizing our proposal to accept the HCPAC recommended work RVUs for CPT codes 97760, 97761, and 97763. Because these codes are subject to the same MPPR policy as the 19 PM&R codes discussed in the above section, we are not finalizing our proposal to retain the existing PE inputs for these three codes. Instead, we are not finalizing our proposal to retain the existing PE inputs for these three codes because, as we discussed in an above section on PM&R codes, we were persuaded by the HCPAC that the PE Subcommittee took into account the 50 percent MPPR policy when developing the PE inputs for these codes.

We also note that these codes are designated as ''always therapy,'' meaning that they always represent therapy services regardless of who furnishes them; and that a GO or GP therapy modifier is always required to indicate that the services are furnished under an OT or PT plan of care, respectively. As ''always therapy,'' these codes are subject to the therapy MPPR and the statutory therapy caps.

(56) Assessment of and Care Planning for Patients With Cognitive Impairment (CPT Code 99483)

For CY 2017, CMS began making separate payment for HCPCS code G0505 (Assessment and care planning for patients with cognitive impairment) as an interim means of facilitating payment for a CPT code that was forthcoming for CY 2018, eventual CPT code 99483. As part of public comment on the CY 2017 PFS proposed rule, the RUC submitted recommended values for this code, which we adopted in the CY 2017 PFS final rule. For CY 2018, CMS is adopting CPT code 99483, and deleting the interim HCPCS code G0505. As is our longstanding practice, when we propose to accept the RUC-recommended values for a code and did not have any significant concerns, we did not write about this proposal in the preamble to the CY 2018 PFS proposed rule.

Comment: Several commenters supported the adoption of CPT code 99483. Commenters stated that by making separate payment for this code, we were helping patients with dementia gain access to valuable medical care. One commenter also included questions that it had gathered from practitioners about billing HCPCS code G0505. We did not receive any comments that opposed adoption of CPT code 99483.

Response: We thank commenters for their support, and will consider the practitioners' questions for forthcoming guidance, as appropriate.

Comment: A few commenters noted that there were slight variations in scope of service elements between the HCPCS code G0505 and CPT code 99483.

Response: We believe that despite the differences, the policies of CPT code 99483 conform to those of the HCPCS G-code and intend to monitor this service and seek input from stakeholders as to whether we should issue additional regulatory or sub-regulatory guidance.

For CY 2018, CMS is deleting the interim HCPCS code G0505 and replacing it with CPT code 99483. After consideration of these comments, we are finalizing the new descriptor for CPT code 99483, as proposed. We note that we previously adopted the RUC-recommended values for this service in the CY 2017 PFS final rule and will continue to use the RUC-recommended values with our adoption of CPT code 99483.

(57) Psychiatric Collaborative Care Management Services (CPT Codes 99492, 99493, 99494, and 99484).

In the CY 2017 PFS final rule (81 FR 80230), we established separate

payment for three services (HCPCS codes G0502, G0503, and G0504) under the psychiatric collaborative care model that paralleled CPT codes that were being created to report these services as well as a G-code for general behavioral health integration (BHI) services (HCPCS code G0507).

For CY 2018, the CPT Editorial Panel is creating CPT codes 99492, 99493, 99494, and 99484 to describe these services. For CY 2018, we are adopting these CPT codes and deleting HCPCS codes G0502, G0503, G0504, and G0507. We proposed the RUC-recommended work RVUs for each of these CPT codes, which are identical to the current values for HCPCS codes G0502, G0503, G0504, and G0507.

We proposed the RUC-recommended PE inputs, with one refinement. The RUC-recommended values included clinical labor inputs in the facility setting, but we did not propose to include these minutes in developing the facility PE RVUs.

Were we to develop facility PE RVUs for these services that included clinical staff time, when a practitioner working in a provider-based department of a hospital was furnishing these services, both the professional and the hospital would be paid for the same clinical labor costs. We presumed that this aspect of the RUC's recommendation reflects the circumstance where the patient receiving the services spends a significant period of time in a facility setting, but the billing practitioner is nonetheless incurring the cost associated with the non-face-to-face clinical staff time over the course of a month. We recognized that the binary site of service differential may not recognize the different models of this kind of care and may not be appropriate in some cases. We sought comments on how to best address this valuation issue for these and other monthly care management services. We noted that we could consider a range of options for future rulemaking, including allowing separate billing for the professional, technical, and global components of these services to allow practitioners to bill the component of the service they furnish.

We stated in the CY 2017 PFS final rule (81 FR 80236) that the general BHI code (CPT code 99484) may be used to report a range of models of BHI services and that we expected this code to be refined over time as we receive more information about other BHI models in use. We remain interested in how this code is being used and look forward to hearing from stakeholders regarding its use in reporting different models of BHI services. Additionally, we have received inquiries from stakeholders about whether or not professionals who cannot report E/M services to Medicare might nonetheless serve as a primary hub for BHI services. For example, stakeholders have suggested that a clinical psychologist might serve as the primary practitioner that integrates medical care and psychiatric expertise. For purposes of future rulemaking, we sought comment on the circumstances under which this model of care is happening and whether additional coding would be needed to accurately describe and value other models of care.

Comment: A few commenters noted that the logic that would dictate a lower PE RVU in a facility does not fit with the care management model and one commenter also noted that patients in facility settings are more medically and behaviorally complex. Some commenters stated that they would be open to separate billing for the professional, technical, and global components of these services in order to allow practitioners to appropriately bill the component of the service they furnish and preferred that option over not including clinical staff time in the facility setting. One commenter suggested that CMS instruct practitioners billing for these services to report the place of service where they practice rather than the location of the patient.

Response: We will consider the commenters' input on solutions to the site of service differential for care management services for future notice and comment rulemaking. We also note that because these codes describe services that take place over the course of a calendar month, we have issued additional guidance, which can be found on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Behavioral-Health-Integration-FAQs.pdf.*

Comment: A few commenters suggested that CMS create separate codes to describe behavioral health care management services that could be billed by psychologists and other non-physician practitioners who are not authorized to bill Medicare for E/M services. One commenter suggested that CMS include psychiatric diagnostic evaluation services that can be furnished and billed by psychologists as eligible initiating visits. Another commenter urged CMS to expand coverage to make separate reimbursement to the psychiatric consultant in the collaborative care model. Alternatively, another commenter noted that integration of medical and psychiatric care requires the ability to advise and make medical recommendations as needed for all relevant medical care, including treatment for physical health conditions, which may include psychiatric and other medical differential diagnosis, treatment strategies regarding appropriate therapies, medication management, and medical management of complications associated with treatment of psychiatric disorders. Commenters also described other models of care that are in use, including the STAR–VA model and a model used in outpatient health care settings where a clinical social worker not only provides psychiatric care but also assists with psychosocial aspects of medical care.

Response: We thank commenters for their input and note that there were several issues for which there was not stakeholder consensus. We will consider all of the comments for future notice and comment rulemaking.

For CY 2018, CMS is deleting the interim HCPCS codes G0502, G0503, G0504, and G0507 and replacing them with CPT codes 99492, 99493, 99494, and 99484, respectively. After consideration of these comments, for CY 2018, we are finalizing the coding and valuation for CPT codes 99492, 99493, 99494, and 99484, as proposed.

(58) Hyperbaric Oxygen Therapy (HCPCS Code G0277)

In the CY 2016 PFS final rule with comment period (80 FR 71005), we discussed the CY 2015 valuation of hyperbaric oxygen therapy services (79 FR 67677). Prior to CY 2015, CPT code 99183 was used to report both the professional attendance and supervision, and the costs associated with treatment delivery were included in the nonfacility direct PE inputs for the code. We created HCPCS code G0277 to be used to report the treatment delivery separately, consistent with the OPPS coding mechanism, to allow the use of the same coding structure across multiple settings. In establishing interim final direct PE inputs for HCPCS code G0277, we used the RUC-recommended direct PE inputs for CPT code 99183, which assumed a 120-minute treatment interval and adjusted them to align with the 30-minute treatment interval of HCPCS code G0277. We observed that the quantity of oxygen increased significantly relative to the previous inputs for CPT code 99183.

To better understand why the oxygen supply increased, we reviewed the instruction manual for the Sechrist Model 3600E Hyperbaric Chamber, which was the model noted on the invoice that was included with the RUC

recommendations for use in pricing the capital equipment. The instruction manual for the Sechrist 3600E model provided guidance regarding the quantity of oxygen to be used in furnishing the service described by HCPCS code G0277. Based on our review at that time, we determined that 12,000 liters, rather than 47,000 liters, was the typical number of units for the oxygen gas. Therefore, in aligning the direct PE inputs as described in the CY 2016 final rule with comment period, we first adjusted the units of oxygen to 12,000 liters for the recommended 120 minute time, and subsequently adjusted it to align with the 30-minute G-code by dividing by 4. We stated that we agreed that an initial high purge flow rate is needed to reach maximum pressure/O_2; however, we still had not seen data that demonstrated the need to continue the high purge flow rate throughout the entire session. According to the manufacturer's instruction manual for this model, ''once the nitrogen has been purged from the chamber and the internal oxygen concentration has exceeded 95 percent, high flows are no longer needed to maintain the patient's saturation level.'' The manual also stated that ''the plateau purge flow can be set to 80 liters per minute (lpm).'' We calculated that 13 minutes at 400 lpm plus 120 minutes at 80 lpm equals 14,800 liters of oxygen. We stated that based on information in the manufacturer's manual that was publicly available at the time, we believed that this represented the typical usage for a 120-minute treatment. That amount represented an increase from the interim final amount of 12,000 liters. We aligned this total oxygen requirement to the 30-minute G-code by dividing 14,800 liters of oxygen by 4 and stated we were updating the direct PE inputs to 3,700 liters of oxygen for HCPCS code G0277.

For CY 2018, we received requests from stakeholders to update the direct PE inputs for HCPCS code G0277. In the CY 2016 PFS final rule with comment period (80 FR 71005), we explained that we had previously established values for this service based on information suggesting that the Sechrist Model 3600E Hyperbaric Chamber was typically used in furnishing the service in the non-facility setting. As we noted in that rule, we established the amount of oxygen used in furnishing the service based on use of the equipment item described as part of the RUC recommendation, instead of the RUC-recommended amount of oxygen, which appeared to be based on use of a different equipment product, the Sechrist Model 3200. Based on information received from stakeholders, we proposed in the CY 2018 PFS proposed rule to update both the equipment item and the amount of oxygen so that the amount of oxygen conforms to the RUC-recommended value of 47,600 liters of oxygen, which we divided by 4 to conform to the 30-minute service period for HCPCS code G0277, and that the equipment item is consistent with that recommendation. The proposed direct PE inputs for HCPCS code G0277 were displayed in the proposed CY 2018 direct PE input database, available on the CMS Web site under the downloads for the CY 2018 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

We also proposed to exclude this change in direct PE inputs from the calculation of the misvalued code target, since we viewed this proposed change as a refinement of a single recommendation over several years. Since the initial recommendation (79 FR 67677) was undertaken in a year without the misvalued code target, we believed it would be consistent with our previously established policy (80 FR 70923) to exclude this change from the calculation. We noted that this change would represent an increase from the current PE RVUs for this service.

Comment: Commenters were supportive of our proposal to update the equipment item and the quantity of oxygen in the supply items for this service.

Response: We appreciate the commenters' feedback.

After consideration of the comments received, we are finalizing the direct PE inputs for HCPCS code G0277 as proposed. The direct PE inputs for HCPCS code G0277 are displayed in the CY 2018 final rule direct PE Input database, available on the CMS Web site under the downloads for the CY 2018 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

(59) Payment Accuracy for Prolonged Preventive Services (HCPCS Codes G0513 and G0514)

Many services paid under the PFS are coded to reflect differential resource costs associated with different levels of care. However, this level of granularity is not applied evenly across the PFS. For example, there are far fewer E/M visit codes than there are codes that describe procedures. While not a comprehensive solution to address the differential resource costs of certain E/M visits, prolonged services codes can be used to report medically necessary E/M visits that require additional amounts of time. Like E/M visit codes, many of the Medicare-covered preventive services codes describe a service that has an atypically broad range of potential resource costs, including differential amounts of time required to furnish services. However, unlike for most E/M visit codes, there are not prolonged services codes that apply to Medicare-covered preventive services.

Some stakeholders expressed concerns to CMS regarding the lack of a coding mechanism for practitioners to report the additional time sometimes required to appropriately furnish care to a patient receiving a Medicare-covered preventive service. We noted that Medicare covers a broad range of preventive services, such as a ''Welcome to Medicare Preventive Visit'', yearly wellness visits, cancer screenings, and many types of counseling. Medicare beneficiary coinsurance and deductible payments are not applicable for certain Medicare-covered preventive services. Additional information about preventive services covered under Medicare, including whether beneficiary coinsurance or deductible apply, is available on the CMS Web site at *https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/Downloads/MPS-QuickReferenceChart-1TextOnly.pdf.* To more accurately reflect the differential resource costs when additional time is required to furnish a Medicare-covered preventive service, we proposed to make payment for prolonged preventive services using two new HCPCS G-codes that could be billed along with the Medicare-covered preventive service codes, when a clinician provides a prolonged Medicare-covered preventive service.

- *G0513:* Prolonged preventive service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; first 30 minutes (List separately in addition to code for preventive service)), and
- *G0514:* Prolonged preventive service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (List separately in addition to code for preventive service)).

We proposed that HCPCS codes G0513 and G0514 could only be billed with Medicare-covered preventive services. Beneficiary coinsurance and

deductible would not be applicable for HCPCS codes G0513 and G0514 because the codes can only be reported to describe prolonged portions of services where beneficiary coinsurance and deductible are not applicable.

We proposed to create prolonged services codes in 30-minute increments instead of the 60-minute increments that apply for the parallel office/outpatient prolonged services codes, since some Medicare-covered preventive services have a shorter duration than E/M visits. For purposes of valuation for both initial and additional 30 minute codes, we proposed to use one half of the current work RVUs and direct PE inputs for CPT code 99354 (Prolonged evaluation and management or psychotherapy service(s) beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; first hour (List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service)). CPT code 99354 has a total time of 60 minutes and a work RVU of 2.33. Therefore, we proposed a work RVU of 1.17 and 30 minutes of total work time for HCPCS codes G0513 and G0514. We proposed to use one half of the direct PE inputs for CPT code 99354, which resulted in a proposal of 7 minutes of clinical labor type L037D (RN/LPN/MTA) and 15 minutes for equipment type EF031 (table, power) for HCPCS codes G0513 and G0514 as the best reflection of typical direct PE costs. We understood that these specific clinical labor and equipment types may be functioning as proxy inputs for some Medicare-covered preventive services.

We proposed that HCPCS codes G0513 and G0514 be billed for prolonged preventive services beyond the typical service time of the primary procedure. For preventive services with both physician work and PE, we considered the typical service time of the primary procedure to be the intraservice work time used for the purposes of PFS ratesetting. For Medicare-covered preventive services with no face-to-face physician work, the typical time is the service period clinical staff time that best represents the face-to-face time with the patient. The counted time guidelines (derived from the typical times assumed for PFS ratesetting) for all eligible companion Medicare-covered preventive services are available in the file called ''CY 2018 Preventive Services Billed with Prolonged Preventives Code'' on the CMS Web site under downloads for the CY 2018 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Comment: Many commenters supported our proposal to pay separately for prolonged preventive services. Commenters stated that by paying separately for necessary additional time spent with patients during preventive visits, CMS was both improving payment accuracy and increasing accessibility to these services. Commenters also agreed with our decision to only allow HCPCS codes G0513 and G0514 to be billed with the preventive services where beneficiary coinsurance and deductible are not applicable.

Response: We thank the commenters for their support of coding and valuation for prolonged preventive services.

Comment: One commenter urged CMS to continue to work with the disability community on innovative solutions as part of a broader approach to ensuring equal health care access for people with disabilities and suggested additional activities.

Response: We thank the commenter for the suggestions and look forward to collaborating on other steps to improve access for people with disabilities.

Comment: One commenter suggested that CMS allow HCPCS codes G0513 and G0514 to be billed with HCPCS code G0296 (Counseling visit to discuss need for lung cancer screening using low dose CT scan), while another commenter recommended that CMS expand use of these codes beyond preventive services. One commenter requested that CMS allow HCPCS codes G0513 and G0514 to be billed with HCPCS code G0447 (Face-to-face behavioral counseling for obesity, 15 minutes). This commenter expressed concern that there were very few cognitive services on the list of eligible codes, yet the nature of a cognitive service may require more time to furnish to a patient.

Response: We appreciate the commenters' interest in adding to the types of services that can be billed with these codes. For many services on the PFS, there are already coding mechanisms in place to account for extra time spent with patients such as the CPT codes available to account for prolonged E/M services (CPT codes 99354 and 99355). However, as we have previously noted, there continue to be areas where we believe that current PFS coding may not accurately reflect the differential resource costs associated with certain visits, and we remain committed to working with beneficiaries, advocates, and practitioners to continue to explore improvements in payment accuracy for these services. To continue address this issue and to better align coding and payment for prolonged E/M services with prolonged preventive services, we proposed the above codes. As Medicare preventive services, these codes may only be added on to other Medicare covered preventive services for which there is also no applicable cost sharing.

With regard to HCPCS code G0447, we do not believe that HCPCS codes G0513 and G0514 are coded to be applicable to timed services. We welcome additional input from stakeholders regarding appropriate coding and billing for these services and will consider addressing these issues in future rulemaking. Finally, we note that HCPCS code G0296 is eligible to be billed with prolonged preventive services.

Comment: Several commenters made specific suggestions as to the format of the file CMS released with the typical times for eligible preventive services. One commenter stated that releasing the file as a download on the CY 2018 PFS final rule Web page was insufficient, and that we should also include the typical times in the text of the CY 2018 PFS final rule as well. Another commenter stated that they appreciated CMS releasing a file with the typical times, and encouraged us to incorporate this information into other sources, such as the Provider Payment Summary file.

Response: We appreciate these suggestions. We will make the file with the typical times available via the downloads section of the CY 2018 PFS final rule as this is sufficiently accessible for practitioners and stakeholders.

Comment: One commenter requested that CMS clarify whether it would be able to bill the prolonged preventives codes if the additional time was distributed across multiple services performed on a single encounter.

Response: We believe that it would be appropriate to bill the prolonged preventive services if all of the services performed are un-timed preventive services with no beneficiary cost-sharing.

Comment: Several commenters provided suggestions as to how CMS could further engage in outreach and guidance for practitioners. One commenter provided feedback on the kinds of monitoring and incentivizing activities CMS could undertake to advance beneficiary access to these services.

Response: We thank commenters for their suggestions, and will consider them for the future.

After consideration of comments received, we are finalizing our proposal for prolonged preventive services using HCPCS codes G0513 and G0514 with the work RVUs, work times, direct PE inputs, and requirements for these codes as proposed.

(60) Physician Coding for Insertion and Removal of Subdermal Drug Implants for the Treatment of Opioid Addiction (HCPCS Codes G0516, G0517, and G0518)

We met with representatives from the American Society of Addiction Medicine (ASAM) in April 2016 to discuss the possibility of making separate payment for insertion and removal of buprenorphine hydrochloride, formulated as a 4-rod, 80 mg, long-acting subdermal drug implant for the treatment of opioid addiction. There are existing CPT codes that broadly describe the insertion and removal of non-biodegradable drug delivery implants (CPT codes 11981 through 11983). However, ASAM contended that the resources associated with the administration of this particular drug are greater than that of other drug delivery implants, stating that the physician must insert four rods using a newly designed applicator and obturator and use a specially designed clamp to remove the four rods, which in some cases requires careful shaving of tissue that has attached to the rods during the 6-month period that the rods have been inserted. They noted that these procedures can have unique challenges associated with treating patients with opioid addiction, who often have complications and/or co-morbidities. They also noted that the FDA has recognized the complexity of the technology and patient needs by establishing regulatory standards to adhere to the protocol and imposing special training requirements on physicians. ASAM indicated that they would pursue an application to the CPT Editorial Panel for new CPT codes.

ASAM informed CMS that the CPT Editorial Panel did not approve its application; therefore, ASAM repeated its request that CMS establish separate payment for the insertion, removal, and removal with reinsertion of the buprenorphine subdermal implants.

To improve payment accuracy, for CY 2018, we proposed to make separate payment for the insertion, removal, and removal with reinsertion of Buprenorphine subdermal implants using HCPCS G codes:

- *HCPCS code G0516:* Insertion, non-biodegradable drug delivery implants, 4 or more.
- *HCPCS code G0517:* Removal, non-biodegradable drug delivery implants, 4 or more.
- *HCPCS code G0518:* Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more.

For HCPCS code G0516, ASAM stated that performing the procedure according to the FDA-required Risk Evaluation and Mitigation Strategies (REMS) program takes approximately 23–25 minutes for the a physician who is not a trainer/proctor for this procedure. They stated that in developing crosswalk recommendations for physician work values, they used a total time of 35–40 minutes, which is based on a preservice time of 10 minutes, an intraservice time of 20–25 minutes, and a postservice time of 5 minutes. Based on ASAM's recommendations, we proposed a work RVU of 1.82 for HCPCS code G0516, which is supported by a direct crosswalk to CPT code 64644 (Chemodenervation of one extremity; 5 or more muscles).

For HCPCS code G0517, ASAM stated that data from physicians who perform this procedure indicated that it takes approximately 15–20 additional minutes compared to the insertion procedure (HCPCS code G0516) based on the FDA-required REMS program for removal of the implant. ASAM noted that this procedure is of a higher intensity compared to CPT code 11982 as this service requires identification and removal of multiple subdermal implants. ASAM stated that in developing crosswalk recommendations for physician work values, they used a total time of 45–60 minutes, which is based on a preservice time of 10 minutes, an intraservice time of 30–45 minutes, and a postservice time of 5 minutes. Based on ASAM's recommendations, we proposed a work RVU of 2.10 for HCPCS code G0517, which is supported by a direct crosswalk to CPT code 96922 (Laser treatment for inflammatory skin disease (psoriasis); over 500 sq cm).

For HCPCS code G0518, ASAM indicated that there is minimal consolidation of effort since the removal of the implants from one arm is followed by insertion of a new set of implants in the contralateral arm. Physician data from those who have performed this procedure indicated that it takes approximately 70 minutes of total intra-service time. ASAM stated that in developing crosswalk recommendations for physician work values, they assumed a preservice evaluation time of 10 minutes (7 minutes for removal and 3 minutes for insertion), positioning of 4 minutes (2 minutes for each arm), and wait time of 2 minutes (1 minute for each arm). ASAM stated that using the multiple surgical procedure rule, they calculated an intraservice time of 40–58 minutes based on 100 percent of the intraservice time for HCPCS code G0517 (30–45 minutes) and 50 percent of the intraservice time for HCPCS code G0516 ($0.5 \times (20 - 25) = 10 - 13$). ASAM used a postservice time of 8 minutes based on 100 percent of the postservice time for the removal arm and 50 percent of the postservice time for the insertion arm, equaling a total time of 58–76 minutes. Based on ASAM's recommendations, we proposed a work RVU of 3.55 for HCPCS code G0518, which is supported by a direct crosswalk to CPT code 31628 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), single lobe).

We proposed to use the direct PE inputs requested by ASAM for HCPCS codes G0516, G0517, and G0518, which are reflected in the Direct PE Inputs public use files for clinical labor, supplies, and equipment, available on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

In addition to seeking comment on the proposal to make separate payment for these services using HCPCS codes, we also sought comment on the appropriateness and accuracy of our proposed work RVUs and direct PE inputs.

Comment: We received several comments on this proposal, which were unanimously supportive. Commenters commended CMS for its ongoing efforts to address the national opioid epidemic and ensure that patients with substance use disorders have access to medically necessary care.

Response: We appreciate the commenters' support of the proposal. After consideration of the public comments, we are finalizing our proposal for separate payment for insertion, removal, and removal with reinsertion of Buprenorphine subdermal implants using HCPCS codes G0516, G0517, and G0518, and the valuation for HCPCS codes G0516, G0517, and G0518, as proposed.

(60) Superficial Radiation Treatment Planning and Management (HCPCS Code GRRR1)

In the CY 2015 PFS final rule with comment period (79 FR 67666 through 67667), we noted that changes to the CPT prefatory language limited the

codes that could be reported when describing services associated with superficial radiation treatment (SRT) delivery, described by CPT code 77401 (radiation treatment delivery, superficial and/or ortho voltage, per day). The changes effectively meant that many other related services were bundled with CPT code 77401, instead of being separately reported. For example, CPT guidance clarified that certain codes used to describe clinical treatment planning, treatment devices, isodose planning, physics consultation, and radiation treatment management cannot be reported when furnished in association with superficial radiation treatment. Stakeholders stated that these changes to the CPT prefatory language prohibited them from billing Medicare for codes that were previously frequently billed in addition to CPT code 77401. We solicited comments as to whether the coding for SRT allowed for accurate reporting of the associated services.

In the CY 2016 PFS final rule with comment period (80 FR 70955), we noted that the RUC did not review the inputs for SRT procedures, and therefore did not assess whether changes in valuation were appropriate in light of the bundling of associated services. In addition, we solicited recommendations from stakeholders regarding whether or not it would be appropriate to add physician work for this service, even though physician work is not included in other radiation treatment services. As commenters were not in agreement as to whether the service should be valued with physician work, we introduced the possibility of creating a HCPCS G-code to describe total work associated with the course of treatment for these services. The 2016 National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services stated that radiation oncology services may not be separately reported with E/M codes. While this edit is no longer active, stakeholders have stated that MACs have denied claims for E/M services associated with SRT based on the NCCI policy manual language. According to stakeholders, the bundling of services associated with SRT, as well as the confusion regarding the appropriate use of E/M coding to report associated physician work, meant that practitioners were not being accurately paid for planning and treatment management associated with furnishing SRT.

Due to these concerns regarding reporting of services associated with SRT, in the CY 2018 PFS proposed rule, we proposed to make separate payment for the professional planning and management associated with SRT using HCPCS code GRRR1 (Superficial radiation treatment planning and management related services, including but not limited to, when performed, clinical treatment planning (for example, 77261, 77262, 77263), therapeutic radiology simulation-aided field setting (for example, 77280, 77285, 77290, 77293), basic radiation dosimetry calculation (for example, 77300), treatment devices (for example, 77332, 77333, 77334), isodose planning (for example, 77306, 77307, 77316, 77317, 77318), radiation treatment management (for example, 77427, 77431, 77432, 77435, 77469, 77470, 77499), and associated E/M per course of treatment). We proposed for this code to describe the range of professional services associated with a course of SRT, including services similar to those not otherwise separately reportable under CPT guidance and the NCCI manual. To value this code, we included the physician work and time associated with radiation management-related services that we think would be typical for a course of SRT treatment. These services include: CPT code 77261 (Therapeutic radiology treatment planning; simple), CPT code 77280 (Therapeutic radiology simulation-aided field setting; simple), CPT code 77300 (Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician), CPT code 77306 (Teletherapy isodose plan; simple (1 or 2 unmodified ports directed to a single area of interest), includes basic dosimetry calculation(s)), CPT code 77332 (Treatment devices, design and construction; simple (simple block, simple bolus)), and CPT code 77427 (Radiation treatment management, 5 treatments). Therefore, for CY 2018, we proposed a work RVU of 7.93 for HCPCS code GRRR1. To develop the proposed direct PE inputs for this code, we proposed to use the RUC-recommended direct PE inputs from the aforementioned codes with several adjustments. We proposed to apply the staff type ''RN/LPN/MTA'' for all of the clinical labor inputs for this code because we believe that the typical office performing SRT would be staffed with this labor type, rather than with another clinical labor type such as radiation therapists, and we sought comment as to the appropriateness of the staff type ''RN/LPN/MTA'' for this SRT-related service. Some stakeholders have suggested that many services related to SRT are personally performed by the billing practitioner rather than by clinical staff. We proposed to remove the supply items ''gown, patient'' and ''pillow case'' that are associated with CPT code 77280, as these items are included in the minimum multispecialty visit pack that is associated with CPT code 77427. We did not propose to include the equipment items ''radiation virtual simulation system,'' ''room, CT'' and ''PACS Workstation Proxy'' that are associated with CPT code 77280, as we do not believe that a typical office furnishing SRT uses this kind of equipment. Instead, we included additional time for the capital equipment used in delivering SRT in the proposed direct PE inputs.

For ''radiation dose therapy plan,'' we proposed to apply the clinical labor time that is associated with CPT code 77300 to HCPCS code GRRR1 for purposes of developing a proposed value, but we sought comment as to whether the clinical staff would typically perform the radiation dose therapy planning for this service, or if the physician would perform this and/or other tasks, and, in the case of the latter, what the appropriate physician time would be. Likewise, we solicited comment as to whether the clinical labor associated with the teletherapy isodose plan would be performed by the physician. We proposed to assign 14 minutes each to the equipment items ''radiation therapy dosimetry software (Argus QC)'', ''computer workstation'', and ''3D teletherapy treatment planning'' as these are the times assigned to these equipment items for CPT code 77300. We did not propose to include inputs related to radiation physics consultation, described by CPT code 77336, as we think that a typical course of SRT would not require this service, and the typical practitioner providing SRT would not be performing physics consultation, and we sought comment as to whether inputs associated with this code or other inputs used in furnishing analogous services should be included. We did not propose to include the post-operative office visits included in the valuation of CPT code 77427, as we did not believe that a typical course of SRT would require post-operative visits; however, we solicited comment regarding the amount of face-to-face time typically spent by the practitioner with the patient for radiation treatment management associated with SRT. As discussed in the CY 2016 PFS final rule with comment period (80 FR 70924 through

70927), in the case of new codes that describe services that were previously included in the payment for other codes, we finalized the policy that these new codes are excluded from the misvalued code target when they were previously bundled into a set of broadly reported E/M codes and services that include E/M visits. We noted that we did not believe that the change to separate payment for these kinds of services should be counted as increases that are included in calculating ''net reductions'' in expenditures attributable to adjustments for misvalued codes. Therefore, we proposed to exclude HCPCS code GRRR1 from the misvalued code target.

Comment: Many commenters did not support our proposal to make separate payment for HCPCS code GRRR1 for CY 2018. These commenters stated that our proposed valuation of HCPCS code GRRR1 would represent a significant payment reduction for the associated services as compared with the list of services that they are currently billing in association with SRT. Many commenters stated that this new coding would inhibit access to care for these services, discouraging the use of SRT as a non-surgical alternative to Mohs surgery. Many suggested potential coding solutions to these concerns, including: Our proposed G-code should include inputs associated with more services, such as those associated with the intermediate and complex codes for services such as clinical treatment planning, simulating-aided field setting, and treatment devices; our proposed code should include inputs for fewer services; and the code for planning and management services associated with SRT should be billable in multiple units such as for once per day or once per lesion, rather than once for a full course of treatment as proposed. Some commenters expressed preference for multiple G-codes specific to each aspect of SRT delivery rather than a single bundle for all associated SRT-related services. More specifically, some commenters recommended three G-codes, representing treatment planning, treatment devices, and treatment management. According to some commenters, our proposal to value the planning and management services associated with SRT with one code does not recognize variation in services related to factors such as tumor type and location, and if the service is for skin cancer or keloid scar. Commenters noted a preference that new coding for these services should be developed through the CPT/RUC process. Commenters also expressed concerns about specific direct PE inputs, such as the clinical labor type assigned to HCPCS code GRRR1, stating that radiation therapists, not the staff type ''RN/LPN/MTA'' should be applied to this code. There was some disagreement among commenters about whether or not qualified medical physicists (QMPs) would typically be employed by dermatologists for SRT. A few commenters supported our proposal to make payment for planning and management services associated with SRT using HCPCS code GRRR1.

Response: We appreciate the comments. Given the various concerns expressed by commenters, and the variety of potential solutions offered, we are not finalizing our proposed separate payment and coding for planning and management services associated with SRT at this time. We expect to continue considering alternative solutions. The impetus for making this proposal was based on our understanding that there are limits to the appropriate reporting of professional services associated with SRT, and the intent of this policy was to address gaps in what the current coding allows for in relation to SRT. However, commenters have indicated concerns with our proposed coding and valuation, including access to care concerns; therefore. Therefore we believe additional analysis is necessary and will further consider coding and payment for professional services associated with SRT in light of commenter concerns, and we are not establishing codes related to planning and management services associated with SRT in this final rule. We look forward to continuing our dialogue with stakeholders regarding the appropriate coding and valuation for SRT-related professional services, which we expect to address in future rulemaking.

Comment: Several commenters stated that CPT code 77401 is undervalued and that it should be valued with a physician work component.

Response: We note that our proposed G-code was designed, in part, to address feedback that has indicated that the current coding, including CPT code 77401, does not adequately account for the professional services associated with SRT delivery. We did not propose to value CPT code 77401, so we decline to do so now. We look forward to addressing these potential coding gaps in future rulemaking.

After consideration of the comments received, we are not finalizing our proposal to make separate payment for the planning and management services associated with SRT using HCPCS code GRRR1. We will continue our dialogue with stakeholders to address appropriate coding and payment for professional services associated with SRT.

We note that we did not propose and are not making any changes to the coding or valuation for CPT code 77401 (radiation treatment delivery, superficial and/or ortho voltage, per day) in this final rule. Providers can continue to bill CPT code 77401 as appropriate. However, under the CPT guidance that has been in effect for several years, certain codes used to describe clinical treatment planning, treatment devices, isodose planning, physics consultation, and radiation treatment management cannot be billed in addition to CPT code 77401. These planning and management codes, however, can continue to be billed in addition to other codes involving other types of radiation treatment, such as HCPCS code G6003 (Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: up to 5 mev) and CPT code 77523 (Proton treatment delivery; intermediate) in accordance with applicable guidance and requirements.

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TABLE 12: CY 2018 Work RVUs for New, Revised and Potentially Misvalued Codes

HCPCS Code	Long Descriptor	CY 2017 Work RVU	Proposed CY 2018 Work RVU	Final CY 2018 Work RVU	CMS Work Time Refinement
00731	Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum; not otherwise specified	NEW	0.00	0.00	No
00732	Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum; endoscopic retrograde cholangiopancreatography (ERCP)	NEW	0.00	0.00	No
00811	Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; not otherwise specified	NEW	0.00	0.00	No
00812	Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; screening colonoscopy	NEW	0.00	0.00	No
00813	Anesthesia for combined upper and lower gastrointestinal endoscopic procedures, endoscope introduced both proximal to and distal to the duodenum	NEW	0.00	0.00	No
10040	Acne surgery (eg, marsupialization, opening or removal of multiple milia, comedones, cysts, pustules)	1.21	0.91	0.91	No
15730	Midface flap (ie, zygomaticofacial flap) with preservation of vascular pedicle(s)	NEW	13.50	13.50	No
15733	Muscle, myocutaneous, or fasciocutaneous flap; head and neck with named vascular pedicle (ie, buccinators, genioglossus, temporalis, masseter, sternocleidomastoid, levator scapulae)	NEW	15.68	15.68	No
15734	Muscle, myocutaneous, or fasciocutaneous flap; trunk	19.86	23.00	23.00	No
15736	Muscle, myocutaneous, or fasciocutaneous flap; upper extremity	17.04	17.04	17.04	No
15738	Muscle, myocutaneous, or fasciocutaneous flap; lower extremity	19.04	19.04	19.04	No
19294	Preparation of tumor cavity with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with partial mastectomy	NEW	3.00	3.00	No
19303	Mastectomy, simple, complete	15.85	15.00	15.00	No
20939	Bone marrow aspiration for bone grafting, spine surgery only, through separate skin or fascial incision	NEW	1.16	1.16	No
29445	Application of rigid total contact leg cast	1.78	1.78	1.78	No
29580	Strapping; Unna boot	0.55	0.55	0.55	No
29581	Application of multi-layer compression system; leg (below knee), including ankle and foot	0.25	0.60	0.60	No
30140	Submucous resection inferior turbinate, partial or complete, any method	3.57	3.00	3.00	No
30901	Control nasal hemorrhage, anterior, simple (limited cautery and/or packing) any method	1.10	1.10	1.10	No

HCPCS Code	Long Descriptor	CY 2017 Work RVU	Proposed CY 2018 Work RVU	Final CY 2018 Work RVU	CMS Work Time Refinement
30903	Control nasal hemorrhage, anterior, complex (extensive cautery and/or packing) any method	1.54	1.54	1.54	No
30905	Control nasal hemorrhage, posterior, with posterior nasal packs and/or cautery, any method; initial	1.97	1.97	1.97	No
30906	Control nasal hemorrhage, posterior, with posterior nasal packs and/or cautery, any method; subsequent	2.45	2.45	2.45	No
31241	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery	NEW	8.00	8.00	No
31253	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including frontal sinus exploration, with removal of tissue from frontal sinus, when performed	NEW	9.00	9.00	No
31254	Nasal/sinus endoscopy, surgical with ethmoidectomy; partial (anterior)	4.64	4.27	4.27	No
31255	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior)	6.95	5.75	5.75	No
31256	Nasal/sinus endoscopy, surgical, with maxillary antrostomy	3.29	3.11	3.11	No
31257	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy	NEW	8.00	8.00	No
31259	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy, with removal of tissue from the sphenoid sinus	NEW	8.48	8.48	No
31267	Nasal/sinus endoscopy, surgical, with maxillary antrostomy; with removal of tissue from maxillary sinus	5.45	4.68	4.68	No
31276	Nasal/sinus endoscopy, surgical, with frontal sinus exploration, including removal of tissue from frontal sinus, when performed	8.84	6.75	6.75	No
31287	Nasal/sinus endoscopy, surgical, with sphenoidotomy	3.91	3.50	3.50	No
31288	Nasal/sinus endoscopy, surgical, with sphenoidotomy; with removal of tissue from the sphenoid sinus	4.57	4.10	4.10	No
31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or canine fossa	2.70	2.70	2.70	No
31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)	3.29	3.10	3.10	No
31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)	2.64	2.44	2.44	No
31298	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (eg, balloon dilation)	NEW	4.50	4.50	No
31600	Tracheostomy, planned (separate procedure)	7.17	5.56	5.56	No

HCPCS Code	Long Descriptor	CY 2017 Work RVU	Proposed CY 2018 Work RVU	Final CY 2018 Work RVU	CMS Work Time Refinement
31601	Tracheostomy, planned (separate procedure); younger than 2 years	4.44	8.00	8.00	No
31603	Tracheostomy, emergency procedure; transtracheal	4.14	6.00	6.00	No
31605	Tracheostomy, emergency procedure; cricothyroid membrane	3.57	6.45	6.45	No
31610	Tracheostomy, fenestration procedure with skin flaps	9.38	12.00	12.00	No
31645	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed with therapeutic aspiration of tracheobronchial tree, initial	2.91	2.88	2.88	No
31646	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed with therapeutic aspiration of tracheobronchial tree, subsequent, same hospital stay	2.47	2.78	2.78	No
32994	Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; cryoablation	NEW	9.03	9.03	No
32998	Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; radiofrequency	5.68	9.03	9.03	No
33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy	NEW	49.00	49.00	No
33928	Removal of a total replacement heart system (artificial heart) for heart transplantation	NEW	C	C	No
33929	Removal and replacement of total replacement heart system (artificial heart)	NEW	C	C	No
34701	Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for other than rupture (eg, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)	NEW	23.71	23.71	No
34702	Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device	NEW	36.00	36.00	No

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	selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion when performed (eg, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)				
34703	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uniiliac endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for other than rupture (eg, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)	NEW	26.52	26.52	No
34704	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uniiliac endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion when performed (eg, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)	NEW	45.00	45.00	No
34705	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-biiliac endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for other than rupture (eg, for aneurysm, pseudoaneurysm, dissection,	NEW	29.58	29.58	No

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	penetrating ulcer)				
34706	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-biiliac endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion when performed (eg, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)	NEW	45.00	45.00	No
34707	Endovascular repair of iliac artery by deployment of an ilio-iliac tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally to the iliac bifurcation, and treatment zone angioplasty/stenting when performed, unilateral; for other than rupture (eg, for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation)	NEW	22.28	22.28	No
34708	Endovascular repair of iliac artery by deployment of an ilio-iliac tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally to the iliac bifurcation, and treatment zone angioplasty/stenting when performed, unilateral; for rupture including temporary aortic and/or iliac balloon occlusion when performed (eg, for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, traumatic disruption)	NEW	36.50	36.50	No
34709	Placement of extension prosthesis(es) distal to the common iliac artery(ies) or proximal to the renal artery(ies) for endovascular repair of infrarenal abdominal aortic or iliac aneurysm, false aneurysm, dissection, penetrating ulcer, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone	NEW	6.50	6.50	No

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	angioplasty/stenting when performed, per vessel treated				
34710	Delayed placement of distal or proximal extension prosthesis for endovascular repair of infrarenal abdominal aortic or iliac aneurysm, false aneurysm, dissection, endoleak, or endograft migration, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting when performed; initial vessel treated	NEW	15.00	15.00	No
34711	Delayed placement of distal or proximal extension prosthesis for endovascular repair of infrarenal abdominal aortic or iliac aneurysm, false aneurysm, dissection, endoleak, or endograft migration, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting when performed; each additional vessel treated	NEW	6.00	6.00	No
34712	Transcatheter delivery of enhanced fixation device(s) to the endograft (eg, anchor, screw, tack) and all associated radiological supervision and interpretation	NEW	12.00	12.00	No
34713	Percutaneous access and closure of femoral artery for delivery of endograft through a large sheath (12 French or larger), including ultrasound guidance, when performed, unilateral	NEW	2.50	2.50	No
34714	Open femoral artery exposure with creation of conduit for delivery of endovascular prosthesis or for establishment of cardiopulmonary bypass, by groin incision, unilateral	NEW	5.25	5.25	No
34715	Open axillary/subclavian artery exposure for delivery of endovascular prosthesis by infraclavicular or supraclavicular incision, unilateral	NEW	6.00	6.00	No
34716	Open axillary/subclavian artery exposure with creation of conduit for delivery of endovascular prosthesis or for establishment of cardiopulmonary bypass, by infraclavicular or supraclavicular incision, unilateral	NEW	7.19	7.19	No
34812	Open femoral artery exposure for delivery of endovascular prosthesis by groin incision, unilateral	6.74	4.13	4.13	No
34820	Open iliac artery exposure for delivery of endovascular prosthesis or iliac occlusion by abdominal or retroperitoneal incision, unilateral	9.74	7.00	7.00	No

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34833	Open iliac artery exposure with creation of conduit for delivery of endovascular prosthesis or for establishment of cardiopulmonary bypass, by abdominal or retroperitoneal incision, unilateral	11.98	8.16	8.16	No
34834	Open brachial artery exposure for delivery of endovascular prosthesis unilateral	5.34	2.65	2.65	No
36215	Selective catheter placement, arterial system; each first order thoracic or brachiocephalic branch, within a vascular family	4.67	4.17	4.17	No
36216	Selective catheter placement, arterial system; initial second order thoracic or brachiocephalic branch, within a vascular family	5.27	5.27	5.27	No
36217	Selective catheter placement, arterial system; initial third order or more selective thoracic or brachiocephalic branch, within a vascular family	6.29	6.29	6.29	No
36218	Selective catheter placement, arterial system; additional second order, third order, and beyond, thoracic or brachiocephalic branch, within a vascular family	1.01	1.01	1.01	No
36465	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (eg, great saphenous vein, accessory saphenous vein)	NEW	2.35	2.35	No
36466	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (eg, great saphenous vein, accessory saphenous vein), same leg	NEW	3.00	3.00	No
36470	Injection of sclerosant; single incompetent vein (other than telangiectasia)	1.10	0.75	0.75	No
36471	Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg	1.65	1.50	1.50	No
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated	NEW	3.50	3.50	No
36483	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites	NEW	1.75	1.75	No

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36511	Therapeutic apheresis; for white blood cells	1.74	2.00	2.00	No
36512	Therapeutic apheresis; for red blood cells	1.74	2.00	2.00	No
36513	Therapeutic apheresis; for platelets	1.74	2.00	2.00	No
36514	Therapeutic apheresis; for plasma pheresis	1.74	1.81	1.81	No
36516	Therapeutic apheresis; with extracorporeal selective adsorption or selective filtration and plasma reinfusion	1.22	1.56	1.56	No
36522	Photopheresis, extracorporeal	1.67	1.75	1.75	No
36555	Insertion of non-tunneled centrally inserted central venous catheter; younger than 5 years of age	2.43	1.93	1.93	No
36556	Insertion of non-tunneled centrally inserted central venous catheter; age 5 years or older	2.50	1.75	1.75	No
36569	Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump; age 5 years or older	1.82	1.70	1.70	No
36620	Arterial catheterization or cannulation for sampling, monitoring or transfusion (separate procedure); percutaneous	1.15	1.00	1.00	No
36901	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report;	2.82	-	3.36	No
36902	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty	4.24	-	4.83	No
36903	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging	5.85	-	6.39	No

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	from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transcatheter placement of intravascular stent(s), peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the stenting, and all angioplasty within the peripheral dialysis segment				
36904	Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s);	6.73	-	7.50	No
36905	Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty	8.46	-	9.00	No
36906	Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transcatheter placement of intravascular stent(s), peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the stenting, and all angioplasty within the peripheral dialysis circuit	9.88	-	10.42	No
36907	Transluminal balloon angioplasty, central dialysis segment, performed through dialysis circuit, including all imaging and radiological supervision and interpretation required to perform the angioplasty	2.48	-	3.00	No
36908	Transcatheter placement of intravascular	3.73	-	4.25	No

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	stent(s), central dialysis segment, performed through dialysis circuit, including all imaging radiological supervision and interpretation required to perform the stenting, and all angioplasty in the central dialysis segment				
36909	Dialysis circuit permanent vascular embolization or occlusion (including main circuit or any accessory veins), endovascular, including all imaging and radiological supervision and interpretation necessary to complete the intervention	3.48	-	4.12	No
38220	Diagnostic bone marrow; aspiration(s)	1.08	1.20	1.20	No
38221	Diagnostic bone marrow; biopsy(ies)	1.37	1.28	1.28	No
38222	Diagnostic bone marrow; biopsy(ies) and aspiration(s)	NEW	1.44	1.44	No
38573	Laparoscopy, surgical; with bilateral total pelvic lymphadenectomy and peri-aortic lymph node sampling peritoneal washings, peritoneal biopsy(s), omentectomy, and diaphragmatic washings, including biopsy(s) when performed	NEW	20.00	20.00	No
43107	Total or near total esophagectomy, without thoracotomy; with pharyngogastrostomy or cervical esophagogastrostomy, with or without pyloroplasty (transhiatal)	44.18	52.05	52.05	No
43112	Total or near total esophagectomy, with thoracotomy; with pharyngogastrostomy or cervical esophagogastrostomy, with or without pyloroplasty (ie, McKeown esophagectomy, or tri-incisional esophagectomy)	47.48	62.00	62.00	No
43117	Partial esophagectomy, distal two-thirds, with thoracotomy and separate abdominal incision, with or without proximal gastrectomy; with thoracic esophagogastrostomy, with or without pyloroplasty (Ivor Lewis)	43.65	57.50	57.50	No
43286	Esophagectomy, total or near total, with laparoscopic mobilization of the abdominal and mediastinal esophagus and proximal gastrectomy, with laparoscopic pyloric drainage procedure if performed, with open cervical pharyngogastrostomy or esophagogastrostomy (ie, laparoscopic transhiatal esophagectomy)	NEW	55.00	55.00	No
43287	Esophagectomy, distal two-thirds, with laparoscopic mobilization of the abdominal and lower mediastinal esophagus and proximal gastrectomy, with laparoscopic pyloric drainage procedure if performed, with separate thoracoscopic mobilization of the middle and upper mediastinal esophagus and thoracic esophagogastrostomy (ie, laparoscopic thoracoscopic esophagectomy, Ivor Lewis	NEW	63.00	63.00	No

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	esophagectomy)				
43288	Esophagectomy, total or near total, with thoracoscopic mobilization of the upper, middle, and lower mediastinal esophagus, with separate laparoscopic proximal gastrectomy, with laparoscopic pyloric drainage procedure if performed, with open cervical pharyngogastrostomy or esophagogastrostomy (ie, thoracoscopic, laparoscopic and cervical incision esophagectomy, McKeown esophagectomy, tri-incisional esophagectomy)	NEW	66.42	66.42	No
51798	Measurement of post-voiding residual urine and/or bladder capacity by ultrasound, non-imaging	0.00	0.00	0.00	No
52601	Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)	15.26	13.16	13.16	No
55874	Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed	NEW	3.03	3.03	No
57240	Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele, including cystourethroscopy, when performed	11.50	10.08	10.08	No
57250	Posterior colporrhaphy, repair of rectocele with or without perineorrhaphy	11.50	10.08	10.08	No
57260	Combined anteroposterior colporrhaphy, including cystourethroscopy, when performed	14.44	13.25	13.25	No
57265	Combined anteroposterior colporrhaphy, including cystourethroscopy, when performed; with enterocele repair	15.94	15.00	15.00	No
58575	Laparoscopy, surgical, total hysterectomy; with or without salpingo-oophorectomy, unilateral or bilateral, with resection of malignancy (tumor debulking), with omentectomy	NEW	32.60	32.60	No
64418	Injection, anesthetic agent; suprascapular nerve	1.32	1.10	1.10	No
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve	2.36	6.13	6.13	No
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)	2.32	5.76	5.76	No
64910	Nerve repair; with synthetic conduit or vein allograft (eg, nerve tube), each nerve	11.39	10.52	10.52	No
64911	Nerve repair; with autogenous vein graft (includes harvest of vein graft), each nerve	14.39	14.00	14.00	No
64912	Nerve repair; with nerve allograft, each nerve, first strand (cable)	NEW	12.00	12.00	No
64913	Nerve repair; with nerve allograft, each	NEW	3.00	3.00	No

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	additional strand				
67820	Correction of trichiasis; epilation, by forceps only	0.71	0.32	0.32	No
70490	Computed tomography, soft tissue neck; without contrast material	1.28	1.28	1.28	No
70491	Computed tomography, soft tissue neck; with contrast material(s)	1.38	1.38	1.38	No
70492	Computed tomography, soft tissue neck; without contrast material followed by contrast material(s) and further sections	1.45	1.62	1.62	No
70544	Magnetic resonance angiography, head; without contrast material(s)	1.20	1.20	1.20	No
70545	Magnetic resonance angiography, head; with contrast material(s)	1.20	1.20	1.20	No
70546	Magnetic resonance angiography, head; without contrast material(s), followed by contrast material(s) and further sequences	1.80	1.48	1.48	No
70547	Magnetic resonance angiography, neck; without contrast material(s)	1.20	1.20	1.20	No
70548	Magnetic resonance angiography, neck; with contrast material(s)	1.20	1.50	1.50	No
70549	Magnetic resonance angiography, neck; without contrast material(s), followed by contrast material(s) and further sequences	1.80	1.80	1.80	No
71045	Radiologic examination, chest; single view	NEW	0.18	0.18	No
71046	Radiologic examination, chest; 2 views	NEW	0.22	0.22	No
71047	Radiologic examination, chest; 3 views	NEW	0.27	0.27	No
71048	Radiologic examination, chest; 4 or more views	NEW	0.31	0.31	No
71100	Radiologic examination, ribs, unilateral; 2 views	0.22	0.22	0.22	No
71101	Radiologic examination, ribs, unilateral; including posteroanterior chest, minimum of 3 views	0.27	0.27	0.27	No
71110	Radiologic examination, ribs, bilateral; 3 views	0.27	0.29	0.29	No
71111	Radiologic examination, ribs, bilateral; including posteroanterior chest, minimum of 4 views	0.32	0.32	0.32	No
71250	Computed tomography, thorax; without contrast material	1.02	1.16	1.16	No
71260	Computed tomography, thorax; with contrast material(s)	1.24	1.24	1.24	No
71270	Computed tomography, thorax; without contrast material, followed by contrast material(s) and further sections	1.38	1.38	1.38	No
72195	Magnetic resonance (eg, proton) imaging, pelvis; without contrast material(s)	1.46	1.46	1.46	No
72196	Magnetic resonance (eg, proton) imaging, pelvis; with contrast material(s)	1.73	1.73	1.73	No
72197	Magnetic resonance (eg, proton) imaging, pelvis; without contrast material(s), followed by	2.26	2.20	2.20	No

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	contrast material(s) and further sequences				
73100	Radiologic examination, wrist; 2 views	0.16	0.16	0.16	No
73110	Radiologic examination, wrist; complete, minimum of 3 views	0.17	0.17	0.17	No
73120	Radiologic examination, hand; 2 views	0.16	0.16	0.16	No
73130	Radiologic examination, hand; minimum of 3 views	0.17	0.17	0.17	No
73140	Radiologic examination, finger(s), minimum of 2 views	0.13	0.13	0.13	No
73718	Magnetic resonance (eg, proton) imaging, lower extremity other than joint; without contrast material(s)	1.35	1.35	1.35	No
73719	Magnetic resonance (eg, proton) imaging, lower extremity other than joint; with contrast material(s)	1.62	1.62	1.62	No
73720	Magnetic resonance (eg, proton) imaging, lower extremity other than joint; without contrast material(s), followed by contrast material(s) and further sequences	2.15	2.15	2.15	No
74022	Radiologic examination, abdomen; complete acute abdomen series, including supine, erect, and/or decubitus views, single view chest	0.32	0.32	0.32	No
74018	Radiologic examination, abdomen; 1 view	NEW	0.18	0.18	No
74019	Radiologic examination, abdomen; 2 views	NEW	0.23	0.23	No
74021	Radiologic examination, abdomen; 3 or more views	NEW	0.27	0.27	No
74181	Magnetic resonance (eg, proton) imaging, abdomen; without contrast material(s)	1.46	1.46	1.46	No
74182	Magnetic resonance (eg, proton) imaging, abdomen; with contrast material(s)	1.73	1.73	1.73	No
74183	Magnetic resonance (eg, proton) imaging, abdomen; without contrast material(s), followed by with contrast material(s) and further sequences	2.26	2.20	2.20	No
75635	Computed tomographic angiography, abdominal aorta and bilateral iliofemoral lower extremity runoff, with contrast material(s), including noncontrast images, if performed, and image postprocessing	2.40	2.40	2.40	No
75710	Angiography, extremity, unilateral, radiological supervision and interpretation	1.14	1.75	1.75	No
75716	Angiography, extremity, bilateral, radiological supervision and interpretation	1.31	1.97	1.97	No
76510	Ophthalmic ultrasound, diagnostic; B-scan and quantitative A-scan performed during the same patient encounter	1.55	0.70	0.70	No
76511	Ophthalmic ultrasound, diagnostic; quantitative A-scan only	0.94	0.64	0.64	No
76512	Ophthalmic ultrasound, diagnostic; B-scan (with or without superimposed non-quantitative	0.94	0.56	0.56	No

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	A-scan)				
76516	Ophthalmic biometry by ultrasound echography, A-scan	0.54	0.40	0.40	No
76519	Ophthalmic biometry by ultrasound echography, A-scan; with intraocular lens power calculation	0.54	0.54	0.54	No
76881	Ultrasound, extremity, nonvascular, real-time with image documentation; complete	0.63	0.63	0.63	No
76882	Ultrasound, extremity, nonvascular, real-time with image documentation; limited, anatomic specific	0.49	0.49	0.49	No
77261	Therapeutic radiology treatment planning; simple	1.39	1.30	1.30	No
77262	Therapeutic radiology treatment planning; intermediate	2.11	2.00	2.00	No
77263	Therapeutic radiology treatment planning; complex	3.14	3.14	3.14	No
78300	Bone and/or joint imaging; limited area	0.62	0.62	0.62	No
78305	Bone and/or joint imaging; multiple areas	0.83	0.83	0.83	No
78306	Bone and/or joint imaging; whole body	0.86	0.86	0.86	No
88184	Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker	0.00	-	0.00	No
88185	Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; each additional marker	0.00	-	0.00	No
88333	Pathology consultation during surgery; cytologic examination (eg, touch prep, squash prep), initial site	1.20	1.20	1.20	No
88334	Pathology consultation during surgery; cytologic examination (eg, touch prep, squash prep), each additional site	0.73	0.73	0.73	No
88360	Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure; manual	1.10	0.85	0.85	No
88361	Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure; using computer-assisted technology	1.18	0.95	0.95	No
92136	Ophthalmic biometry by partial coherence interferometry with intraocular lens power calculation	0.54	0.54	0.54	No
93279	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values	0.65	0.65	0.65	No

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	with analysis, review and report by a physician or other qualified health care professional; single lead pacemaker system				
93280	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; dual lead pacemaker system	0.77	0.77	0.77	No
93281	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead pacemaker system	0.90	0.85	0.85	No
93282	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead transvenous implantable defibrillator system	0.85	0.85	0.85	No
93283	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; dual lead transvenous implantable defibrillator system	1.15	1.15	1.15	No
93284	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system	1.25	1.25	1.25	No
93285	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; implantable loop recorder system	0.52	0.52	0.52	No
93286	Peri-procedural device evaluation (in person) and programming of device system parameters	0.30	0.30	0.30	No

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	before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead pacemaker system				
93287	Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead implantable defibrillator system	0.45	0.45	0.45	No
93288	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead pacemaker system	0.43	0.43	0.43	No
93289	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements	0.92	0.75	0.75	No
93290	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable cardiovascular monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors	0.43	0.43	0.43	No
93291	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable loop recorder system, including heart rhythm derived data analysis	0.43	0.37	0.37	No
93292	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; wearable defibrillator system	0.43	0.43	0.43	No
93293	Transtelephonic rhythm strip pacemaker evaluation(s) single, dual, or multiple lead pacemaker system, includes recording with and	0.32	0.31	0.31	No

HCPCS Code	Long Descriptor	CY 2017 Work RVU	Proposed CY 2018 Work RVU	Final CY 2018 Work RVU	CMS Work Time Refinement
	without magnet application with analysis, review and report(s) by a physician or other qualified health care professional, up to 90 days				
93294	Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional	0.65	0.60	0.60	No
93295	Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead implantable defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional	1.29	0.74	0.74	No
93296	Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results	0.00	0.00	0.00	No
93297	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular 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; implantable loop recorder 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
93299	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular monitor system or implantable loop recorder system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results	0.00	0.00	0.00	No
93306	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler echocardiography	1.30	1.50	1.50	No
93307	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, without spectral or color Doppler echocardiography	0.92	0.92	0.92	No
93308	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, follow-up or	0.53	0.53	0.53	No

HCPCS Code	Long Descriptor	CY 2017 Work RVU	Proposed CY 2018 Work RVU	Final CY 2018 Work RVU	CMS Work Time Refinement
	limited study				
93350	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report;	1.46	1.46	1.46	No
93351	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report; including performance of continuous electrocardiographic monitoring, with supervision by a physician or other qualified health care professional	1.75	1.75	1.75	No
93503	Insertion and placement of flow directed catheter (eg, Swan-Ganz) for monitoring purposes	2.91	2.00	2.00	No
93613	Intracardiac electrophysiologic 3-dimensional mapping	6.99	5.23	5.23	No
93668	Peripheral arterial disease (PAD) rehabilitation, per session	N	0.00	0.00	No
93792	Patient/caregiver training for initiation of home INR monitoring under the direction of a physician or other qualified health care professional, including face-to-face, use and care of the INR monitor, obtaining blood sample, instructions for reporting home INR test results, and documentation of patient's/caregiver's ability to perform testing and report results	NEW	0.00	0.00	No
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	NEW	0.18	0.18	No
94617	Exercise test for bronchospasm, including pre- and post-spirometry and pulse oximetry	NEW	0.70	0.70	No
94618	Pulmonary stress testing (eg, 6-minute walk test), including measurement of heart rate, oximetry, and oxygen titration, when performed	NEW	0.48	0.48	No
94621	Cardiopulmonary exercise testing, including measurements of minute ventilation, CO2 production, O2 uptake, and electrocardiographic recordings	1.42	1.42	1.42	No
95004	Percutaneous tests (scratch, puncture, prick)	0.01	0.01	0.01	No

HCPCS Code	Long Descriptor	CY 2017 Work RVU	Proposed CY 2018 Work RVU	Final CY 2018 Work RVU	CMS Work Time Refinement
	with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests				
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording	0.00	0.00	0.00	No
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report	0.85	0.70	0.70	No
95930	Visual evoked potential (VEP) testing central nervous system except glaucoma, checkerboard or flash, with interpretation and report	0.35	0.35	0.35	No
96160	Administration of patient-focused health risk assessment instrument (eg, health hazard appraisal) with scoring and documentation, per standardized instrument	0.00	0.00	0.00	No
96161	Administration of caregiver-focused health risk assessment instrument (eg, depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument	0.00	0.00	0.00	No
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	0.17	0.17	0.17	No
96361	Intravenous infusion, hydration; each additional hour	0.09	0.09	0.09	No
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	0.17	0.17	0.17	No
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	0.18	0.18	0.18	No
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug	0.10	0.10	0.10	No
96377	Application of on-body injector (includes cannula insertion) for timed subcutaneous injection	0.00	0.17	0.17	No
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic	0.21	0.21	0.21	No
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic	0.19	0.19	0.19	No
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	0.24	0.24	0.24	No
96411	Chemotherapy administration; intravenous,	0.20	0.20	0.20	No

HCPCS Code	Long Descriptor	CY 2017 Work RVU	Proposed CY 2018 Work RVU	Final CY 2018 Work RVU	CMS Work Time Refinement
	push technique, each additional substance/drug				
96573	Photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitizing drug(s), per day	NEW	0.48	0.48	No
96574	Debridement of premalignant hyperkeratotic lesion(s) (ie, targeted curettage, abrasion) followed with photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitizing drug(s), per day	NEW	1.01	1.01	No
96910	Photochemotherapy; tar and ultraviolet B (Goeckerman treatment) or petrolatum and ultraviolet B	0.00	0.00	0.00	No
97012	Application of a modality to 1 or more areas; traction, mechanical	0.25	0.25	0.25	No
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)	0.18	0.18	0.18	No
97016	Application of a modality to 1 or more areas; vasopneumatic devices	0.18	0.18	0.18	No
97018	Application of a modality to 1 or more areas; paraffin bath	0.06	0.06	0.06	No
97022	Application of a modality to 1 or more areas; whirlpool	0.17	0.17	0.17	No
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes	0.25	0.25	0.25	No
97033	Application of a modality to 1 or more areas; iontophoresis, each 15 minutes	0.26	0.26	0.26	No
97034	Application of a modality to 1 or more areas; contrast baths, each 15 minutes	0.21	0.21	0.21	No
97035	Application of a modality to 1 or more areas; ultrasound, each 15 minutes	0.21	0.21	0.21	No
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility	0.45	0.45	0.45	No
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	0.45	0.50	0.50	No
97113	Therapeutic procedure, 1 or more areas, each 15 minutes; aquatic therapy with therapeutic exercises	0.44	0.48	0.48	No
97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)	0.40	0.45	0.45	No
97127	Therapeutic interventions that focus on	NEW	I	I	Yes

HCPCS Code	Long Descriptor	CY 2017 Work RVU	Proposed CY 2018 Work RVU	Final CY 2018 Work RVU	CMS Work Time Refinement
	cognitive function (eg, attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (eg, managing time or schedules, initiating, organizing and sequencing tasks, direct (one-on-one) patient contact (do not report 97X11 in conjunction with 0364T, 0365T, 0368T, 0369T) (report 97X11 only once per day)				
97140	Manual therapy techniques (eg, mobilization/ manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes	0.43	0.43	0.43	No
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes	0.44	0.44	0.44	No
97533	Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one-on-one) patient contact, each 15 minutes	0.44	0.48	0.48	No
97535	Self-care/home management training (eg, activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes	0.45	0.45	0.45	No
97537	Community/work reintegration training (eg, shopping, transportation, money management, avocational activities and/or work environment/modification analysis, work task analysis, use of assistive technology device/adaptive equipment), direct one-on-one contact, each 15 minutes	0.45	0.48	0.48	No
97542	Wheelchair management (eg, assessment, fitting, training), each 15 minutes	0.45	0.48	0.48	No
97760	Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes	0.45	0.50	0.50	No
97761	Prosthetic(s) training, upper and/or lower extremity(ies), initial prosthetic(s) encounter, each 15 minutes	0.45	0.50	0.50	No
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	NEW	0.48	0.48	No

HCPCS Code	Long Descriptor	CY 2017 Work RVU	Proposed CY 2018 Work RVU	Final CY 2018 Work RVU	CMS Work Time Refinement
99091	Collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time	B	-	1.10	No
99483	Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements:Cognition-focused evaluation including a pertinent history and examination;Medical decision making of moderate or high complexity;Functional assessment (eg, Basic and Instrumental Activities of Daily Living), including decision-making capacity;Use of standardized instruments for staging of dementia (eg, Functional Assessment Staging Test [FAST], Clinical Dementia Rating [CDR]);Medication reconciliation and review for high-risk medications;Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s);Evaluation of safety (eg, home), including motor vehicle operation;Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks;Development, updating or revision, or review of an Advance Care Plan;Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neuro-cognitive symptoms, functional limitations, and referral to community resources as needed (eg, rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support.Typically, 50 minutes are spent face-to-face with the patient and/or family or caregiver.	NEW	3.44	3.44	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 rating	NEW	0.61	0.61	No

HCPCS Code	Long Descriptor	CY 2017 Work RVU	Proposed CY 2018 Work RVU	Final CY 2018 Work RVU	CMS Work Time Refinement
	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; andContinuity of care with a designated member of the care team				
99492	Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements:outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional; initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan; review by the psychiatric consultant with modifications of the plan if recommended; entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant; andprovision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies.	NEW	1.70	1.70	No
99493	Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements:tracking patient follow-up and progress using the registry, with appropriate documentation; participation in weekly caseload consultation with the psychiatric consultant; ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers; additional review of progress and recommendations for changes in	NEW	1.53	1.53	No

HCPCS Code	Long Descriptor	CY 2017 Work RVU	Proposed CY 2018 Work RVU	Final CY 2018 Work RVU	CMS Work Time Refinement
	treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant;provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies;monitoring of patient outcomes using validated rating scales; and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment.				
99494	Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional	NEW	0.82	0.82	No
G0283	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care	0.18	0.18	0.18	No
G0513	Prolonged preventive service(s), initial 30 minutes	NEW	1.17	1.17	No
G0514	Prolonged preventive service(s), first 30 minutes	NEW	1.17	1.17	No
G0515	Development of cognitive skills to improve attention, memory, or problem solving (includes compensatory training), direct one-on-one patient contact, each 15 minutes	NEW	0.44	0.44	No
G0516	Insertion, non- biodegradable drug delivery implants, 4 or more	NEW	1.82	1.82	No
G0517	Removal, non- biodegradable drug deliver implants, 4 or more	NEW	2.10	2.10	No
G0518	Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more	NEW	3.55	3.55	No

TABLE 13: CY 2018 Codes with Direct PE Input Recommendations with 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)
15730	Mdfc flap w/prsrv vasc pedcl	ED050	Technologist PACS workstation	NF		115	117	E15: Refined equipment time to conform to changes in clinical labor time	$0.04
15730	Mdfc flap w/prsrv vasc pedcl	EF014	light, surgical	NF		115	117	E15: Refined equipment time to conform to changes in clinical labor time	$0.02
15730	Mdfc flap w/prsrv vasc pedcl	EF031	table, power	NF		115	117	E15: Refined equipment time to conform to changes in clinical labor time	$0.03
15730	Mdfc flap w/prsrv vasc pedcl	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		115	117	E15: Refined equipment time to conform to changes in clinical labor time	$0.03
15730	Mdfc flap w/prsrv vasc pedcl	EQ110	electrocautery-hyfrecator, up to 45 watts	NF		115	117	E15: Refined equipment time to conform to changes in clinical labor time	$0.01
15730	Mdfc flap w/prsrv vasc pedcl	EQ138	instrument pack, medium ($1500 and up)	NF		127	129	E15: Refined equipment time to conform to changes in clinical labor time	$0.01
15730	Mdfc flap w/prsrv vasc pedcl	L038A	COMT/COT/RN/CST	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.76
29445	Apply rigid leg cast	EF031	table, power	NF		69	67	E15: Refined equipment time to conform to changes in clinical labor time	-$0.03
29445	Apply rigid leg cast	EQ080	cast cart	NF		69	67	E15: Refined equipment time to conform to changes in clinical labor time	-$0.02

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)
29445	Apply rigid leg cast	EQ168	light, exam	NF		69	67	E15: Refined equipment time to conform to changes in clinical labor time	-$0.01
29445	Apply rigid leg cast	L037D	RN/LPN/MTA	NF	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	5	3	L1: Refined time to standard for this clinical labor task	-$0.74
29580	Application of paste boot	EF023	table, exam	NF		35	34	E15: Refined equipment time to conform to changes in clinical labor time	$0.00
29580	Application of paste boot	EQ168	light, exam	NF		35	34	E15: Refined equipment time to conform to changes in clinical labor time	$0.00
29580	Application of paste boot	L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-$0.37
29581	Apply multlay comprs lwr leg	EF023	table, exam	NF		37	36	E15: Refined equipment time to conform to changes in clinical labor time	$0.00
29581	Apply multlay comprs lwr leg	EQ168	light, exam	NF		37	36	E15: Refined equipment time to conform to changes in clinical labor time	$0.00
29581	Apply multlay comprs lwr leg	L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-$0.37
30140	Resect inferior turbinate	EF008	chair with headrest, exam, reclining	NF		98	100	E15: Refined equipment time to conform to changes in clinical labor	$0.02

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)
								time	
30140	Resect inferior turbinate	EQ137	instrument pack, basic ($500-$1499)	NF		102	104	E15: Refined equipment time to conform to changes in clinical labor time	$0.00
30140	Resect inferior turbinate	EQ170	light, fiberoptic headlight w-source	NF		98	100	E15: Refined equipment time to conform to changes in clinical labor time	$0.02
30140	Resect inferior turbinate	EQ234	suction and pressure cabinet, ENT (SMR)	NF		98	100	E15: Refined equipment time to conform to changes in clinical labor time	$0.02
30140	Resect inferior turbinate	EQ383	reusable shaver blade, 2mm	NF		102	104	E15: Refined equipment time to conform to changes in clinical labor time	$0.01
30140	Resect inferior turbinate	EQ384	Microdebrider handpiece	NF		98	100	E15: Refined equipment time to conform to changes in clinical labor time	$0.03
30140	Resect inferior turbinate	EQ385	Microdebrider console	NF		98	100	E15: Refined equipment time to conform to changes in clinical labor time	$0.06
30140	Resect inferior turbinate	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.74
30901	Control of nosebleed	EF008	chair with headrest, exam, reclining	NF		22	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.04
30901	Control of nosebleed	EQ137	instrument pack, basic ($500-$1499)	NF		29	33	E5: Refined equipment time to conform to established policies for surgical instrument	$0.01

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								packs	
30901	Control of nosebleed	EQ170	light, fiberoptic headlight w-source	NF		22	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.03
30901	Control of nosebleed	EQ234	suction and pressure cabinet, ENT (SMR)	NF		22	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.04
30903	Control of nosebleed	EF008	chair with headrest, exam, reclining	NF		27	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.04
30903	Control of nosebleed	EQ110	electrocautery-hyfrecator, up to 45 watts	NF		27	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
30903	Control of nosebleed	EQ137	instrument pack, basic ($500-$1499)	NF		34	38	E5: Refined equipment time to conform to established policies for surgical instrument packs	$0.01
30903	Control of nosebleed	EQ170	light, fiberoptic headlight w-source	NF		27	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.03
30903	Control of nosebleed	EQ234	suction and pressure cabinet, ENT (SMR)	NF		27	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.04
30905	Control of	EF008	chair with headrest,	NF		32	62	E1: Refined equipment	$0.32

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)
	nosebleed		exam, reclining					time to conform to established policies for non-highly technical equipment	
30905	Control of nosebleed	EQ110	electrocautery-hyfrecator, up to 45 watts	NF		32	62	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.08
30905	Control of nosebleed	EQ137	instrument pack, basic ($500-$1499)	NF		39	69	E5: Refined equipment time to conform to established policies for surgical instrument packs	$0.07
30905	Control of nosebleed	EQ170	light, fiberoptic headlight w-source	NF		32	62	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.24
30905	Control of nosebleed	EQ234	suction and pressure cabinet, ENT (SMR)	NF		32	62	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.28
30906	Repeat control of nosebleed	EF008	chair with headrest, exam, reclining	NF		42	72	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.32
30906	Repeat control of nosebleed	EQ110	electrocautery-hyfrecator, up to 45 watts	NF		42	72	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.08
30906	Repeat control of nosebleed	EQ137	instrument pack, basic ($500-$1499)	NF		49	79	E5: Refined equipment time to conform to established policies for	$0.07

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)
								surgical instrument packs	
30906	Repeat control of nosebleed	EQ170	light, fiberoptic headlight w-source	NF		42	72	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.24
30906	Repeat control of nosebleed	EQ234	suction and pressure cabinet, ENT (SMR)	NF		42	72	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.28
31254	Nsl/sins ndsc w/prtl ethmdct	EF008	chair with headrest, exam, reclining	NF		47	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.05
31254	Nsl/sins ndsc w/prtl ethmdct	EF015	mayo stand	NF		47	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
31254	Nsl/sins ndsc w/prtl ethmdct	EQ138	instrument pack, medium ($1500 and up)	NF		59	64	E5: Refined equipment time to conform to established policies for surgical instrument packs	$0.03
31254	Nsl/sins ndsc w/prtl ethmdct	EQ167	light source, xenon	NF		47	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.14
31254	Nsl/sins ndsc w/prtl ethmdct	EQ170	light, fiberoptic headlight w-source	NF		47	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.04

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31254	Nsl/sins ndsc w/prtl ethmdct	EQ234	suction and pressure cabinet, ENT (SMR)	NF		47	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.05
31254	Nsl/sins ndsc w/prtl ethmdct	EQ383	reusable shaver blade, 2mm	NF		47	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.02
31254	Nsl/sins ndsc w/prtl ethmdct	EQ384	Microdebrider handpiece	NF		47	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.06
31254	Nsl/sins ndsc w/prtl ethmdct	EQ385	Microdebrider console	NF		47	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.15
31254	Nsl/sins ndsc w/prtl ethmdct	ES005	endoscope disinfector, rigid or fiberoptic, w-cart	NF		37	51	E4: Refined equipment time to conform to established policies for scopes	$0.85
31254	Nsl/sins ndsc w/prtl ethmdct	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		47	44	E19: Refined equipment time to conform to established policies for scope accessories	-$0.39
31254	Nsl/sins ndsc w/prtl ethmdct	ES040	PROXY endoscope, rigid, sinoscopy (0 degrees)	NF		37	51	E4: Refined equipment time to conform to established policies for scopes	$0.11
31254	Nsl/sins ndsc w/prtl ethmdct	L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic and referral forms	3	0	L1: Refined time to standard for this clinical labor task	-$1.11
31254	Nsl/sins ndsc	L037D	RN/LPN/MTA	NF	Complete pre-	3	0	L1: Refined time to	-$1.11

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)
	w/prtl ethmdct				procedure phone calls and prescription			standard for this clinical labor task	
31254	Nsl/sins ndsc w/prtl ethmdct	L037D	RN/LPN/MTA	NF		3	5	L1: Refined time to standard for this clinical labor task	$0.74
31254	Nsl/sins ndsc w/prtl ethmdct	L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent	3	0	L1: Refined time to standard for this clinical labor task	-$1.11
31295	Sinus endo w/balloon dil	EF008	chair with headrest, exam, reclining	NF		37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.05
31295	Sinus endo w/balloon dil	EF015	mayo stand	NF		37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
31295	Sinus endo w/balloon dil	EQ138	instrument pack, medium ($1500 and up)	NF		49	54	E5: Refined equipment time to conform to established policies for surgical instrument packs	$0.03
31295	Sinus endo w/balloon dil	EQ167	light source, xenon	NF		37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.14
31295	Sinus endo w/balloon dil	EQ170	light, fiberoptic headlight w-source	NF		37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.04
31295	Sinus endo w/balloon dil	EQ234	suction and pressure cabinet, ENT (SMR)	NF		37	42	E1: Refined equipment time to conform to	$0.05

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)
								established policies for non-highly technical equipment	
31295	Sinus endo w/balloon dil	EQ383	reusable shaver blade, 2mm	NF		37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.02
31295	Sinus endo w/balloon dil	EQ384	Microdebrider handpiece	NF		37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.06
31295	Sinus endo w/balloon dil	EQ385	Microdebrider console	NF		37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.15
31295	Sinus endo w/balloon dil	ES005	endoscope disinfector, rigid or fiberoptic, w-cart	NF		27	41	E4: Refined equipment time to conform to established policies for scopes	$0.85
31295	Sinus endo w/balloon dil	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		37	34	E19: Refined equipment time to conform to established policies for scope accessories	-$0.39
31295	Sinus endo w/balloon dil	ES040	PROXY endoscope, rigid, sinoscopy (0 degrees)	NF		27	41	E4: Refined equipment time to conform to established policies for scopes	$0.11
31295	Sinus endo w/balloon dil	L037D	RN/LPN/MTA	NF	Complete pre-procedure phone calls and prescription	3	0	L1: Refined time to standard for this clinical labor task	-$1.11
31295	Sinus endo w/balloon dil	L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic and	3	0	L1: Refined time to standard for this clinical labor task	-$1.11

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)
					referral forms				
31295	Sinus endo w/balloon dil	L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent	3	0	L1: Refined time to standard for this clinical labor task	-$1.11
31295	Sinus endo w/balloon dil	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.74
31296	Sinus endo w/balloon dil	EF008	chair with headrest, exam, reclining	NF		40	45	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.05
31296	Sinus endo w/balloon dil	EF015	mayo stand	NF		40	45	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
31296	Sinus endo w/balloon dil	EQ138	instrument pack, medium ($1500 and up)	NF		52	57	E5: Refined equipment time to conform to established policies for surgical instrument packs	$0.03
31296	Sinus endo w/balloon dil	EQ167	light source, xenon	NF		40	45	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.14
31296	Sinus endo w/balloon dil	EQ170	light, fiberoptic headlight w-source	NF		40	45	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.04
31296	Sinus endo w/balloon dil	EQ234	suction and pressure cabinet, ENT (SMR)	NF		40	45	E1: Refined equipment time to conform to established policies for non-highly technical	$0.05

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)
								equipment	
31296	Sinus endo w/balloon dil	EQ383	reusable shaver blade, 2mm	NF		40	45	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.02
31296	Sinus endo w/balloon dil	EQ384	Microdebrider handpiece	NF		40	45	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.06
31296	Sinus endo w/balloon dil	EQ385	Microdebrider console	NF		40	45	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.15
31296	Sinus endo w/balloon dil	ES005	endoscope disinfector, rigid or fiberoptic, w-cart	NF		32	44	E4: Refined equipment time to conform to established policies for scopes	$0.73
31296	Sinus endo w/balloon dil	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		40	37	E19: Refined equipment time to conform to established policies for scope accessories	-$0.39
31296	Sinus endo w/balloon dil	ES040	PROXY endoscope, rigid, sinoscopy (0 degrees)	NF		32	44	E4: Refined equipment time to conform to established policies for scopes	$0.09
31296	Sinus endo w/balloon dil	L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent	3	0	L1: Refined time to standard for this clinical labor task	-$1.11
31296	Sinus endo w/balloon dil	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.74
31296	Sinus endo w/balloon dil	L037D	RN/LPN/MTA	NF	Complete pre-procedure phone	3	0	L1: Refined time to standard for this clinical	-$1.11

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)
					calls and prescription			labor task	
31296	Sinus endo w/balloon dil	L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic and referral forms	3	0	L1: Refined time to standard for this clinical labor task	-$1.11
31297	Sinus endo w/balloon dil	EF008	chair with headrest, exam, reclining	NF		37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.05
31297	Sinus endo w/balloon dil	EF015	mayo stand	NF		37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
31297	Sinus endo w/balloon dil	EQ138	instrument pack, medium ($1500 and up)	NF		49	54	E5: Refined equipment time to conform to established policies for surgical instrument packs	$0.03
31297	Sinus endo w/balloon dil	EQ167	light source, xenon	NF		37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.14
31297	Sinus endo w/balloon dil	EQ170	light, fiberoptic headlight w-source	NF		37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.04
31297	Sinus endo w/balloon dil	EQ234	suction and pressure cabinet, ENT (SMR)	NF		37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.05
31297	Sinus endo	EQ383	reusable shaver blade,	NF		37	42	E1: Refined equipment	$0.02

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	w/balloon dil		2mm					time to conform to established policies for non-highly technical equipment	
31297	Sinus endo w/balloon dil	EQ384	Microdebrider handpiece	NF		37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.06
31297	Sinus endo w/balloon dil	EQ385	Microdebrider console	NF		37	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.15
31297	Sinus endo w/balloon dil	ES005	endoscope disinfector, rigid or fiberoptic, w-cart	NF		27	41	E4: Refined equipment time to conform to established policies for scopes	$0.85
31297	Sinus endo w/balloon dil	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		37	34	E19: Refined equipment time to conform to established policies for scope accessories	-$0.39
31297	Sinus endo w/balloon dil	ES040	PROXY endoscope, rigid, sinoscopy (0 degrees)	NF		27	41	E4: Refined equipment time to conform to established policies for scopes	$0.11
31297	Sinus endo w/balloon dil	L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent	3	0	L1: Refined time to standard for this clinical labor task	-$1.11
31297	Sinus endo w/balloon dil	L037D	RN/LPN/MTA	NF	Complete pre-procedure phone calls and prescription	3	0	L1: Refined time to standard for this clinical labor task	-$1.11
31297	Sinus endo w/balloon dil	L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic and	3	0	L1: Refined time to standard for this clinical labor task	-$1.11

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)
					referral forms				
31297	Sinus endo w/balloon dil	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.74
31298	Nsl/sins ndsc w/sins dilat	EF008	chair with headrest, exam, reclining	NF		59	64	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.05
31298	Nsl/sins ndsc w/sins dilat	EF015	mayo stand	NF		59	64	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
31298	Nsl/sins ndsc w/sins dilat	EQ138	instrument pack, medium ($1500 and up)	NF		71	76	E5: Refined equipment time to conform to established policies for surgical instrument packs	$0.03
31298	Nsl/sins ndsc w/sins dilat	EQ167	light source, xenon	NF		59	64	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.14
31298	Nsl/sins ndsc w/sins dilat	EQ170	light, fiberoptic headlight w-source	NF		59	64	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.04
31298	Nsl/sins ndsc w/sins dilat	EQ234	suction and pressure cabinet, ENT (SMR)	NF		59	64	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.05
31298	Nsl/sins ndsc w/sins dilat	EQ383	reusable shaver blade, 2mm	NF		59	64	E1: Refined equipment time to conform to established policies for	$0.02

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)
								non-highly technical equipment	
31298	Nsl/sins ndsc w/sins dilat	EQ384	Microdebrider handpiece	NF		59	64	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.06
31298	Nsl/sins ndsc w/sins dilat	EQ385	Microdebrider console	NF		59	64	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.15
31298	Nsl/sins ndsc w/sins dilat	ES005	endoscope disinfector, rigid or fiberoptic, w-cart	NF		57	73	E4: Refined equipment time to conform to established policies for scopes	$0.97
31298	Nsl/sins ndsc w/sins dilat	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		59	56	E19: Refined equipment time to conform to established policies for scope accessories	-$0.39
31298	Nsl/sins ndsc w/sins dilat	ES040	PROXY endoscope, rigid, sinoscopy (0 degrees)	NF		57	73	E4: Refined equipment time to conform to established policies for scopes	$0.12
31298	Nsl/sins ndsc w/sins dilat	L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent	3	0	L1: Refined time to standard for this clinical labor task	-$1.11
31298	Nsl/sins ndsc w/sins dilat	L037D	RN/LPN/MTA	NF	Complete pre-procedure phone calls and prescription	3	0	L1: Refined time to standard for this clinical labor task	-$1.11
31298	Nsl/sins ndsc w/sins dilat	L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic and referral forms	3	0	L1: Refined time to standard for this clinical labor task	-$1.11
31298	Nsl/sins ndsc	L037D	RN/LPN/MTA	NF	Obtain vital	3	5	L1: Refined time to	$0.74

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	w/sins dilat				signs			standard for this clinical labor task	
31645	Brnchsc w/ther aspir 1st	EF027	table, instrument, mobile	NF		57	0	G1: See preamble text	-$0.08
31645	Brnchsc w/ther aspir 1st	EF031	table, power	NF		57	58	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.02
31645	Brnchsc w/ther aspir 1st	EQ004	CO2 respiratory profile monitor	NF		57	58	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.03
31645	Brnchsc w/ther aspir 1st	EQ032	IV infusion pump	NF		57	0	G1: See preamble text	-$0.36
31645	Brnchsc w/ther aspir 1st	EQ235	suction machine (Gomco)	NF		57	58	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.00
31645	Brnchsc w/ther aspir 1st	ES017	fiberscope, flexible, bronchoscopy	NF		72	82	E4: Refined equipment time to conform to established policies for scopes	$0.82
31645	Brnchsc w/ther aspir 1st	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		42	55	E19: Refined equipment time to conform to established policies for scope accessories	$1.68
32994	Ablate puml tumor perq crybl	ED050	Technologist PACS workstation	NF		138	117	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.46
32994	Ablate puml tumor perq	EL007	room, CT	NF		103	101	E2: Refined equipment time to conform to	-$9.73

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	crybl							established policies for highly technical equipment	
32994	Ablate puml tumor perq crybl	EQ168	light, exam	NF		103	112	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.04
32994	Ablate puml tumor perq crybl	EQ302	cryosurgery system (for tumor ablation)	NF		103	101	E2: Refined equipment time to conform to established policies for highly technical equipment	-$0.19
32998	Ablate pulm tumor perq rf	ED050	Technologist PACS workstation	NF		133	112	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.46
32998	Ablate pulm tumor perq rf	EL007	room, CT	NF		98	96	E2: Refined equipment time to conform to established policies for highly technical equipment	-$9.73
32998	Ablate pulm tumor perq rf	EQ168	light, exam	NF		98	107	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.04
32998	Ablate pulm tumor perq rf	EQ214	radiofrequency generator (NEURO)	NF		98	96	E2: Refined equipment time to conform to established policies for highly technical equipment	-$0.25
36215	Place catheter in artery	ED050	Technologist PACS workstation	NF		61	59	E15: Refined equipment time to conform to changes in clinical labor time	-$0.04
36215	Place	EF027	table, instrument,	NF		180	0	G1: See preamble text	-$0.25

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	catheter in artery		mobile						
36215	Place catheter in artery	L037D	RN/LPN/MTA	NF	Other Clinical Activity - specify: Post-procedure doppler evaluation (extremity)	3	1	G1: See preamble text	-$0.74
36216	Place catheter in artery	ED050	Technologist PACS workstation	NF		76	74	E15: Refined equipment time to conform to changes in clinical labor time	-$0.04
36216	Place catheter in artery	EF027	table, instrument, mobile	NF		180	0	G1: See preamble text	-$0.25
36216	Place catheter in artery	L037D	RN/LPN/MTA	NF	Other Clinical Activity - specify: Post-procedure doppler evaluation (extremity)	3	1	G1: See preamble text	-$0.74
36217	Place catheter in artery	ED050	Technologist PACS workstation	NF		91	89	E15: Refined equipment time to conform to changes in clinical labor time	-$0.04
36217	Place catheter in artery	EF027	table, instrument, mobile	NF		180	0	G1: See preamble text	-$0.25
36217	Place catheter in artery	L037D	RN/LPN/MTA	NF	Circulator (25%)	12	15	G1: See preamble text	$1.11
36217	Place catheter in artery	L037D	RN/LPN/MTA	NF	Other Clinical Activity - specify: Post-procedure	3	1	G1: See preamble text	-$0.74

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					doppler evaluation (extremity)				
36465	Njx noncmpnd sclrsnt 1 vein	EF014	light, surgical	NF		48	43	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
36465	Njx noncmpnd sclrsnt 1 vein	EF031	table, power	NF		48	43	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.08
36465	Njx noncmpnd sclrsnt 1 vein	EQ250	ultrasound unit, portable	NF		48	43	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.58
36465	Njx noncmpnd sclrsnt 1 vein	L037D	RN/LPN/MTA	NF	Check dressings, catheters, wounds	5	3	L1: Refined time to standard for this clinical labor task	-$0.74
36465	Njx noncmpnd sclrsnt 1 vein	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.74
36465	Njx noncmpnd sclrsnt 1 vein	L054A	Vascular Technologist	NF	Setup scope (nonfacility setting only)	2	0	G1: See preamble text	-$1.08
36465	Njx noncmpnd sclrsnt 1 vein	L054A	Vascular Technologist	NF	Prepare room, equipment and supplies	0	2	G1: See preamble text	$1.08
36465	Njx noncmpnd sclrsnt 1	SG055	gauze, sterile 4in x 4in	NF		6	0	S7: Supply item replaced by another item; see preamble SG056	-$0.95

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	vein								
36465	Njx noncmpnd sclrsnt 1 vein	SG056	gauze, sterile 4in x 4in (10 pack uou)	NF		0	1	S8: Supply item replaces another item; see preamble SG055	$0.80
36466	Njx noncmpnd sclrsnt mlt vn	EF014	light, surgical	NF		58	53	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
36466	Njx noncmpnd sclrsnt mlt vn	EF031	table, power	NF		58	53	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.08
36466	Njx noncmpnd sclrsnt mlt vn	EQ250	ultrasound unit, portable	NF		58	53	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.58
36466	Njx noncmpnd sclrsnt mlt vn	L037D	RN/LPN/MTA	NF	Check dressings, catheters, wounds	5	3	L1: Refined time to standard for this clinical labor task	-$0.74
36466	Njx noncmpnd sclrsnt mlt vn	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.74
36466	Njx noncmpnd sclrsnt mlt vn	L054A	Vascular Technologist	NF	Prepare room, equipment and supplies	0	2	G1: See preamble text	$1.08
36466	Njx noncmpnd sclrsnt mlt vn	L054A	Vascular Technologist	NF	Setup scope (nonfacility setting only)	2	0	G1: See preamble text	-$1.08
36466	Njx	SG055	gauze, sterile 4in x 4in	NF		6	0	S7: Supply item replaced	-$0.95

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	noncmpnd sclrsnt mlt vn							by another item; see preamble SG056	
36466	Njx noncmpnd sclrsnt mlt vn	SG056	gauze, sterile 4in x 4in (10 pack uou)	NF		0	1	S8: Supply item replaces another item; see preamble SG055	$0.80
36470	Njx sclrsnt 1 incmptnt vein	L037D	RN/LPN/MTA	NF	Check dressings, catheters, wounds	5	3	L1: Refined time to standard for this clinical labor task	-$0.74
36470	Njx sclrsnt 1 incmptnt vein	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.74
36470	Njx sclrsnt 1 incmptnt vein	SG055	gauze, sterile 4in x 4in	NF		6	0	S7: Supply item replaced by another item; see preamble SG056	-$0.95
36470	Njx sclrsnt 1 incmptnt vein	SG056	gauze, sterile 4in x 4in (10 pack uou)	NF		0	1	S8: Supply item replaces another item; see preamble SG055	$0.80
36471	Njx sclrsnt mlt incmptnt vn	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.74
36471	Njx sclrsnt mlt incmptnt vn	L037D	RN/LPN/MTA	NF	Check dressings, catheters, wounds	5	3	L1: Refined time to standard for this clinical labor task	-$0.74
36471	Njx sclrsnt mlt incmptnt vn	SG055	gauze, sterile 4in x 4in	NF		6	0	S7: Supply item replaced by another item; see preamble SG056	-$0.95
36471	Njx sclrsnt mlt incmptnt vn	SG056	gauze, sterile 4in x 4in (10 pack uou)	NF		0	1	S8: Supply item replaces another item; see preamble SG055	$0.80
36482	Endoven ther chem adhes 1st	EF014	light, surgical	NF		58	53	E1: Refined equipment time to conform to established policies for non-highly technical	-$0.05

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								equipment	
36482	Endoven ther chem adhes 1st	EF031	table, power	NF		58	53	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.08
36482	Endoven ther chem adhes 1st	EQ250	ultrasound unit, portable	NF		58	53	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.58
36482	Endoven ther chem adhes 1st	L037D	RN/LPN/MTA	NF	Check dressings, catheters, wounds	5	3	L1: Refined time to standard for this clinical labor task	-$0.74
36482	Endoven ther chem adhes 1st	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.74
36482	Endoven ther chem adhes 1st	L054A	Vascular Technologist	NF	Prepare room, equipment and supplies	0	2	G1: See preamble text	$1.08
36482	Endoven ther chem adhes 1st	L054A	Vascular Technologist	NF	Setup scope (nonfacility setting only)	2	0	G1: See preamble text	-$1.08
36482	Endoven ther chem adhes 1st	SG055	gauze, sterile 4in x 4in	NF		6	0	S7: Supply item replaced by another item; see preamble SG056	-$0.95
36482	Endoven ther chem adhes 1st	SG056	gauze, sterile 4in x 4in (10 pack uou)	NF		0	1	S8: Supply item replaces another item; see preamble SG055	$0.80
36555	Insert non-tunnel cv cath	EF023	table, exam	NF		68	38	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.09
36555	Insert non-tunnel cv	EQ011	ECG, 3-channel (with SpO2, NIBP, temp,	NF		68	0	G1: See preamble text	-$0.95

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	cath		resp)						
36555	Insert non-tunnel cv cath	EQ168	light, exam	NF		68	38	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.13
36555	Insert non-tunnel cv cath	L037D	RN/LPN/MTA	NF	Monitor pt. following procedure/check tubes, monitors, drains, multitasking 1:4	7.5	0	L11: Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure	-$2.78
36569	Insert picc cath	EF023	table, exam	NF		30	32	E15: Refined equipment time to conform to changes in clinical labor time	$0.01
36569	Insert picc cath	EQ168	light, exam	NF		30	32	E15: Refined equipment time to conform to changes in clinical labor time	$0.01
36569	Insert picc cath	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.74
38220	Dx bone marrow aspirations	EF023	table, exam	NF		84	82	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.01
38220	Dx bone marrow aspirations	L033A	Lab Technician	NF	Other Clinical Activity - specify:Lab Tech activities	12	9	G1: See preamble text	-$0.99
38221	Dx bone marrow biopsies	EF023	table, exam	NF		83	82	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.00

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38221	Dx bone marrow biopsies	L033A	Lab Technician	NF	Other Clinical Activity - specify:Lab Tech activities	7.5	7	G1: See preamble text	-$0.17
38222	Dx bone marrow bx & aspir	EF023	table, exam	NF		95	92	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.01
38222	Dx bone marrow bx & aspir	L033A	Lab Technician	NF	Other Clinical Activity - specify:Lab Tech activities	12.5	10	G1: See preamble text	-$0.83
55874	Tprnl plmt biodegrdabl matrl	EF031	table, power	NF		63	65	E15: Refined equipment time to conform to changes in clinical labor time	$0.03
55874	Tprnl plmt biodegrdabl matrl	EQ250	ultrasound unit, portable	NF		48	50	E15: Refined equipment time to conform to changes in clinical labor time	$0.23
55874	Tprnl plmt biodegrdabl matrl	EQ386	Endocavitary US probe	NF		48	50	E15: Refined equipment time to conform to changes in clinical labor time	$0.13
55874	Tprnl plmt biodegrdabl matrl	ER061	stepper, stabilizer, template (for brachytherapy treatment)	NF		48	50	E15: Refined equipment time to conform to changes in clinical labor time	$0.12
55874	Tprnl plmt biodegrdabl matrl	ER062	stirrups (for brachytherapy table)	NF		48	50	E15: Refined equipment time to conform to changes in clinical labor time	$0.02
55874	Tprnl plmt biodegrdabl matrl	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.74
58575	Laps tot hyst	EQ168	light, exam	F		142	125	E7: Refined equipment	-$0.07

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	resj mal							time to conform to office visit duration	
58575	Laps tot hyst resj mal	SA051	pack, pelvic exam	F		4	3	G1: See preamble text	-$1.17
67820	Revise eyelashes	L038A	COMT/COT/RN/CST	F	Follow-up phone calls and prescriptions	3	0	G1: See preamble text	-$1.14
67820	Revise eyelashes	L038A	COMT/COT/RN/CST	F	Coordinate pre-surgery services	3	0	G1: See preamble text	-$1.14
70544	Mr angiography head w/o dye	ED050	Technologist PACS workstation	NF		72	69	E15: Refined equipment time to conform to changes in clinical labor time	-$0.07
70544	Mr angiography head w/o dye	ED053	Professional PACS Workstation	NF		17	15	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.12
70544	Mr angiography head w/o dye	EL008	room, MR	NF		39	38	E15: Refined equipment time to conform to changes in clinical labor time	-$3.38
70544	Mr angiography head w/o dye	L047A	MRI Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	4	3	L1: Refined time to standard for this clinical labor task	-$0.47
70544	Mr angiography head w/o dye	L047A	MRI Technologist	NF	Provide pre-service education/obtain consent	7	5	G1: See preamble text	-$0.94
70545	Mr angiography head w/dye	ED050	Technologist PACS workstation	NF		75	74	E15: Refined equipment time to conform to changes in clinical labor time	-$0.02
70545	Mr angiography	ED053	Professional PACS Workstation	NF		17	15	E18: Refined equipment time to conform to	-$0.12

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	head w/dye							established policies for PACS Workstations	
70545	Mr angiography head w/dye	EL008	room, MR	NF		37	36	E15: Refined equipment time to conform to changes in clinical labor time	-$3.38
70545	Mr angiography head w/dye	L047A	MRI Technologist	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.94
70545	Mr angiography head w/dye	L047A	MRI Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	4	3	L1: Refined time to standard for this clinical labor task	-$0.47
70545	Mr angiography head w/dye	L047A	MRI Technologist	NF	Provide pre-service education/obtain consent	9	7	G1: See preamble text	-$0.94
70546	Mr angiograph head w/o&w/dye	ED050	Technologist PACS workstation	NF		116	115	E15: Refined equipment time to conform to changes in clinical labor time	-$0.02
70546	Mr angiograph head w/o&w/dye	ED053	Professional PACS Workstation	NF		20	18	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.12
70546	Mr angiograph head w/o&w/dye	EL008	room, MR	NF		58	57	E15: Refined equipment time to conform to changes in clinical labor time	-$3.38
70546	Mr angiograph head w/o&w/dye	L047A	MRI Technologist	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.94
70546	Mr angiograph	L047A	MRI Technologist	NF	Technologist QCs images in	4	3	L1: Refined time to standard for this clinical	-$0.47

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	head w/o&w/dye				PACS, checking all images, reformats, and dose page			labor task	
70546	Mr angiograph head w/o&w/dye	L047A	MRI Technologist	NF	Provide pre-service education/obtain consent	9	7	G1: See preamble text	-$0.94
70547	Mr angiography neck w/o dye	ED050	Technologist PACS workstation	NF		72	69	E15: Refined equipment time to conform to changes in clinical labor time	-$0.07
70547	Mr angiography neck w/o dye	ED053	Professional PACS Workstation	NF		17	15	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.12
70547	Mr angiography neck w/o dye	EL008	room, MR	NF		39	38	E15: Refined equipment time to conform to changes in clinical labor time	-$3.38
70547	Mr angiography neck w/o dye	L047A	MRI Technologist	NF	Provide pre-service education/obtain consent	7	5	G1: See preamble text	-$0.94
70547	Mr angiography neck w/o dye	L047A	MRI Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	4	3	L1: Refined time to standard for this clinical labor task	-$0.47
70548	Mr angiography neck w/dye	ED050	Technologist PACS workstation	NF		75	74	E15: Refined equipment time to conform to changes in clinical labor time	-$0.02
70548	Mr angiography neck w/dye	ED053	Professional PACS Workstation	NF		20	18	E18: Refined equipment time to conform to established policies for	-$0.12

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								PACS Workstations	
70548	Mr angiography neck w/dye	EL008	room, MR	NF		37	36	E15: Refined equipment time to conform to changes in clinical labor time	-$3.38
70548	Mr angiography neck w/dye	L047A	MRI Technologist	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.94
70548	Mr angiography neck w/dye	L047A	MRI Technologist	NF	Provide pre-service education/obtain consent	9	7	G1: See preamble text	-$0.94
70548	Mr angiography neck w/dye	L047A	MRI Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	4	3	L1: Refined time to standard for this clinical labor task	-$0.47
70549	Mr angiograph neck w/o&w/dye	ED050	Technologist PACS workstation	NF		116	115	E15: Refined equipment time to conform to changes in clinical labor time	-$0.02
70549	Mr angiograph neck w/o&w/dye	ED053	Professional PACS Workstation	NF		25	23	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.12
70549	Mr angiograph neck w/o&w/dye	EL008	room, MR	NF		58	57	E15: Refined equipment time to conform to changes in clinical labor time	-$3.38
70549	Mr angiograph neck w/o&w/dye	L047A	MRI Technologist	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.94
70549	Mr angiograph neck	L047A	MRI Technologist	NF	Provide pre-service education/obtain	9	7	G1: See preamble text	-$0.94

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	w/o&w/dye				consent				
70549	Mr angiograph neck w/o&w/dye	L047A	MRI Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	4	3	L1: Refined time to standard for this clinical labor task	-$0.47
71250	Ct thorax w/o dye	ED053	Professional PACS Workstation	NF		20	18	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.12
71260	Ct thorax w/dye	ED053	Professional PACS Workstation	NF		21	19	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.12
71270	Ct thorax w/o & w/dye	ED053	Professional PACS Workstation	NF		25	23	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.12
72195	Mri pelvis w/o dye	ED053	Professional PACS Workstation	NF		25	23	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.12
72196	Mri pelvis w/dye	ED050	Technologist PACS workstation	NF		64	66	E15: Refined equipment time to conform to changes in clinical labor time	$0.04
72196	Mri pelvis w/dye	ED053	Professional PACS Workstation	NF		30	28	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.12
72196	Mri pelvis w/dye	L047A	MRI Technologist	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.94
72197	Mri pelvis w/o & w/dye	ED050	Technologist PACS workstation	NF		79	81	E15: Refined equipment time to conform to changes in clinical labor	$0.04

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								time	
72197	Mri pelvis w/o & w/dye	ED053	Professional PACS Workstation	NF		32	30	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.12
72197	Mri pelvis w/o & w/dye	L047A	MRI Technologist	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.94
73718	Mri lower extremity w/o dye	ED053	Professional PACS Workstation	NF		20	18	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.12
73719	Mri lower extremity w/dye	ED050	Technologist PACS workstation	NF		62	66	E15: Refined equipment time to conform to changes in clinical labor time	$0.09
73719	Mri lower extremity w/dye	ED053	Professional PACS Workstation	NF		25	23	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.12
73719	Mri lower extremity w/dye	L047A	MRI Technologist	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.94
73719	Mri lower extremity w/dye	L047A	MRI Technologist	NF	Provide pre-service education/obtain consent	5	7	G1: See preamble text	$0.94
73720	Mri lwr extremity w/o&w/dye	ED050	Technologist PACS workstation	NF		77	81	E15: Refined equipment time to conform to changes in clinical labor time	$0.09
73720	Mri lwr extremity w/o&w/dye	ED053	Professional PACS Workstation	NF		29	27	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.12
73720	Mri lwr extremity	L047A	MRI Technologist	NF	Provide pre-service	5	7	G1: See preamble text	$0.94

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	w/o&w/dye				education/obtain consent				
73720	Mri lwr extremity w/o&w/dye	L047A	MRI Technologist	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.94
74181	Mri abdomen w/o dye	ED053	Professional PACS Workstation	NF		25	23	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.12
74182	Mri abdomen w/dye	ED050	Technologist PACS workstation	NF		74	76	E15: Refined equipment time to conform to changes in clinical labor time	$0.04
74182	Mri abdomen w/dye	ED053	Professional PACS Workstation	NF		30	28	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.12
74182	Mri abdomen w/dye	L047A	MRI Technologist	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.94
74183	Mri abdomen w/o & w/dye	ED050	Technologist PACS workstation	NF		79	81	E15: Refined equipment time to conform to changes in clinical labor time	$0.04
74183	Mri abdomen w/o & w/dye	ED053	Professional PACS Workstation	NF		35	33	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.12
74183	Mri abdomen w/o & w/dye	L047A	MRI Technologist	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.94
75635	Ct angio abdominal arteries	ED050	Technologist PACS workstation	NF		119	124	E18: Refined equipment time to conform to established policies for PACS Workstations	$0.11
75635	Ct angio abdominal	ED053	Professional PACS Workstation	NF		49	44	E18: Refined equipment time to conform to	-$0.29

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	arteries							established policies for PACS Workstations	
75635	Ct angio abdominal arteries	EL007	room, CT	NF		71	70	E15: Refined equipment time to conform to changes in clinical labor time	-$2.70
75635	Ct angio abdominal arteries	L046A	CT Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	4	3	L1: Refined time to standard for this clinical labor task	-$0.46
75710	Artery x-rays arm/leg	ED050	Technologist PACS workstation	NF		52	49	E15: Refined equipment time to conform to changes in clinical labor time	-$0.07
75710	Artery x-rays arm/leg	ED053	Professional PACS Workstation	NF		55	48	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.41
75710	Artery x-rays arm/leg	L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies	2	0	G1: See preamble text	-$0.82
75710	Artery x-rays arm/leg	L041B	Radiologic Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	4	3	L1: Refined time to standard for this clinical labor task	-$0.41
75716	Artery x-rays arms/legs	ED050	Technologist PACS workstation	NF		62	59	E15: Refined equipment time to conform to changes in clinical labor time	-$0.07
75716	Artery x-rays arms/legs	ED053	Professional PACS Workstation	NF		65	58	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.41

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75716	Artery x-rays arms/legs	L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies	2	0	G1: See preamble text	-$0.82
75716	Artery x-rays arms/legs	L041B	Radiologic Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	4	3	L1: Refined time to standard for this clinical labor task	-$0.41
76881	Us xtr non-vasc complete	EF031	table, power	NF		8	7	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.02
76881	Us xtr non-vasc complete	EQ250	ultrasound unit, portable	NF		8	7	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.12
76881	Us xtr non-vasc complete	L026A	Medical/Technical Assistant	NF	Exam document scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	1	0	G1: See preamble text	-$0.26
76882	Us xtr non-vasc lmtd	EL015	room, ultrasound, general	NF		24	0	G1: See preamble text	-$33.64
76882	Us xtr non-vasc lmtd	EQ250	ultrasound unit, portable	NF		0	29	G1: See preamble text	$3.37
78300	Bone imaging limited area	ED053	Professional PACS Workstation	NF		15	13	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.12

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78305	Bone imaging multiple areas	ED053	Professional PACS Workstation	NF		15	13	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.12
78306	Bone imaging whole body	ED053	Professional PACS Workstation	NF		78	13	E18: Refined equipment time to conform to established policies for PACS Workstations	-$3.76
88333	Intraop cyto path consult 1	L033A	Lab Technician	NF	Prepare room. Filter and replenish stains and supplies. (including OCT blocks, set up grossing station with colored stains)	10	2	G1: See preamble text	-$2.64
88333	Intraop cyto path consult 1	L037B	Histotechnologist	NF	Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure)	5	1	L1: Refined time to standard for this clinical labor task	-$1.48
88360	Tumor immunohisto chem/manua l	L033A	Lab Technician	NF	Recycle xylene from tissue processor and stainer	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-$0.33
88360	Tumor immunohisto chem/manua l	L037B	Histotechnologist	NF	Enter patient data, computational prep for antibody testing,	5	1	L1: Refined time to standard for this clinical labor task	-$1.48

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)
					generate and apply bar codes to slides, and enter data for automated slide stainer				
88360	Tumor immunohistochem/manual	L037B	Histotechnologist	NF	Verify results and complete work load recording logs	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-$0.37
88361	Tumor immunohistochem/comput	L033A	Lab Technician	NF	Recycle xylene from tissue processor and stainer	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-$0.33
88361	Tumor immunohistochem/comput	L037B	Histotechnologist	NF	Gate areas to be counted by the machine	1	0	G1: See preamble text	-$0.37
88361	Tumor immunohistochem/comput	L037B	Histotechnologist	NF	Enter patient data, computational prep for antibody testing, generate and apply bar codes to slides, and enter data for automated slide stainer	5	1	L1: Refined time to standard for this clinical labor task	-$1.48
88361	Tumor immunohistochem/comput	L037B	Histotechnologist	NF	Performing instrument calibration, instrument qc and start up and shutdown.	1	0	G1: See preamble text	-$0.37

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88361	Tumor immunohistochem/comput	L037B	Histotechnologist	NF	Verify results and complete work load recording logs	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-$0.37
93279	Pm device progr eval sngl	EF023	table, exam	NF		33	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.02
93279	Pm device progr eval sngl	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		33	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.53
93279	Pm device progr eval sngl	L026A	Medical/Technical Assistant	NF	Complete diagnostic forms, lab, X-ray requisitions	2	0	L2: Clinical labor task redundant with clinical labor task L037D	-$0.52
93279	Pm device progr eval sngl	L037D	RN/LPN/MTA	NF	Other Clinical Activity - specify: Review charts	2	0	L1: Refined time to standard for this clinical labor task	-$0.74
93280	Pm device progr eval dual	EF023	table, exam	NF		38	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.02
93280	Pm device progr eval dual	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		38	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.53
93280	Pm device progr eval dual	L026A	Medical/Technical Assistant	NF	Complete diagnostic forms, lab, X-ray requisitions	2	0	L2: Clinical labor task redundant with clinical labor task L037D	-$0.52

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93280	Pm device progr eval dual	L037D	RN/LPN/MTA	NF	Other Clinical Activity - specify: Review charts	2	0	L1: Refined time to standard for this clinical labor task	-$0.74
93281	Pm device progr eval multi	EF023	table, exam	NF		39	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.02
93281	Pm device progr eval multi	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		39	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.61
93281	Pm device progr eval multi	L026A	Medical/Technical Assistant	NF	Complete diagnostic forms, lab, X-ray requisitions	2	0	L2: Clinical labor task redundant with clinical labor task L037D	-$0.52
93281	Pm device progr eval multi	L037D	RN/LPN/MTA	NF	Other Clinical Activity - specify: Review charts	2	0	L1: Refined time to standard for this clinical labor task	-$0.74
93281	Pm device progr eval multi	L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	16	15	L15: Refined clinical labor time to match intraservice work time	-$0.37
93282	Prgrmg eval implantable dfb	EF023	table, exam	NF		35	28	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.02
93282	Prgrmg eval implantable dfb	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		35	28	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.53
93282	Prgrmg eval implantable	L026A	Medical/Technical Assistant	NF	Complete diagnostic	2	0	L2: Clinical labor task redundant with clinical	-$0.52

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	dfb				forms, lab, X-ray requisitions			labor task L037D	
93282	Prgrmg eval implantable dfb	L037D	RN/LPN/MTA	NF	Other Clinical Activity - specify: Review charts	2	0	L1: Refined time to standard for this clinical labor task	-$0.74
93283	Prgrmg eval implantable dfb	EF023	table, exam	NF		38	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.02
93283	Prgrmg eval implantable dfb	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		38	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.53
93283	Prgrmg eval implantable dfb	L026A	Medical/Technical Assistant	NF	Complete diagnostic forms, lab, X-ray requisitions	2	0	L2: Clinical labor task redundant with clinical labor task L037D	-$0.52
93283	Prgrmg eval implantable dfb	L037D	RN/LPN/MTA	NF	Other Clinical Activity - specify: Review charts	2	0	L1: Refined time to standard for this clinical labor task	-$0.74
93284	Prgrmg eval implantable dfb	EF023	table, exam	NF		40.5	33.5	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.02
93284	Prgrmg eval implantable dfb	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		40.5	33.5	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.53
93284	Prgrmg eval implantable dfb	L026A	Medical/Technical Assistant	NF	Complete diagnostic forms, lab, X-	2	0	L2: Clinical labor task redundant with clinical labor task L037D	-$0.52

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					ray requisitions				
93284	Prgrmg eval implantable dfb	L037D	RN/LPN/MTA	NF	Other Clinical Activity - specify: Review charts	2	0	L1: Refined time to standard for this clinical labor task	-$0.74
93285	Ilr device eval progr	EF023	table, exam	NF		30	25	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.01
93285	Ilr device eval progr	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		30	25	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.38
93285	Ilr device eval progr	L026A	Medical/Technical Assistant	NF	Complete diagnostic forms, lab, X-ray requisitions	1	0	L2: Clinical labor task redundant with clinical labor task L037D	-$0.26
93285	Ilr device eval progr	L037D	RN/LPN/MTA	NF	Other Clinical Activity - specify: Review charts	2	0	L1: Refined time to standard for this clinical labor task	-$0.74
93286	Peri-px pacemaker device evl	EF023	table, exam	NF		27	20	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.02
93286	Peri-px pacemaker device evl	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		27	20	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.53
93286	Peri-px pacemaker device evl	L026A	Medical/Technical Assistant	NF	Complete diagnostic forms, lab, X-ray requisitions	2	0	L2: Clinical labor task redundant with clinical labor task L037D	-$0.52

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93286	Peri-px pacemaker device evl	L037D	RN/LPN/MTA	NF	Other Clinical Activity - specify: Review charts	2	0	L1: Refined time to standard for this clinical labor task	-$0.74
93287	Peri-px device eval & prgr	EF023	table, exam	NF		27	20	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.02
93287	Peri-px device eval & prgr	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		27	20	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.53
93287	Peri-px device eval & prgr	L026A	Medical/Technical Assistant	NF	Complete diagnostic forms, lab, X-ray requisitions	2	0	L2: Clinical labor task redundant with clinical labor task L037D	-$0.52
93287	Peri-px device eval & prgr	L037D	RN/LPN/MTA	NF	Other Clinical Activity - specify: Review charts	2	0	L1: Refined time to standard for this clinical labor task	-$0.74
93288	Pm device eval in person	EF023	table, exam	NF		33	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.02
93288	Pm device eval in person	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		33	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.53
93288	Pm device eval in person	L026A	Medical/Technical Assistant	NF	Complete diagnostic forms, lab, X-ray requisitions	2	0	L2: Clinical labor task redundant with clinical labor task L037D	-$0.52
93288	Pm device	L037D	RN/LPN/MTA	NF	Other Clinical	2	0	L1: Refined time to	-$0.74

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	eval in person				Activity - specify: Review charts			standard for this clinical labor task	
93289	Interrog device eval heart	EF023	table, exam	NF		33	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.02
93289	Interrog device eval heart	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		33	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.53
93289	Interrog device eval heart	L026A	Medical/Technical Assistant	NF	Complete diagnostic forms, lab, X-ray requisitions	2	0	L2: Clinical labor task redundant with clinical labor task L037D	-$0.52
93289	Interrog device eval heart	L037D	RN/LPN/MTA	NF	Other Clinical Activity - specify: Review charts	2	0	L1: Refined time to standard for this clinical labor task	-$0.74
93290	Icm device eval	EF023	table, exam	NF		28	24	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.01
93290	Icm device eval	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		28	24	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.30
93290	Icm device eval	L026A	Medical/Technical Assistant	NF	Complete diagnostic forms, lab, X-ray requisitions	1	0	L2: Clinical labor task redundant with clinical labor task L037D	-$0.26
93290	Icm device eval	L037D	RN/LPN/MTA	NF	Other Clinical Activity -	2	0	L1: Refined time to standard for this clinical	-$0.74

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					specify: Review charts			labor task	
93291	Ilr device interrogate	EF023	table, exam	NF		27	22	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.01
93291	Ilr device interrogate	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		27	22	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.38
93291	Ilr device interrogate	L026A	Medical/Technical Assistant	NF	Complete diagnostic forms, lab, X-ray requisitions	1	0	L2: Clinical labor task redundant with clinical labor task L037D	-$0.26
93291	Ilr device interrogate	L037D	RN/LPN/MTA	NF	Other Clinical Activity - specify: Review charts	2	0	L1: Refined time to standard for this clinical labor task	-$0.74
93292	Wcd device interrogate	EF023	table, exam	NF		30	25	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.01
93292	Wcd device interrogate	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		30	25	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.38
93292	Wcd device interrogate	L026A	Medical/Technical Assistant	NF	Complete diagnostic forms, lab, X-ray requisitions	1	0	L2: Clinical labor task redundant with clinical labor task L037D	-$0.26
93292	Wcd device interrogate	L037D	RN/LPN/MTA	NF	Other Clinical Activity - specify: Review	2	0	L1: Refined time to standard for this clinical labor task	-$0.74

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					charts				
93350	Stress tte only	ED053	Professional PACS Workstation	NF		20	18	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.12
93351	Stress tte complete	ED050	Technologist PACS workstation	NF		104	114	E18: Refined equipment time to conform to established policies for PACS Workstations	$0.22
93351	Stress tte complete	ED053	Professional PACS Workstation	NF		30	25	E18: Refined equipment time to conform to established policies for PACS Workstations	-$0.29
93351	Stress tte complete	EQ078	cardiac monitor w-treadmill (12-lead PC-based ECG)	NF		104	91	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.49
93351	Stress tte complete	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.74
93351	Stress tte complete	L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-$0.37
93351	Stress tte complete	L051A	RN	NF	Setup scope (non facility setting only)	5	0	G1: See preamble text	-$2.55
93792	Pt/caregiver trainj home inr	SC021	lancet	NF		4	6	G1: See preamble text	$0.08
93792	Pt/caregiver trainj home inr	SJ053	swab-pad, alcohol	NF		4	6	G1: See preamble text	$0.03
93792	Pt/caregiver trainj home inr	SJ055	test strip, INR	NF		4	6	G1: See preamble text	$11.32

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94617	Exercise tst brncspsm	EQ043	Vmax 29s (spirometry testing equip, computer system)	NF		87	83	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time	-$0.31
94617	Exercise tst brncspsm	EQ078	cardiac monitor w-treadmill (12-lead PC-based ECG)	NF		87	83	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time	-$0.15
94617	Exercise tst brncspsm	EQ211	pulse oximeter w-printer	NF		87	83	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time	-$0.02
94617	Exercise tst brncspsm	L047C	RN/Respiratory Therapist	NF	Complete diagnostic forms, lab, X-ray requisitions	4	3	L1: Refined time to standard for this clinical labor task	-$0.47
94618	Pulmonary stress testing	EQ211	pulse oximeter w-printer	NF		17	15	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$0.01
94618	Pulmonary stress testing	L047C	RN/Respiratory Therapist	NF	Complete diagnostic forms, lab, X-ray requisitions	2	3	L1: Refined time to standard for this clinical labor task	$0.47
94621	Cardiopulm exercise testing	EQ042	Vmax 29c (cardio-pulm stress test equip, treadmill, computer system)	NF		127	117	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time	-$1.65
94621	Cardiopulm exercise testing	EQ211	pulse oximeter w-printer	NF		127	117	E6: Refined equipment time to conform to established policies for equipment with 4x	-$0.04

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								monitoring time	
94621	Cardiopulm exercise testing	L047C	RN/Respiratory Therapist	NF	Complete diagnostic forms, lab, X-ray requisitions	5	3	L1: Refined time to standard for this clinical labor task	-$0.94
94621	Cardiopulm exercise testing	L047C	RN/Respiratory Therapist	NF	Provide pre-service education/obtain consent	10	5	G1: See preamble text	-$2.35
95004	Percut allergy skin tests	EF015	mayo stand	NF		1.28	1.58	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time	$0.00
95004	Percut allergy skin tests	EF023	table, exam	NF		1.28	1.58	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time	$0.00
96160	Pt-focused hlth risk assmt	L026A	Medical/Technical Assistant	NF	Explain purpose of assessment to patient/caregiver and answer questions	2	0	G1: See preamble text	-$0.52
96160	Pt-focused hlth risk assmt	L026A	Medical/Technical Assistant	NF	Remain in exam room with patient/caregiver exclusive to completion of assessment	2	0	G1: See preamble text	-$0.52
96160	Pt-focused hlth risk assmt	L026A	Medical/Technical Assistant	NF	Collate and score data elements on assessment in advance of physician exam	1	0	G1: See preamble text	-$0.26
96160	Pt-focused	L026A	Medical/Technical	NF	Scan assessment	2	0	G1: See preamble text	-$0.52

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	hlth risk assmt		Assistant		or enter data elements and total score into electronic health record				
96160	Pt-focused hlth risk assmt	L026A	Medical/Technical Assistant	NF	Administration, scoring, and documenting results of completed standardized instrument	0	7	G1: See preamble text	$1.82
96161	Caregiver health risk assmt	L026A	Medical/Technical Assistant	NF	Collate and score data elements on assessment in advance of physician exam	1	0	G1: See preamble text	-$0.26
96161	Caregiver health risk assmt	L026A	Medical/Technical Assistant	NF	Administration, scoring, and documenting results of completed standardized instrument	0	7	G1: See preamble text	$1.82
96161	Caregiver health risk assmt	L026A	Medical/Technical Assistant	NF	Scan assessment or enter data elements and total score into electronic health record	2	0	G1: See preamble text	-$0.52
96161	Caregiver health risk assmt	L026A	Medical/Technical Assistant	NF	Explain purpose of assessment to patient/caregiver and answer questions	2	0	G1: See preamble text	-$0.52
96161	Caregiver	L026A	Medical/Technical	NF	Remain in exam	2	0	G1: See preamble text	-$0.52

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	health risk assmt		Assistant		room with patient/caregiver exclusive to completion of assessment				
96360	Hydration iv infusion init	EF023	table, exam	NF		16	24	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time	$0.02
96360	Hydration iv infusion init	EQ032	IV infusion pump	NF		16	24	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time	$0.05
96360	Hydration iv infusion init	L056A	RN/OCN	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$1.58
96361	Hydrate iv infusion add-on	EF023	table, exam	NF		7	9	E15: Refined equipment time to conform to changes in clinical labor time	$0.01
96361	Hydrate iv infusion add-on	EQ032	IV infusion pump	NF		7	9	E15: Refined equipment time to conform to changes in clinical labor time	$0.01
96361	Hydrate iv infusion add-on	L056A	RN/OCN	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$1.58
96372	Ther/proph/diag inj sc/im	EF023	table, exam	NF		12	9	E15: Refined equipment time to conform to changes in clinical labor time	-$0.01
96372	Ther/proph/diag inj sc/im	EQ189	otoscope-ophthalmoscope (wall unit)	NF		12	9	E15: Refined equipment time to conform to changes in clinical labor time	-$0.01

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96372	Ther/proph/diag inj sc/im	L037D	RN/LPN/MTA	NF	Clean room/equipment by physician staff	1	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-$0.37
96372	Ther/proph/diag inj sc/im	L037D	RN/LPN/MTA	NF	Document lot number and expiration date	1	0	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family	-$0.37
96372	Ther/proph/diag inj sc/im	L037D	RN/LPN/MTA	NF	Complete medical record documentation	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-$0.37
96374	Ther/proph/diag inj iv push	EF023	table, exam	NF		23	31	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time	$0.02
96374	Ther/proph/diag inj iv push	EQ189	otoscope-ophthalmoscope (wall unit)	NF		23	31	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time	$0.01
96374	Ther/proph/diag inj iv push	L056A	RN/OCN	NF	Complete medical record documentation	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-$0.79
96375	Tx/pro/dx inj new drug addon	EF023	table, exam	NF		12	17	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time	$0.01
96375	Tx/pro/dx inj new drug addon	EQ189	otoscope-ophthalmoscope (wall unit)	NF		12	17	E6: Refined equipment time to conform to established policies for	$0.01

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								equipment with 4x monitoring time	
96375	Tx/pro/dx inj new drug addon	L056A	RN/OCN	NF	Complete medical record documentation	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-$0.79
96377	Applicaton on-body injector	EF023	table, exam	NF		12	11	E15: Refined equipment time to conform to changes in clinical labor time	$0.00
96377	Applicaton on-body injector	EQ189	otoscope-ophthalmoscope (wall unit)	NF		12	11	E15: Refined equipment time to conform to changes in clinical labor time	$0.00
96377	Applicaton on-body injector	L056A	RN/OCN	NF	Complete medical record documentation	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-$0.79
96402	Chemo hormon antineopl sq/im	EF023	table, exam	NF		31	34	E15: Refined equipment time to conform to changes in clinical labor time	$0.01
96402	Chemo hormon antineopl sq/im	EP016	hood, biohazard	NF		31	34	E15: Refined equipment time to conform to changes in clinical labor time	$0.05
96402	Chemo hormon antineopl sq/im	L037D	RN/LPN/MTA	NF	Obtain vital signs	2	5	L1: Refined time to standard for this clinical labor task	$1.11
96573	Pdt dstr prmlg les phys/qhp	EF031	table, power	NF		230	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$2.91

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)
96573	Pdt dstr prmlg les phys/qhp	EQ169	light, external PDT, w-probe set (LumaCare)	NF		20	52	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$1.12
96573	Pdt dstr prmlg les phys/qhp	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.74
96574	Dbrdmt prmlg les w/pdt	EF031	table, power	NF		232	54	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-$2.91
96574	Dbrdmt prmlg les w/pdt	EQ168	light, exam	NF		52	54	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
96574	Dbrdmt prmlg les w/pdt	EQ169	light, external PDT, w-probe set (LumaCare)	NF		20	54	E1: Refined equipment time to conform to established policies for non-highly technical equipment	$1.19
96574	Dbrdmt prmlg les w/pdt	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.74
96910	Photochemot herapy with uv-b	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	5	L1: Refined time to standard for this clinical labor task	$0.74
96910	Photochemot herapy with uv-b	L037D	RN/LPN/MTA	NF	Complete diagnostic forms, lab & X-ray requisitions, and documentation	2	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-$0.74
99484	Care mgmt svc bhvl hlth	L057B	Behavioral Health Care Manager	F	Other clinical Activity -	20	0	G1: See preamble text	-$11.40

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)
	cond				specify: G0507				
99492	1st psyc collab care mgmt	EF042	One Couch and Two Chairs	F		38	0	G1: See preamble text	-$0.15
99492	1st psyc collab care mgmt	L057B	Behavioral Health Care Manager	F	Other clinical Activity - specify: 994X1 and 994X3	85	0	G1: See preamble text	-$48.45
99493	Sbsq psyc collab care mgmt	EF042	One Couch and Two Chairs	F		27	0	G1: See preamble text	-$0.11
99493	Sbsq psyc collab care mgmt	L057B	Behavioral Health Care Manager	F	Other clinical Activity - specify: 994X2	60	0	G1: See preamble text	-$34.20
99494	1st/sbsq psyc collab care	EF042	One Couch and Two Chairs	F		13.5	0	G1: See preamble text	-$0.05
99494	1st/sbsq psyc collab care	L057B	Behavioral Health Care Manager	F	Other clinical Activity - specify: 994X1 and 994X3	30	0	G1: See preamble text	-$17.10
G0249	Provide inr test mater/equip	SC021	lancet	NF		4	6	G1: See preamble text	$0.08
G0249	Provide inr test mater/equip	SJ053	swab-pad, alcohol	NF		4	6	G1: See preamble text	$0.03
G0249	Provide inr test mater/equip	SJ055	test strip, INR	NF		4	6	G1: See preamble text	$11.32
G0507	Care manage serv minimum 20	L057B	Behavioral Health Care Manager	F	Other clinical Activity - specify: G0507	20	0	G1: See preamble text	-$11.40

TABLE 14: CY 2018 Codes with Direct PE Input Recommendations without Refinement

HCPCS	Description
00731	Anes upr gi ndsc px nos
00732	Anes upr gi ndsc px ercp
00811	Anes lwr intst ndsc nos
00812	Anes lwr intst scr colsc
00813	Anes upr lwr gi hdsc px
10040	Acne surgery
15733	Musc myoq/fscq flp h&n pedcl
15734	Muscle-skin graft trunk
15736	Muscle-skin graft arm
15738	Muscle-skin graft leg
19303	Mast simple complete
31241	Nsl/sins ndsc w/artery lig
31253	Nsl/sins ndsc total
31255	Nsl/sins ndsc w/tot ethmdct
31256	Exploration maxillary sinus
31257	Nsl/sins ndsc tot w/sphendt
31259	Nsl/sins ndsc sphn tiss rmvl
31267	Endoscopy maxillary sinus
31276	Nsl/sins ndsc frnt tiss rmvl
31287	Nasal/sinus endoscopy surg
31288	Nasal/sinus endoscopy surg
31600	Incision of windpipe
31601	Incision of windpipe
31603	Incision of windpipe
31610	Incision of windpipe
31646	Brnchsc w/ther aspir sbsq
34701	Evasc rpr a-ao ndgft
34702	Evasc rpr a-ao ndgft rpt
34703	Evasc rpr a-unilac ndgft
34704	Evasc rpr a-unilac ndgft rpt
34705	Evac rpr a-biiliac ndgft
34706	Evasc rpr a-biiliac rpt
34707	Evasc rpr ilio-iliac ndgft
34708	Evasc rpr ilio-iliac rpt
34709	Plmt xtn prosth evasc rpr
34710	Dlyd plmt xtn prosth 1st vsl
34711	Dlyd plmt xtn prosth ea addl
34712	Tcat dlvr enhncd fixj dev
34713	Perq access & clsr fem art
34714	Opn fem art expos cndt crtj
34715	Opn ax/subcla art expos
34716	Opn ax/subcla art expos cndt
34812	Opn fem art expos
34820	Opn ilac art expos
34833	Opn ilac art expos cndt crtj
34834	Opn brach art expos
36218	Place catheter in artery
36483	Endoven ther chem adhes sbsq
36514	Apheresis plasma
36516	Apheresis immunoads slctv
36522	Photopheresis
36556	Insert non-tunnel cv cath
38573	Laps pelvic lymphadec
43107	Removal of esophagus
43112	Esphg tot w/thrcm
43117	Partial removal of esophagus
43286	Esphg tot w/laps moblj
43287	Esphg dstl 2/3 w/laps moblj
43288	Esphg tot thrsc moblj
51798	Us urine capacity measure
52601	Prostatectomy (turp)
57240	Anterior colporrhaphy
57250	Repair rectum & vagina
57260	Cmbn ant pst colprhy
57265	Cmbn ap colprhy w/ntrcl rpr
64418	N block inj suprascapular
64553	Implant neuroelectrodes
64555	Implant neuroelectrodes
64910	Nerve repair w/allograft
64911	Neurorraphy w/vein autograft
64912	Nrv rpr w/nrv algrft 1st
70490	Ct soft tissue neck w/o dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
71045	X-ray exam chest 1 view
71046	X-ray exam chest 2 views
71047	X-ray exam chest 3 views
71048	X-ray exam chest 4+ views

HCPCS	Description
71100	X-ray exam ribs uni 2 views
71101	X-ray exam unilat ribs/chest
71110	X-ray exam ribs bil 3 views
71111	X-ray exam ribs/chest4/> vws
73100	X-ray exam of wrist
73110	X-ray exam of wrist
73120	X-ray exam of hand
73130	X-ray exam of hand
73140	X-ray exam of finger(s)
74018	X-ray exam abdomen 1 view
74019	X-ray exam abdomen 2 views
74021	X-ray exam abdomen 3+ views
74022	X-ray exam series abdomen
76510	Ophth us b & quant a
76511	Ophth us quant a only
76512	Ophth us b w/non-quant a
76516	Echo exam of eye
76519	Echo exam of eye
88334	Intraop cyto path consult 2
92136	Ophthalmic biometry
93293	Pm phone r-strip device eval
93296	Pm/icd remote tech serv
93299	Icm/ilr remote tech serv
93306	Tte w/doppler complete
93307	Tte w/o doppler complete
93308	Tte f-up or lmtd
93793	Anticoag mgmt pt warfarin
95249	Cont gluc mntr pt prov eqp
95250	Glucose monitoring cont
95930	Visual ep test cns w/i&r
96401	Chemo anti-neopl sq/im
96409	Chemo iv push sngl drug
96411	Chemo iv push addl drug
96567	Pdt dstr prmlg les skn
97012	Mechanical traction therapy
97014	Electric stimulation therapy
97016	Vasopneumatic device therapy
97018	Paraffin bath therapy
97022	Whirlpool therapy
97032	Electrical stimulation
97033	Electric current therapy
97034	Contrast bath therapy
97035	Ultrasound therapy
97110	Therapeutic exercises
97112	Neuromuscular reeducation
97113	Aquatic therapy/exercises
97116	Gait training therapy
97140	Manual therapy 1/> regions
97530	Therapeutic activities
97533	Sensory integration
97535	Self care mngment training
97537	Community/work reintegration
97542	Wheelchair mngment training
97760	Orthotic mgmt&trainj 1st enc
97761	Prosthetic trainj 1st enc
97763	Orthc/prostc mgmt sbsq enc
99483	Assmt & care pln pt cog imp
G0515	Cognitive skills development

TABLE 15: CY 2018 Final Rule – Invoices Received for New Direct PE Inputs

CPT/HCPCS codes	Item Name	CMS Code	Average Price	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
30140, 31254, 31295, 31296, 31297, 31298	reusable shaver blade, 2mm	EQ383	790.00	1	39,006
30140	Tubing set, sterile	SD322	25.00	1	3,435
30140, 31254, 31295, 31296, 31297, 31298	Microdebrider handpiece	EQ384	4,760.00	1	39,006
30140, 31254, 31295, 31296, 31297, 31298	Microdebrider console	EQ385	9,034.00	1	39,006
36482	Venaseal (glue)	SD323	1,495.00	1	387
36465, 36466	Varithena (foam)	SD324	3,195.00	2	1550
36465, 36466	Varithena admin pack	SA125	40.00	2	1550
41530	single-channel radio-frequency handpiece	SD328	353.64	1	41
55874	Endocavity Balloon	SD325	39.90	1	4
55874	Biodegradeable Material Kit - PeriProstatic	SA126	2,850.00	3	4
55874	Endocavitary US probe	EQ386	16,146.00	1	4
76510, 76511, 76516, 76519	scleral shell tubing kit	SA124	2.35	2	421,539
95004	allergen, diagnostic, multi (eg, pollen, mold, environmental)	SJ092	8.44	209	9,931,981
95004	allergy single-test device	SJ093	0.19	5	9,931,981
96573, 96574	patient/clinician goggles	SD326	6.00	1	119,786
96910	Sauna suit	SB054	9.99	1	387,359

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TABLE 16: CY 2018 Final Rule – 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
17000, 17003, 17004, 46607, 96567, 96573, 96574	LMX 4% anesthetic cream	SH092	1.60	1.36	-15%	1	23,584,412
20982, 32998, 50592	probe, radiofrequency, 3 array (StarBurstSDE)	SD109	353.64	2233.00	531%	1	2,972
30140, 30901, 30903, 30905, 30906, 31231, 31237, 31238, 43197, 43198	Atomizer tips (disposable)	SL464	0.00	2.66		1	625,876
36514	cell separator system	EQ084	59,320.00	80,000.00	35%	1	1,237
36514	tubing set, plasma exchange	SC085	173.33	273.66	58%	1	1,237
36514, 36516	ACD-A anticoagulant	SJ071	6.58	7.10	8%	1	2,517
36514, 36516, 36522	blood warmer	EQ072	3,840.00	4,000.00	4%	1	2,542
none (formerly in deleted code 36515)	kit, apheresis treatment	SA072	140.00	243.33	74%	1	0
36522	kit, photopheresis procedure	SA024	858.00	1598.00	86%	1	25
36522	photopheresor system	EQ206	65,000.00	70,000.00	8%	1	25
36522, 96567, 96910, 96912, 96913, 96920, 96921, 96922	goggles, uv-blocking	SJ027	2.30	7.95	246%	1	697,047
50200, 88108, 88120, 88121, 88173	cytology, preservative and vial (Preserv-cyt)	SL040	0.80	1.19	49%	1	342,095
88358, 88361	DNA/digital image analyzer	EP001	195,000.00	248,946.30	28%	1	78,649
88360, 88361	Antibody Estrogen Receptor monoclonal	SL493	14.00	14.47	3%	3	209,384
95004, 95017, 95018	negative control, allergy test	SH101	5.08	5.17	2%	2	10,036,050
95004, 95017, 95018	positive control, allergy test	SH102	17.28	26.12	51%	6	10,036,050
95250	sensor, glucose monitoring (interstitial)	SD114	29.50	53.08	80%	19	26,205
95250	glucose continuous monitoring system	EQ125	2465.00	1170.54	-53%	5	26,205
93792, G0249	test strip, INR	SJ055	21.88	5.66	-74%	2	1,265,540

I. Evaluation & Management (E/M) Guidelines and Care Management Services

In recent years, we have sought to recognize significant changes in health care practice, especially innovations in the active management and ongoing care of chronically ill patients. We have been engaged in an ongoing incremental effort to identify gaps in appropriate coding and payment for care management/coordination, cognitive services and primary care within the PFS. This has included working with the CPT Editorial Panel (CPT) to develop and value (or revalue) the following service codes:

- Transitional care management (TCM) services (2013).
- Chronic care management services (CCM) (2015, 2017).
- Behavioral health integration (BHI) services (2017).
- Assessment/care planning services for cognitive impairment (2017).
- Prolonged E/M services without direct patient contact (2017).

In response to public feedback regarding the initial implementation of TCM and CCM, in the CY 2017 PFS final rule (81 FR 80225 through 80256), we finalized significant administrative burden reduction for CCM and focused on limiting as much as possible the ways in which Medicare's rules differed from the CPT guidance that generally applies for all payers. We also worked with the CPT Editorial Panel and other stakeholders to develop coding and improve payment accuracy for BHI, cognitive impairment assessment/management, and prolonged services. In the CY 2017 PFS final rule (81 FR 80255), we also reiterated our commitment to addressing disparities for individuals with disabilities and advancing health equity, and noted that we will continue to explore improvements in payment accuracy for services furnished to individuals with disabilities. We look forward to continued work with stakeholders to ensure that the coding and valuation of these services accurately reflects the resource costs involved in furnishing these services. In the CY 2018 PFS proposed rule (82 FR 34078 through 34080), we solicited public comments on ways we might further reduce administrative burden for these and similar services under the PFS.

1. E/M Guidelines

a. Background

Most physicians and other billing practitioners bill patient visits to the PFS under a relatively generic set of codes that distinguish level of complexity, site of care, and in some cases, between new or established patients. These codes are called Evaluation and Management (E/M) visit codes. For example, there are generally three levels of hospital and nursing facility inpatient E/M visit codes, and five levels of office or hospital outpatient E/M visit codes, that vary based on complexity. The latter also distinguish whether or not the patient is new to the billing practitioner.

Billing practitioners must maintain information in the medical record to document that they have reported the appropriate level of E/M visit code. CMS maintains guidelines that specify the kind of information that is required to support Medicare payment for each level. According to these documentation guidelines, there are three key components to selecting the appropriate level:

- History of Present Illness (HPI or History);
- Physical Examination (Exam); and
- Medical Decision Making (MDM).

There are two versions of the documentation guidelines, commonly referenced based on the year of their release (the ''1995'' and ''1997'' guidelines), available under downloads on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*. The most substantial differences between the two sets of guidelines pertain to requirements for the physical exam. The two versions have a slight difference in requirements for documenting the history, and no difference in requirements for MDM. In documenting a given E/M service, practitioners must use one version of the guidelines or the other, with one exception related to extended histories (see the Evaluation and Management Services guide available on the CMS Web site at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf*). These guidelines are very similar to guidelines within the CPT codebook for E/M visits. We provide an example of how the guidelines distinguish between level 2 and level 3 visits in Table 17.

Stakeholders have long maintained that both the 1995 and 1997 guidelines are administratively burdensome and outdated with respect to the practice of medicine, stating that they are too complex, ambiguous, and that they fail to distinguish meaningful differences among code levels. In general, we agree that there may be unnecessary burden with these guidelines and that they are potentially outdated, and believe this is especially true for the requirements for the history and the physical exam. The guidelines have not been updated to account for significant changes in technology, especially electronic health record (EHR) use, which presents challenges for data and program integrity and potential upcoding given the frequently automated selection of code level.

Although CMS conducts few audits on E/M visits relative to the volume of PFS services they comprise, we have repeatedly heard from practitioners that compliance with the guidelines is a source of significant audit vulnerability and administrative burden. Our prior attempts to revise the guidelines met with a lack of stakeholder consensus and support, which contributed to the current policy that allows practitioners to use either the 1995 guidelines or 1997 guidelines, resulting in further complexity in determining or selecting the applicable requirements.

b. E/M Guidelines Public Comment Solicitation

We continue to agree with stakeholders that the E/M documentation guidelines should be substantially revised. We believe that a comprehensive reform of E/M documentation guidelines would require a multi-year, collaborative effort among stakeholders. We believe that revised guidelines could both reduce clinical burden and improve documentation in a way that would be more effective in clinical workflows and care coordination. We also think updated E/M guidelines coupled with technological advancements in voice recognition, natural language processing and user-centered design of EHRs could improve documentation for patient care while also meeting requirements for billing and population health management. We recognize that achieving the goal of reduced clinician burden and improved, meaningful documentation for patient care will require both updated E/M guidelines, as well as changes in technology, clinician documentation practices and workflow. We solicited input from a broad array of stakeholders, including patient advocates, on the specific changes we should undertake to reform the guidelines, reduce the associated burden, and better align E/M coding and documentation with the current practice of medicine.

We specifically sought comment on how we might focus on initial changes to the guidelines for the history and physical exam, because we believe documentation for these elements may be more significantly outdated, and that

differences in MDM are likely the most important factors in distinctions between visits of different levels. We also specifically sought comment on whether it would be appropriate to remove our documentation requirements for the history and physical exam for all E/M visits at all levels. We stated that we believed MDM and time are the more significant factors in distinguishing visit levels, and that the need for extended histories and exams is being replaced by population-based screening and intervention, at least for some specialties. In addition, an increase in the utilization of EHRs, and to some extent, shared health information via EHRs, may have changed the character of extended patient histories since the guidelines were established. As long as a history and physical exam are documented and generally consistent with complexity of MDM, we believed there may no longer be a need for us to maintain such detailed specifications for what must be performed and documented for the history and physical exam (for example, which and how many body systems are involved). We sought comment on whether clinicians and other stakeholders believe removing the documentation requirements for the history and physical exam would be a good approach.

Although we believed that MDM guidelines may also need to be updated, we stated our belief that in the near term, it may be possible to eliminate the current focus on details of history and physical exam, and allow MDM and/or time to serve as the key determinant of E/M visit level. We sought public comment on this approach. We also sought comment on how such reforms may differentially affect physicians and practitioners of different specialties, including primary care clinicians, and how we could or should account for such effects as we examine this issue.

We noted that there may still be clinical or legal reasons for individual practitioners to document an extended history or physical exam (for example, where there are negative findings for certain body systems in support of differential diagnosis). We additionally sought comment on whether CMS should leave it largely to the discretion of individual practitioners to what degree they should perform and document the history and physical exam.

We also welcomed comments on specific ideas that stakeholders may have on how to update MDM guidelines to foster appropriate documentation for patient care commensurate with the level of patient complexity, while avoiding burdensome documentation requirements and/or inappropriate upcoding.

The following is a summary of the public comments received on the E/M documentation guidelines, and our responses.

Comment: We received many comments on potential updates and revisions to the E/M documentation guidelines. The comments described ways in which the guidelines may be outdated or need to be improved upon, for example to better reflect the content of E/M visit work, team-based care and the advent of EHRs. The commenters were appreciative and generally supportive of CMS undertaking this reform effort. Many of the comments reflected agreement with CMS (and other payers) that documentation standards are necessary to demonstrate and provide a clear record of what was performed in support of payment, as well as for legal and clinical reasons. However, commenters did not agree on how the current standards should be changed, and different specialties expressed different challenges and recommendations regarding the guidelines. Many professional specialty associations urged CMS to employ a more considered, long-term process such as a task force rather than immediate changes.

There appeared to be some agreement among commenters that the documentation requirements for history and physical exam are particularly outdated. Commenters stated, for example, that they are often required to include or cut-and-paste into the record extraneous documentation detail regarding irrelevant history, review of unaffected systems, and unnecessary (and in some cases burdensome to the patient) physical exam elements, in order to justify an E/M code that most adequately reflects their work. They stated that this information bloats the medical record unnecessarily, increasing the time it takes to find or convey to the reader the most important and relevant clinical information at a given point in time. They said this detracts significantly from spending time on more important patient care activities.

A few commenters believe that the two elements of history and exam could be eliminated entirely, while many commenters believe they needed to be retained, but changed or rolled up somehow into MDM. Some commenters believe that MDM is under-emphasized or could be assigned greater weight, while still recognizing the critical role that history and exam continue to play for patients, especially new patients. Some commenters believe that new guidelines to support MDM-driven E/M documentation need to be in place before requirements for history and exam are eliminated. Some specialties (for example, hematology-oncology and emergency medicine) explained that ensuring adequate performance and documentation of both history and physical exam at every visit is critical to their work for clinical, legal, operational, and other reasons.

Some commenters raised the possibility of allowing flexibility at the practitioner or organization level. For example, one commenter suggested that CMS could encourage the use of unspecified standards, while allowing individual physicians to decide what components of a history and physical exam are required or should be documented for individual patients. Some commenters believe there are clinical reasons to include a history and exam in a patient's record, but they are not needed to determine the E/M code level. Others advised CMS to eliminate all numeric (counted) elements for history and exam in the documentation guidelines and allow physicians to document only what is relevant to the patient's specific diagnosis.

There was no consensus among commenters on changes that would need to be made to MDM and time rules in order for CMS to rely more on these elements (in lieu of history and exam) to justify service level billed. Some commenters recommended clarification of ambiguities or more uniform interpretation of the current MDM guidelines. Others believe the existing criteria for assessing MDM are themselves inadequate, and that while MDM should carry the most weight, it is the hardest to measure meaningfully and is frequently subjective. Some commenters recommended alternatives such as different MDM levels reflecting comorbidity or the intensity of a single, highly active medical condition. Some believe that MDM was a key determinant but not sufficient to stand alone.

Some commenters sought clarification on what CMS was proposing with respect to time. They were unclear how CMS envisioned time coming into play in a different way than it currently does. Commenters had differing views on the advisable role of time in determining code level (alone or in combination with MDM). Some recommended expanding the role of time, for example to enumerate time spent with family or spent taking extended histories rather than just counseling time. Others believe work should not be equated with time, or mentioned that relying on

time alone could create a perverse payment incentive.

Some commenters recommended, for immediate relief, that history and exam should not be audited except where there is uncertainty regarding MDM or lack of documentation regarding time. A few commenters suggested alternative E/M service components such as the patient's functional status, review of medications and care coordination. One commenter listed several items they believe deserve CMS' review, even if there is not a broad revision to the guidelines, including perceived overly comprehensive history and exam requirements for the Level 4/5 differential; MDM rules that value a new problem higher than an existing problem, even when it is clinically more minor; MDM rules that do not distinguish medication risk according to how benign the medication is; and the level of audit risk or exposure if less information (history and exam) would be included in the medical record.

Some comments discussed the intersection of the guidelines with EHRs. Some commenters requested alignment of EHR templates with new guidelines, eliminating the need to cut-and-paste medical record information, and eliminating information blocking to outside clinicians (for example, pharmacists seeking information on patient history). There was some support for removing requirements to document social, family and past medical history in the medical record at a given visit when it is already present within an EHR. Similarly, there was support for only requiring full, baseline history and exam at time of first visit/consultation, with updates at subsequent visits only to areas of changes in condition that affect the treatment plan. There was also some support for physicians being allowed to review and cross-reference, or sign off on, certain documentation entered by ancillary staff or technicians, entered directly by patients (such as through a patient portal), or captured automatically by devices.

A number of commenters specified that changes should be effective across all E/M codes of all levels. Some specialties requested particular consideration of care settings other than just outpatient care, such as inpatient or other transitional care settings.

Many commenters urged CMS to proceed cautiously by making changes over a period of multiple years, using a representative task force and additional public forums such as open door forums and listening sessions prior to implementing broad changes. Some commenters suggested that reforming the guidelines is a monumental task that would have a far-reaching impact and needs to be done judiciously since, for example, commercial payers often follow Medicare rules in this area. These commenters stated that, if done correctly, revising the guidelines will be a significant undertaking that is likely to last several years and require an inclusive, transparent, iterative and perhaps transitional process to ensure that all stakeholders across all specialties are involved, that a thoughtful examination of options can take place, and that the benefits and consequences of any potential changes can be identified. Some commenters specified that the CPT Editorial Panel, private insurers and EHR vendors should be involved.

Some commenters recommended clarification and training by CMS of unspecified issues on interpretation of current guidelines, but requested that CMS seek full input before moving forward with any changes, including these clarifications. These commenters stated that even minor changes to the codes or their documentation would require physicians and practices a great deal of time to understand and implement. A number of commenters asked CMS not to make any immediate changes for these or similar reasons.

Response: We thank the commenters for this feedback. We are especially appreciative of the commitment from stakeholders to work with us on developing and implementing potential changes. We also note that commenters frequently suggested that we provide additional avenues for collaboration with stakeholders prior to implementing any changes. We are currently considering the best approaches for such collaboration, and will take the comments into account as we consider the issues for future rulemaking.

In the CY 2018 PFS proposed rule (82 FR 34079), we further noted that through letters, meetings, public comment letters in past rulemaking cycles, and other avenues, we have heard from many stakeholders that the E/M code set itself is outdated and needs to be revised. For example, some stakeholders recommend an extensive research effort to revise and revalue E/M services, especially the work inputs (see 81 FR 46200). In prior rulemaking cycles, we acknowledged the limitations of the current E/M code set. In our proposed rule, we agreed that the structure of the underlying code set and its valuation relative to other PFS services are also important issues that we expect to continue to explore, though we stated our immediate focus on revision of the current E/M guidelines in order to reduce unnecessary administrative burden.

Comment: Some commenters requested that CMS undertake revision or revaluation of the E/M code set itself, without further delay. Some commenters expressed that the failure of the current code set to fully capture cognitive work is more burdensome than the documentation rules and, if addressed, would simultaneously address unnecessary administrative burden. They stated that MDM is key to determining level of service; however MDM is not just a critical documentation requirement. In their view, it is also the critical piece to properly define and value E/M services. Some commenters recommended that the effort to revise documentation rules should be part of a broader initiative to accurately reimburse physicians and other health professionals for the work furnished during E/M visits, and that both issues are important for transition to value-based payment as physicians take on more accountability for their resource utilization. Similarly, some commenters believe the code set itself is a separate issue from the guidelines, but should be equally addressed by CMS and the AMA/CPT Editorial Panel in the longer-term.

In contrast, other commenters believe that the current valuation of all E/M services should be presumed correct, and that the goal of reforming the guidelines is to make them consistent with current medical practice. Several commenters recommended that CMS consider the E/M definitional and valuation issues separate from E/M guideline revision. They believe that changes in the guidelines should not automatically require a review of current valuation. Also several commenters asked CMS to reinstate the specialist consultation codes that were discontinued for payment in 2010.

Response: We thank the commenters for this feedback. We believe the public comments illustrate 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. We also believe the public comments illustrate that many of the issues with the E/M documentation guidelines are not simply a matter of undue administrative burden. The guidelines reflect how work was performed and valued a number of years ago, and are intimately related to the definition and description of E/M work as well as its valuation. Opinions on potential redefinition and revaluation of the E/M code set tend to differ by specialty,

according to the type of work dominating each 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). We expect to continue to work on all of these issues with stakeholders in future years though we are immediately focused on revision of the current E/M guidelines in order to reduce unnecessary administrative burden.

2. Care Management Public Comment Solicitation

In the CY 2018 PFS proposed rule, we stated our continued interest in the ongoing work of the medical community and other stakeholders to refine the set of codes used to describe care management services. In section II.H of this final rule, we discuss our final policy to adopt CPT codes for CY 2018 to replace the G-codes we established for several new care management service codes finalized last year, describing cognitive impairment assessment and care planning, and behavioral health integration services. In CY 2018, these codes will be added to the suite of CPT care management service codes we adopted in recent years, including transitional care management and chronic care management (CCM) services. In our proposed rule, we also reiterated our commitment to work with stakeholders on necessary refinements to this code set, especially codes that would describe the professional work involved in caring for complex patients in additional clinical contexts. Also we solicited public comment on ways we might further reduce the burden for practitioners reporting care management services, including through stronger alignment between CMS requirements and CPT guidance for existing and potential new care management service codes.

We received a few comments on ways CMS might further improve CCM services, and approaches that CMS might take more broadly to improve payment for care management services. In this section, we discuss the comments and respond.

Comment: We received a few comments requesting a change in the coding or payment for CCM services. Several commenters recommended that CMS develop add-on codes to break out and pay for smaller clinical staff time increments (specifically, breaking out increments of greater than 20 minutes of clinical staff time, such as 21–40 minutes and 41–60 minutes).

Response: We appreciate the suggestion from commenters. At this time, we generally intend to consider pursuing future changes to the CPT codes describing chronic care management services, rather than create new add-on G codes that would be used alongside current CPT codes for CCM services. We urge stakeholders to work through the CPT process to make needed changes or create new codes for the CCM code set as appropriate.

Comment: One commenter recommended that CMS not require that a copy of the care plan must be given to the patient (or caregiver as appropriate). The commenter recommended that CMS instead require that a copy of the plan of care must be available to the patient or caregiver.

Response: In the CY 2017 PFS final rule (81 FR 80250), we revised this language to no longer mandate the format in which the care plan must be provided (written versus verbal) and, rather, to allow the care plan to be provided in a format consistent with patient/caregiver preference. We stated that while beneficiaries must be provided a copy of the care plan, practitioners may choose to provide the care plan in hard copy or electronic form in accordance with patient preferences. We believe our current language is more appropriate than the CPT language or the language recommended by the commenter because it allows flexibility in how the care plan information is transmitted to the patient (or caregiver, if appropriate) in accordance with patient needs or preference, but ensures to a greater degree that the information is actually received by them, whatever the format. We believe a requirement merely to make the information ''available'' may not ensure that it is actually received and understood. If the patient (or caregiver, if appropriate) prefers, the care plan may be provided to them via an electronic portal. Also, whatever format is used to provide the care plan, we expect that the care plan will be discussed with the patient (and/or caregiver as appropriate) as part of the management of their care and consistent with the other CCM scope of service elements.

Comment: One commenter recommended that CMS not require documentation of each minute of service provided.

Response: In addition to CCM, there are many CPT codes that are timed codes (having time within their code descriptor). The same rules should apply for documentation of time for CCM as for other timed services. For program integrity purposes (to ensure timed services are actually performed in full, as described and defined by the code(s)), we expect practitioners to document in the medical record how they spent the qualifying time. In the case of CCM, they must document that the required time was spent performing qualifying activities. This is routine policy for timed service codes. If practitioners have specific questions about the degree to which they must document and time their CCM work using the current CPT codes, they should consult their Medicare Administrative Contractor.

Comment: One commenter recommended that CMS reduce the service elements for CPT code 99490 to require only one of the following service elements to be performed: Comprehensive care management, management of care transitions, or home- and community-based care coordination.

Response: The current code descriptors and required scope of service elements reflect the results of our notice and comment rulemaking with significant contributions from the AMA/CPT Editorial Panel. We believe we should continue to require, for each month in which the service is billed, all of the service elements that are medically necessary for the patient, which we believe is also consistent with CPT reporting rules for CCM.

Comment: One commenter asked CMS to further align its rules with CPT reporting rules by removing the requirement to use a certified EHR.

Response: We continue to believe that use of certified EHR technology is vital to ensure that practitioners are capable of providing the full scope of CCM services, such as timely care coordination and continuity of care (see our prior discussion of this issue at 79 FR 67723). The use of certified EHR technology helps ensure that members of the interdisciplinary care team have timely access to the patient's most updated health information. Also we believe that use of certified EHR technology among physicians and other practitioners will increase as we move forward to implement the Quality Payment Program, including MIPS and Advanced Alternative Payment Models, as well as other value-based payment initiatives. Accordingly, we are not removing the requirement to use a certified EHR.

Comment: One commenter recommended that CMS not require an initiating visit for any CCM patient. The commenter believes that patient consent to receive CCM services could be obtained by a care manager verbally by phone.

Response: Starting in CY 2017, we removed the requirement for all CCM patients to receive initiating visits, instead only requiring it if the patient has not been seen within a year prior to commencement of CCM. Also we changed the consent requirement to allow verbal consent (rather than the written consent we previously required) for all patients, including patients who require an initiating visit. In other words, consent can already be obtained verbally independent of the initiating visit, as long as it is obtained prior to commencement of the monthly CCM services. We continue to believe that if the patient has not been seen within a year, there should be an initiating visit so the billing practitioner can assess or re-assess the patient, gather all necessary data to inform the care plan, and perform other preparatory work. Therefore we are not changing this requirement. We remind stakeholders that consent does not have to be obtained as part of an initiating visit and can be done separately, as long as it is obtained before the first CCM monthly service commences.

Comment: We received a few comments on the add-on code (G0506) describing practitioner assessment and care planning in conjunction with an initiating visit. One commenter said there should not be a requirement for the billing practitioner to create the comprehensive care plan as part of this code. The commenter believes their role should instead be to identify and support patients during the enrollment process, and to generally supervise the creation of the CCM care plan. Another commenter recommended that CMS allow pharmacists to have the care planning in HCPCS code G0506 delegated to them.

Response: We created HCPCS code G0506 explicitly to separately identify and pay for the time and work of the billing practitioner reporting the monthly CCM service, to ensure appropriate payment for their comprehensive assessment and involvement at the outset of CCM, if needed by the patient (81 FR 80245). We did this because we expect that much of the subsequent CCM services will be performed incident to the professional services of the billing practitioner and we wish to ensure appropriate personal involvement of, and payment to, the practitioner who is directly reporting CCM. The purpose for adopting this add-on code was to describe and provide appropriate payment for work that is personally and directly performed by the billing practitioner themselves in preparation for furnishing CCM services. Care planning that is performed by clinical staff incident to the services of the billing practitioner may be counted towards the clinical staff time of the monthly CCM service code(s), but cannot be counted towards G0506.

Comment: One commenter asked CMS to clarify that the CCM planning code, HCPCS code G0506, can be billed on a day separate from an E/M date of service.

Response: G0506 is comprised of a face-to-face assessment and care planning personally performed only once by the practitioner reporting the monthly CCM service, in conjunction with (as an add-on code to) an initiating visit. The face-to-face assessment would be performed the same day as the initiating visit, but some or all of the care planning piece could be performed by the billing practitioner on a subsequent day. Accordingly, we would expect the date of service for HCPCS code G0506 on the claim to be the same as for the base initiating visit code, and we will consider issuing an FAQ specifying this.

Comment: Several commenters recommended that CMS seek ways to eliminate cost sharing for CCM and other care management services. These commenters expressed that it is difficult to explain the mechanics and benefits of care management to patients, given the added cost sharing. They recommended that CMS seek ways to remove the cost sharing, for example through designating the services as preventive services or working with Congress to accomplish it legislatively.

Response: As we stated in our CY 2017 PFS final rule (81 FR 80240), we appreciate the commenters' concerns and recognize many of the challenges associated with patient cost sharing for these kinds of services. At this time, we do not have authority to remove cost sharing for care management services. We appreciate the commenters' acknowledgement of our current limitations and we will continue to consider this issue.

Comment: We received a few comments recommending ways in which we might better involve specialists in the provision of CCM or care management broadly (such as payment to emergency department physicians when they act as primary care practitioners, or payment to multiple practitioners involved in managing a given patient at a given time). Also a few commenters recommended that CMS allow more than one practitioner to bill CCM per month. They believe there were situations where more than one practitioner co-manages a patient, or that particularly complex patients who would benefit from CCM services also benefit from seeing multiple health care providers.

Response: At this time, only one practitioner can report CCM per month, consistent with both CPT guidance and the authorizing statute for payment of CCM services (section 1848(b)(8)(B) of the Act). However, we agree there may be circumstances in which more than one practitioner expends resources managing or helping manage a CCM patient. We will continue to explore ways in which we might better identify and pay for costs incurred by multiple practitioners who coordinate and manage a patient's care within a given month, and are interested in hearing more about the relevant circumstances, potential gaps in coding, and the exact nature of the work performed or costs incurred.

BILLING CODE 4120–01–P

BILLING CODE 4120–01–C

TABLE 17: Key Component Documentation Requirements for Level 2 vs 3 Evaluation & Management (E/M) Visit

Key Component†	Level 2 (1995)	Level 3 (1995)	Level 2 (1997)	Level 3 (1997)
History (History of Present Illness or HPI)	Review of Systems (ROS) n/a	Problem Pertinent ROS: inquires about the system directly related to the problem(s) identified in the HPI	No change from 1995	No change from 1995
Physical Examination (Exam)	A limited examination of the affected body area or organ system	A limited examination of the affected body area or organ system and other symptomatic or related organ system(s)	General multi-system exam: Performance and documentation of one to five elements in one or more organ system(s) or body area(s). Single organ system exam: Performance and documentation of one to five elements	General multi-system exam: Performance and documentation of at least six elements in one or more organ system(s) or body area(s). Single organ system exam: Performance and documentation of at least six elements
Medical Decision Making (MDM) Measured by:* 1. **Problem** – Number of diagnoses/treatment options 2. **Data -** Amount and/or complexity of data to be reviewed 3. **Risk-** Risk of complications and/or morbidity or mortality *Two of three met or exceeded	Straightforward: 1. Minimal 2. Minimal or no data review 3. Minimal risk	Low complexity: 1. Limited 2. Limited data review 3. Low risk	No change from 1995	
†For certain settings and patient types, each of these three key components must be met or exceeded (for example, new patients; initial hospital visits). For others, only two of the three key components must be met or exceeded (for example, established patients, subsequent hospital or other visits).				

M. Therapy Caps

1. Outpatient Therapy Caps for CY 2018

Section 1833(g) of the Act (as amended by section 4541 of the Balanced Budget Act of 1997) (Pub. L. 105–33) requires application of annual per beneficiary limitations on the amount of expenses that can be considered as incurred expenses for outpatient therapy services under Medicare Part B, commonly referred to as ''therapy caps.'' There is one therapy cap for outpatient occupational therapy (OT) services and another separate therapy cap for physical therapy (PT) and speech-language pathology (SLP) services combined. The therapy caps are permanent, meaning that the statute does not specify an end date.

The therapy cap amounts under section 1833(g) of the Act are updated each year based on the MEI. Specifically, the annual caps are calculated by updating the previous year's cap by the MEI for the upcoming calendar year and rounding to the nearest $10.00. Increasing the CY 2017 therapy cap of $1,980 by the CY 2018 adjusted MEI of 1.4 percent and rounding to the nearest $10.00 results in a CY 2018 therapy cap amount of $2,010.

An exceptions process for the therapy caps has been in effect since January 1, 2006. Originally required by section 5107 of the Deficit Reduction Act of 2005 (DRA), which amended section 1833(g)(5) of the Act, the exceptions process for the therapy caps has been extended multiple times through subsequent legislation as described in the CY 2015 PFS final rule with comment period (79 FR 67730). It was most recently extended by section 202 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), and is set to expire on December 31, 2017. The MACRA extension of the therapy cap exceptions process includes the application of the therapy caps to outpatient services furnished by hospitals described at section 1833(a)(8)(B) of the Act by continuing the temporary suspension under section 1833(g)(6)(A) of the Act of the statutory exemption for these hospital therapy services that first became effective October 1, 2012 through the enactment of the Middle Class Tax Relief and Jobs Creation Act of 2012 (MCTRJCA) (Pub. L. 112–96).

CMS tracks each beneficiary's incurred expenses annually and counts them toward the therapy caps by applying the PFS rate for each service less any applicable multiple procedure payment reduction (MPPR) amount. As required by section 1833(g)(6)(B) of the Act, added by section 603(b) of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) and extended by subsequent legislation, the PFS-rate accrual process is applied to outpatient therapy services furnished by CAHs even though they are paid on a cost basis (effective January 1, 2014). As we explained in the CY 2016 PFS final rule with comment period, we use cost-based rates to track each beneficiary's incurred expenses amounts for the outpatient therapy services furnished by the Maryland hospitals paid under the Maryland All-Payer Model, currently being tested under the authority of section 1115A of the Act (effective January 1, 2016). After expenses incurred for the beneficiary's outpatient therapy services for the year have exceeded one or both of the therapy caps, therapy suppliers and providers use the KX modifier on claims for subsequent services to request an exception to the therapy caps. By using the KX modifier, the therapist is attesting that the services above the therapy caps are reasonable and necessary and that there is documentation of medical necessity for the services in the beneficiary's medical record. Claims for outpatient therapy services over the caps without the KX modifier are denied.

Since October 1, 2012, under section 1833(g)(5)(C) of the Act as amended by the Middle Class Tax Relief and Jobs Creation Act of 2012 (MCTRJCA) (Pub. L. 112–96), we have been required to apply a manual medical review process to therapy claims when a beneficiary's incurred expenses for outpatient therapy services exceed a threshold amount of $3,700. Just as there are two separate therapy caps, there are two separate thresholds of $3,700, one for OT services and one for PT and SLP services combined; and incurred expenses are counted towards these thresholds in the same manner as the caps. Under section 1833(g)(5) of the Act, as amended by section 202(b) of the MACRA, not all claims exceeding the therapy thresholds are subject to a manual medical review process as they were before. Instead, we are permitted to do a more targeted medical review on these claims using factors specified in section 1833(g)(5)(E)(ii) of the Act as amended by section 202(b) of the MACRA, including targeting those therapy providers with a high claims denial rate for therapy services or with aberrant billing practices compared to their peers. The manual medical review process required under section 1833(g)(5)(C) of the Act expires at the same time as the exceptions process for therapy caps, on December 31, 2017. For information on the manual medical review process, go to *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/TherapyCap.html*.

The statutory authority for the therapy caps exceptions process will expire on December 31, 2017. Under current law, the therapy caps will be applicable in accordance with the statute to all outpatient therapy settings, except for services furnished and billed by outpatient hospitals described under section 1833(a)(8)(B) of the Act. Without a therapy caps exceptions process, the statutory limitation requires that beneficiaries become financially liable for 100 percent of expenses they incur for services that exceed the therapy caps. In addition, without a therapy caps exceptions process, the therapy caps will be applicable without any further medical review, and any use of the KX modifier on claims for these services by providers of outpatient therapy services will have no effect.

III. Other Provisions of the Proposed Rule

A. New Care Coordination Services and Payment for Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs)

1. Overview

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 Physician Fee Schedule (PFS) to separately recognize and pay for these important services. As part of this initiative, the CY 2016 PFS proposed rule (80 FR 41708) solicited public comments on (1) improving payment for the professional work of care management services; (2) establishing separate payment for collaborative care, particularly inter-professional consultation between primary care physicians, psychiatrists, and other practitioners; and (3) assessing whether current PFS payment for Chronic Care Management (CCM) services is adequate and whether the administrative burden associated with furnishing and billing these services should be reduced.

As a result of the comments we received in response to our request, we established in the PFS separate payment for complex CCM services, and temporary codes to make separate payment for general behavioral health integration (BHI) services and a psychiatric collaborative care model (CoCM). We established four G codes to

describe BHI and psychiatric CoCM services and stated that we would consider whether to adopt and establish values for any associated new CPT codes being developed under our standard process once those codes are active. The separate payment for complex CCM services, general BHI, and psychiatric CoCM services were finalized in the CY 2017 PFS final rule (81 FR 80225) beginning January 1, 2017, for practitioners billing under the PFS. Based on these payments and codes, we proposed revisions to the CCM payment for RHCs and FQHCs, and proposed requirements and payment for general BHI and psychiatric CoCM services furnished in RHCs and FQHCs, beginning on January 1, 2018.

2. Background

a. RHC and FQHC Payment Methodologies

RHC and FQHC visits are face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which time one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, nurse practitioners (NPs), physician assistants (PA), certified nurse midwives (CNMs), clinical psychologists, and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse furnishing care to a homebound RHC or FQHC patient. A Transitional Care Management (TCM) service can also be an RHC or FQHC visit, and a Diabetes Self-Management Training (DSMT) service or a Medical Nutrition Therapy (MNT) service furnished by a certified DSMT or MNT provider may also be an FQHC visit. Only medically-necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment.

RHCs are paid an all-inclusive rate (AIR) for medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). In general, the A/B Medicare Administrative Contractor (MAC) calculates the AIR for each RHC by dividing total allowable costs by the total number of visits for all patients. Productivity, payment limits, and other factors are also considered in the calculation. Allowable costs must be reasonable and necessary and may include practitioner compensation, overhead, equipment, space, supplies, personnel, and other costs incident to the delivery of RHC services. The AIR is subject to a payment limit, except for certain provider-based RHCs that have an exception to the payment limit.

FQHCs were paid under the same AIR methodology until October 1, 2014, when, in accordance with section 1834(o) of the Act (as added by section 10501(i)(3) of the Affordable Care Act), they began to transition to an FQHC PPS system in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF). 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 for the complexity of the patient health care needs, the length of the visit, or the number or type of practitioners involved in the patient's care.

b. Current CCM Requirements and Payment for RHCs and FQHCs

In the CY 2016 PFS final rule with comment period (80 FR 71080), we finalized policies for payment of CCM services in RHCs and FQHCs. Payment for CCM services in RHCs and FQHCs was effective beginning on January 1, 2016, for RHCs and FQHCs that furnish a minimum of 20 minutes of qualifying CCM services during a calendar month to patients with multiple (two or more) chronic conditions that are expected to last at least 12 months or until the death of the patient, and that would place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. The requirement that RHC or FQHC services be furnished face-to-face was waived for CCM services.

In the CY 2017 PFS final rule (81 FR 80256), we finalized revisions to the CCM requirements for RHCs and FQHCs. Specifically, we revised § 405.2413(a)(5) and § 405.2415(a)(5) to state that services and supplies furnished incident to CCM and TCM services can be furnished under general supervision of an RHC or FQHC practitioner, consistent with § 410.26(b)(5), which allows CCM and TCM services and supplies to be furnished by clinical staff under general supervision when billed under the PFS. We also revised requirements pertaining to the provision of CCM services, consistent with the same revisions for practitioners billing under the PFS to reduce the burden of furnishing these services and promote beneficiary access to these services. These revisions were effective beginning on January 1, 2017, and included:

- Revising the requirement that CCM be initiated during a comprehensive evaluation and management (E/M), AWV, or IPPE visit, to require a separately billable initiating visit only for new patients or patients that have not had an E/M, AWV, or IPPE visit within the previous year;
- Revising the requirement that CCM services be available 24/7 with an RHC or FQHC practitioner who has access to the patient's electronic care plan, to allow 24/7 access to auxiliary personnel with a means to make contact with an RHC or FQHC practitioner;
- Removing the restriction on faxing information, and no longer requiring that care plan information be available on a 24/7 basis;
- Removing the requirement that clinical summaries must be formatted according to certified EHR technology, and instead requiring that the RHC or FQHC create, exchange, and transmit continuity of care document(s) in a timely manner with other practitioners and providers;
- Removing the description of the format of the care plan that is given to the patient or caregiver; and
- Revising the requirement that RHCs and FQHCs obtain a written agreement that the elements of CCM were discussed, to allowing this information to be documented in the medical record.

In the CY 2017 PFS final rule, we stated that although CCM is typically associated with primary care conditions, patient eligibility is determined by the RHC or FQHC practitioner, and mental health conditions are not excluded. We invited comments on whether an additional code specifically for mental health conditions is necessary for RHCs and FQHCs that want to include beneficiaries with mental health conditions in their CCM services. We received a few comments regarding mental health services in RHCs and FQHCs and appreciate the information that was provided.

The 2016 and 2017 CCM payment rates for RHCs and FQHCs were set annually based on the PFS national non-facility payment rate, and is paid when CPT code 99490 is billed alone or with

other payable services on an RHC or FQHC claim. The 2017 rate for RHCs and FQHCs is $42.71 for 20 minutes or more of CCM services. This is the only RHC and FQHC service that has been paid in this manner, and RHCs and FQHCs are not currently authorized to be paid for any other CCM or other care management codes. Also, RHCs and FQHCs cannot bill for CCM services for a beneficiary during the same service period as billing for TCM or any other program that provides additional payment for care management services (outside of the RHC AIR or FQHC PPS payment) for the same beneficiary.

Additional information on CCM requirements is available on the CMS Care Management Web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.html* and on the CMS RHC and FQHC Web pages at *https://www.cms.gov/Center/Provider-Type/Rural-Health-Clinics-Center.html* and *https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html*.

c. Payment for Care Management Codes Under the PFS

CCM Services (CPT Code 99487 and CPT Code 99489)

As we stated in the CY 2017 PFS final rule (81 FR 80244), the initial claims data for CCM services billed under the PFS showed that although utilization was increasing steadily, use of CPT code 99490 was still relatively low, and interviews with practitioners indicated that many believed that they were exceeding the 20-minute time threshold for billing this code. To pay as accurately as possible and to encourage access to CCM services, the CY 2017 PFS final rule established separate payment for two additional CCM codes, CPT code 99487 and CPT code 99489, effective beginning on January 1, 2017, for practitioners billing under the PFS. These codes are for complex CCM services that reflect additional clinical staff time, more extensive care planning, and higher complexity of the patient.

CPT code 99487 is for complex CCM services. It requires 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; establishment or substantial revision of a comprehensive care plan; moderate or high complexity medical decision making; and 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.

CPT code 99489 is for each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.

Practitioners paid under the PFS can bill either complex (CPT code 99487 and CPT code 99489) or non-complex (CPT code 99490) CCM services during a given service period, and can submit only one professional claim for CCM services for that service period.

General BHI Services (HCPCS Code G0507)

The types of chronic conditions that are eligible for CCM services are not specified and could include chronic mental health or behavioral health conditions or chronic cognitive disorders as long as the CCM requirements are met. However, because not all behavioral health issues fit into the CCM model, and Medicare beneficiaries with behavioral health conditions often require extensive care management discussions, information-sharing, and planning between a primary care practitioner and a behavioral health specialist, the CY 2017 PFS final rule established HCPCS code G0507 for 20 minutes or more of general BHI services. Payment for this code was effective beginning on January 1, 2017, for practitioners billing under the PFS. Effective January 1, 2018, HCPCS code G0507 is replaced by CPT code 99484.

BHI is a team-based, collaborative approach to care that focuses on integrative treatment of patients with primary care and mental or behavioral health conditions. As finalized in the CY 2017 PFS final rule, requirements for this code include an 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, pharmacotherapy, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.

Psychiatric CoCM Services (HCPCS Codes G0502, G0503, and G0504)

Psychiatric CoCM is a specific model of care provided by a primary care team consisting of a primary care provider and a health care manager who works in collaboration with a psychiatric consultant. As finalized in the CY 2017 PFS final rule, we provide Medicare payment for psychiatric CoCM services to practitioners billing under the PFS when these services are directed by a treating physician or other qualified health care professional. We also finalized that the treating physician or other qualified health care professional directs the behavioral health care manager, who must be an individual with formal education or specialized training in behavioral health, including social work, nursing, or psychology, working under the oversight and direction of the physician or qualified health care professional. We finalized that a psychiatric consultant must be a medical professional trained in psychiatry and qualified to prescribe the full range of medications. Finally, psychiatric CoCM services may be furnished to beneficiaries with any psychiatric or behavioral health condition(s) and may include substance use disorders. The three psychiatric CoCM codes established in the CY 2017 PFS final rule were G0502, G0503, and G0504. Effective January 1, 2018, these codes are replaced by CPT codes 99492, 99493, and 99494, respectively.

HCPCS code G0502 is for 70 minutes or more of initial psychiatric CoCM services in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional. Required elements include: outreach to and treatment of a patient as directed by the treating physician or other qualified health care professional; initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan; review by the psychiatric consultant with modifications of the plan, if recommended; entering of the patient into a registry and tracking patient follow-up and progress using the registry (with appropriate documentation), participation in weekly caseload consultation with the psychiatric consultant; and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies.

HCPCS code G0503 is for 60 minutes of subsequent psychiatric CoCM services in a subsequent month and includes: Tracking patient follow-up and progress using the registry (with appropriate documentation); participation in weekly caseload consultation with the psychiatric consultant; ongoing collaboration with and coordination of the patient's mental health care with the treating physician

or other qualified health care professional and any other treating mental health providers; additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant; provision of brief interventions using evidence-based techniques (such as behavioral activation, motivational interviewing, and other focused treatment strategies); monitoring of patient outcomes using validated rating scales; and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment.

HCPCS code G0504 is for each additional 30 minutes of initial or subsequent psychiatric CoCM services in a calendar month.

3. Proposed Care Management Requirements and Payment for RHCs and FQHCs

To ensure that RHC and FQHC patients have access to new care management services in a manner consistent with the RHC and FQHC per diem payment methodologies, we proposed the establishment of two new G codes for use by RHCs and FQHCs. The first new G code, GCCC1, would be a General Care Management code for RHCs and FQHCs, with the payment amount set at the average of the national non-facility PFS payment rates for CCM (CPT codes 99490 and 99487) and general BHI code G0507. The second new G code for RHCs and FQHCs, GCCC2, would be a Psychiatric CoCM code, with the payment amount set at the average of the national non-facility PFS payment rates for CPT codes G0502 and G0503. (We note that GCCC1 and GCCC2 were placeholder codes and are replaced by G0511 and G0512, respectively, effective January 1, 2018). The following is a detailed discussion of our proposal, as well as alternatives that we considered.

a. Proposed Establishment of a General Care Management Code for RHCs and FQHCs

The RHC AIR and the FQHC PPS rate, which include all costs associated with an RHC or FQHC visit, are based on the RHC's and FQHC's costs. Although many RHCs and FQHCs have always provided some coordination of care within and outside their facilities, the type of structured care management services that are now billable under the PFS are generally not included in the RHC AIR or the FQHC PPS rate. Because CCM services are not required to be face-to-face encounters, and do not require the skill level of an RHC or FQHC practitioner, they do not meet the requirements for an RHC or FQHC billable visit. In addition, RHC and FQHC services cannot be separately billed to the PFS. Therefore, in the CY 2016 PFS final rule with comment period, we established payment for CCM services at the PFS national non-facility rate when CPT code 99490 is billed alone or with other payable services on an RHC or FQHC claim to pay for the costs of CCM services that are not already captured in the RHC AIR or the FQHC PPS payment.

When CCM services were first established for RHCs and FQHCs, CPT code 99490 was the only CCM code that was billable under the PFS. Now that there are additional codes for more complex CCM services and for general BHI and psychiatric CoCM services, we believe it is necessary to revise our payment approach for payment of care management services.

RHCs and FQHCs are paid per-visit rates that are not adjusted based on the complexity of a service or the time spent furnishing services, and the payment rate is not designed to be equal to the payment under the PFS for a specific service. We sought to develop a methodology for payment of care management services that is consistent with the RHC and FQHC payment principles of bundling services and not paying for services based on time increments. We also sought to develop a methodology that would support the provision of care management services without creating additional reporting burdens, while promoting beneficiary access to comprehensive CCM and BHI services furnished by RHCs and FQHCs.

Therefore, effective for services furnished on or after January 1, 2018, we proposed to create General Care Management code GCCC1 for RHCs and FQHCs, with the payment amount set at the average of the 3 national non-facility PFS payment rates for the CCM and general BHI codes and updated annually based on the PFS amounts. The 3 codes are:

- CPT 99490—20 minutes or more of CCM services
- CPT 99487—at least 60 minutes of complex CCM services
- HCPCS G0507—20 minutes or more of BHI services

RHCs and FQHCs could bill the new General Care Management code when the requirements for any of these 3 codes (CPT codes 99490, 99487, or HCPCS code G0507) are met. The General Care Management code would be billed alone or in addition to other services furnished during the RHC or FQHC visit. This code could only be billed once per month per beneficiary, and could not be billed if other care management services (such as TCM or home health care supervision) are billed for the same time period. We note that CPT code 99489 is an add-on code when CPT code 99487 is furnished, and is therefore not included as RHCs and FQHCs are not paid for additional time once the minimum requirements have been met.

As previously noted, the program requirements for RHCs and FQHCs furnishing CCM services were established in the CY 2016 PFS final rule with comment period (80 FR 71080) and revised in the CY 2017 PFS final rule (81 FR 80256). We did not propose any changes to these requirements at this time.

BHI refers to care management services that integrate behavioral health services with primary care and other clinical services. To bill for this service using the proposed General Care Management Code for RHCs and FQHCs, 20 minutes or more of clinical staff time, directed by an RHC or FQHC practitioner, must be furnished per calendar month. We proposed the following requirements for RHCs and FQHCs furnishing BHI services:

- *Initiating Visit:* An E/M, AWV, or IPPE visit with an RHC or FQHC primary care practitioner (physician, NP, PA, or CNM) occurring no more than one-year prior to commencing BHI services. This could be the same initiating visit that is used for initiating CCM services, and would be billed separately as an RHC or FQHC visit (if the RHC or FQHC has not already billed for this visit).
- *Beneficiary Consent:* Documentation in the medical record that the beneficiary has consented to receive BHI services, given permission to consult with relevant specialists as needed, and been informed that there may be beneficiary cost-sharing, including deductible and coinsurance amounts as applicable, for both in-person and non-face-to-face services that are provided. The beneficiary consent process would also include informing the patient that only one practitioner/facility can furnish and be paid for these services during a calendar month, and that the patient can stop care coordination services at any time (effective at the end of the calendar month). This could be obtained at the same time that beneficiary consent is obtained for CCM services.
- *Billing Requirements:* At least 20 minutes of care management services

per calendar month, furnished under the direction of the RHC or FQHC primary care physician, NP, PA, or CNM, and furnished by an RHC or FQHC practitioner, or by clinical personnel under general supervision. These are the same billing requirements as for CCM services. If both CCM and BHI services are furnished in the same month, the time would be combined and billed as one under the new care coordination code.

- *Patient Eligibility:* One or more new or pre-existing behavioral health or psychiatric conditions being treated by the RHC or FQHC primary care practitioner, including substance use disorders, that, in the clinical judgment of the RHC or FQHC primary care practitioner, warrants BHI services.
- *Required Service Elements:* An 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, pharmacotherapy, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.

Both CCM and general BHI services are intended to provide a structured and coordinated approach to care management that is not typically included in the RHC's AIR or the FQHC PPS payment methodology. Care management services are directed by the RHC or FQHC primary care practitioner, who remains involved through ongoing oversight, management, collaboration and reassessment, while care management services are typically furnished in a non-face-to-face setting primarily by a non-RHC or FQHC practitioner working under general supervision requirements. Time spent by administrative or clerical staff cannot be counted towards the time required to bill these services.

Table 18 compares the proposed requirements for CCM and general BHI services. We believe that even though there are some differences in the requirements of CCM and general BHI, grouping them together will help to promote integrated care management services for Medicare beneficiaries who have either or both primary care and behavioral health needs. It will also result in the least amount of reporting burden for RHCs and FQHCs because once the 20-minute threshold is met for either CCM or general BHI, reporting and tracking of additional time increments is not required.

If this policy had been adopted for CY 2017, the payment amount for General Care Management for RHCs and FQHCs would have been approximately $61 (CPT 99490 at $42.71, + CPT 99487 at $93.67, + G0507 at $47.73 = $184.11/3 = $61.37). This is more than the CY 2017 PFS national non-facility rates for CPT code 99490 and HCPCS code G0507, and less than the PFS national non-facility rate for CPT code 99487. We believe that this methodology is consistent with the RHC and FQHC payment methodology of averaging costs to determine a payment rate rather than paying for each individual service.

TABLE 18—COMPARISON OF PROPOSED CCM AND GENERAL BHI REQUIREMENTS AND PAYMENT FOR RHCS AND FQHCS

Requirements	CCM (CPT codes 99490 and 99487)	General BHI (proposed) (HCPCS code G0507)
Initiating Visit	An E/M, AWV, or IPPE visit occurring no more than one-year prior to commencing care coordination services.	Same.
	Furnished by a primary care physician, NP, PA, or CNM.	Same.
	Billed as an RHC/FQHC visit	Same.
Beneficiary Consent	Obtained during or after initiating visit and before provision of care coordination services by RHC or FQHC practitioner or clinical staff.	Same.
	Written or verbal, documented in the medical record	Same.
	Includes information: • On the availability of care coordination services and applicable cost-sharing; • That only one practitioner can furnish and be paid for care coordination services during a calendar month; • That the patient has right to stop care coordination services at any time (effective at the end of the calendar month); and	
	• That the patient has given permission to consult with relevant specialists.	Same.
Billing Requirements	At least 20 minutes of care coordination services per calendar month that is: • Furnished under the direction of the RHC or FQHC primary care physician, NP, PA, or CNM; and	
	• Furnished by an RHC or FQHC practitioner, or by clinical personnel under general supervision.	Same.
Patient Eligibility	Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, and place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline.	Any behavioral health or psychiatric condition being treated by the RHC or FQHC primary care practitioner, including substance use disorders, that, in the clinical judgment of the RHC or FQHC practitioner, warrants BHI services.

TABLE 18—COMPARISON OF PROPOSED CCM AND GENERAL BHI REQUIREMENTS AND PAYMENT FOR RHCS AND FQHCS—Continued

Requirements	CCM (CPT codes 99490 and 99487)	General BHI (proposed) (HCPCS code G0507)
Requirement Service Elements.	Includes: • Structured recording of patient health information using Certified EHR Technology and includes demographics, problems, medications, and medication allergies that inform the care plan, care coordination, and ongoing clinical care; • 24/7 access to physicians or other qualified health care professionals or clinical staff including providing patients/caregivers with a means to make contact with health care professionals in the practice to address urgent needs regardless of the time of day or day of week, and continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments; • Comprehensive care management including systematic assessment of the patient's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of patient self-management of medications; • Comprehensive care plan including the creation, revision, and/or monitoring of an electronic care plan based on a physical, mental, cognitive, psychosocial, functional, and environmental (re)assessment and an inventory of resources and supports; a comprehensive care plan for all health issues with particular focus on the chronic conditions being managed; • Care plan information made available electronically (including fax) in a timely manner within and outside the RHC or FQHC as appropriate and a copy of the plan of care given to the patient and/or caregiver; • Management of care transitions between and among health care providers and settings, including referrals to other clinicians; follow-up after an emergency department visit; and follow-up after discharges from hospitals, skilled nursing facilities, or other health care facilities; timely creation and exchange/transmit continuity of care document(s) with other practitioners and providers; • Coordination with home- and community-based clinical service providers, and documentation of communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits in the patient's medical record; and • Enhanced opportunities for the patient and any caregiver to communicate with the practitioner regarding the patient's care through not only telephone access, but also through the use of secure messaging, Internet, or other asynchronous non-face-to-face consultation methods.	Includes: • 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, pharmacotherapy, counseling and/or psychiatric consultation); and • Continuity of care with a designated member of the care team.
CY 2017 PFS Non-Facility Payment.	CPT 99490—$42.71, CPT 99487—$93.67	G0507—$47.73.
RHC/FQHC Payment for new General Care Management G code.	Current: $42.71 ..... Proposed: Average of CPT codes 99490, 99487 and G0507 (If using the 2017 payment amounts, this would be $61.37).	Current: N/A. Proposed: Average of CPT codes 99490, 99487 and G0507 (If using the 2017 payment amounts, this would be $61.37).

We expect that utilization of care coordination services will continue to increase as more health care practices, including RHCs and FQHCs, implement these services. Because the separate payments for the complex CCM codes have only been implemented this year for practitioners billing under the PFS, we do not have adequate data to determine the frequency of billing for CCM codes CPT codes 99487 by practitioners billing under the PFS compared with CPT code 99490. Although billing practices may vary between physician offices and RHCs and FQHCs (and within and between RHCs and FQHCs), we believe that utilization patterns under the PFS can provide a reasonable proxy for utilization practices in RHCs and FQHCs of care coordination utilization. If the PFS data starts to show definitive trends in billing certain CCM and BHI codes, or if data becomes available that

provides information on the extent of these services in RHCs and FQHCs, we may consider using a weighted average in determining the payment rate in the future. Similarly, if the proposal to create a new care management code for RHCs and FQHCs is finalized, and any additional care management codes become available on the PFS, we would review the new codes to determine if they should also be factored into the RHC and FQHC General Care Management Code. Any changes would be undertaken through future rulemaking.

b. Proposed Establishment of a Psychiatric CoCM Code for RHCs and FQHCs

Psychiatric CoCM is a defined model of care that integrates primary health care services with care management support for patients receiving behavioral health treatment, and includes regular psychiatric inter-specialty consultation with the primary care team, particularly regarding patients whose conditions are not improving. We recognize that the requirements of this model may be challenging for some RHCs and FQHCs, especially those who have difficulty maintaining adequate primary care and mental health staffing in rural and or underserved areas. For those RHCs and FQHCs that choose to offer these services, we believe this model may be particularly helpful, especially for patients with primary care and mental health conditions who have not benefited from standard treatment.

Effective for services furnished on or after January 1, 2018, we proposed to create a psychiatric CoCM code for RHCs and FQHCs, GCCC2, with the payment amount set at the average of the 2 national non-facility PFS payment rates for CoCM codes, to be updated annually based on the PFS amounts. The 2 codes are:

- G0502—70 minutes or more of initial psychiatric CoCM services
- G0503—60 minutes or more of subsequent psychiatric CoCM services

RHCs and FQHCs could bill the new psychiatric CoCM code when the requirements for any of these 2 codes (G0502 or G0503) are met. The psychiatric CoCM code would be billed alone or in addition to other services furnished during the RHC or FQHC visit. To prevent duplication of payment, this code could only be billed once per month per beneficiary, and could not be billed if other care management services, including the proposed General Care Management code, are billed for the same time period. We note that G0504 is an add-on code when G0503 is furnished and is therefore not included as RHCs and FQHCs are not paid for additional time once the minimum requirements have been met.

If this policy had been adopted for CY 2017, the payment amount for psychiatric CoCM for RHCs and FQHCs would have been approximately $134.58 (G0502 at $142.84 + G0503 at $126.33 = $269.17/2 = $134.58).

All care management services, including psychiatric CoCM, require a separately billable initiating visit (E/M, AWV, or IPPE) for new patients or beneficiaries not seen within 1 year prior to commencement of care management services. Prior to commencement of psychiatric CoCM services, the beneficiary must provide consent for this service, including permission to consult with a psychiatric consultant and relevant specialists. Advance consent must also include information on cost sharing for both face-to-face and non-face-to-face services, and acceptance of these requirements must be documented in the medical record.

Patients with mental health, behavioral health, or psychiatric conditions, including substance use disorders, who are being treated by an RHC or FQHC practitioner, may be eligible for psychiatric CoCM services, as determined by the RHC or FQHC practitioner. Psychiatric CoCM services, like CCM and general BHI services, are intended to provide a structured and coordinated approach to care management that is not typically included in the RHC's AIR or the FQHC PPS payment methodology.

The psychiatric CoCM team must include the RHC or FQHC practitioner, a behavioral health care manager, and a psychiatric consultant. Proposed specific requirements of the psychiatric CoCM team are as follows:

Psychiatric CoCM Team—RHC or FQHC Practitioner

For psychiatric CoCM, the RHC or FQHC practitioner may be a primary care physician, NP, PA, or CNM. The psychiatric CoCM requirements of the RHC or FQHC practitioner are to:

- Direct the behavioral health care manager and any other clinical staff;
- Oversee the beneficiary's care, including prescribing medications, providing treatments for medical conditions, and making referrals to specialty care when needed; and
- Remain involved through ongoing oversight, management, collaboration and reassessment.

Psychiatric CoCM Team—Behavioral Health Care Manager

For psychiatric CoCM, the behavioral health care manager is a designated individual with formal education or specialized training in behavioral health such as social work, nursing, or psychology. A behavioral health care manager in an RHC or FQHC would be expected to have a minimum of a bachelor's degree in a behavioral health field (such as in clinical social work or psychology), or be a clinician with behavioral health training, including RNs and LPNs. The behavioral health care manager furnishes both face-to-face and non-face-to-face services under the general supervision of the RHC or FQHC practitioner and may be employed by or working under contract to the RHC or FQHC. The psychiatric CoCM requirements of the behavioral health care manager are:

- Providing assessment and care management services, including the administration of 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; provision of brief psychosocial interventions; ongoing collaboration with the RHC or FQHC practitioner; maintenance of the registry; acting in consultation with the psychiatric consultant;
- Being available to provide services face-to-face with the beneficiary; having a continuous relationship with the patient and a collaborative, integrated relationship with the rest of the care team; and
- Being available to contact the patient outside of regular RHC or FQHC hours as necessary to conduct the behavioral health care manager's duties.

Psychiatric CoCM Team—Psychiatric Consultant

For CoCM, a psychiatric consultant is a medical professional trained in psychiatry and qualified to prescribe the full range of medications. The psychiatric consultant is not required to be on site or to have direct contact with the patient and does not prescribe medications or furnish treatment to the beneficiary directly. The CoCM requirements of the psychiatric consultant are:

- Participating in regular reviews of the clinical status of patients receiving psychiatric CoCM services;
- Advising the RHC or FQHC practitioner regarding diagnosis and options for resolving issues with beneficiary adherence and tolerance of behavioral health treatment; making

adjustments to behavioral health treatment for beneficiaries who are not progressing; managing any negative interactions between beneficiaries' behavioral health and medical treatments; and

- Facilitating referral for direct provision of psychiatric care when clinically indicated.

RHCs and FQHCs could bill the new psychiatric CoCM code, GCCC2, when the requirements for HCPCS code G0502 or G0503 are met. This code could only be billed once per month per beneficiary, and could not be billed if other care management services, including the General Care Management code GCCC1, are billed for the same time period.

As with the proposed General Care Management code GCCC1, we would monitor PFS data to determine if a weighted average would be more appropriate in determining the psychiatric CoCM payment rate for RHCs and FQHCs, and whether any additional codes that may be added to the PFS in the future should also be factored into the RHC and FQHC psychiatric CoCM code. Any changes would be done through future rulemaking.

Table 19 compares the proposed requirements for general BHI, which would be billed using the proposed General Care Management code GCCC1, and psychiatric CoCM services, which would be billed using the proposed psychiatric CoCM code, GCCC2.

TABLE 19—COMPARISON OF PROPOSED GENERAL BHI AND PSYCHIATRIC COCM REQUIREMENTS AND PAYMENT FOR RHCS AND FQHCS

Requirements	General BHI (proposed) (HCPCS code G0507)	Psychiatric CoCM (proposed) (HCPCS code G0502 and G0503)
Initiating Visit	An E/M, AWV, or IPPE visit occurring no more than one-year prior to commencing care coordination services.	Same.
	Furnished by a primary care physician, NP, PA, or CNM.	Same.
	Billed as an RHC or FQHC visit	Same.
Beneficiary Consent	Obtained during or after initiating visit and before provision of care coordination services by RHC or FQHC practitioner or clinical staff.	Same.
	Written or verbal, documented in the medical record	Same.
	Includes information: • On the availability of care coordination services and applicable cost-sharing; • That only one entity can furnish and be paid for care coordination services during a calendar month; • That the patient has the right to stop care coordination services at any time (effective at the end of the calendar month); and • That the patient has given permission to consult with relevant specialists.	Same.
Billing Requirements	At least 20 minutes of care management services per calendar month that is: • Furnished under the direction of the RHC or FQHC primary care physician, NP, PA, or CNM; and • Furnished by an RHC or FQHC practitioner, or by clinical personnel under general supervision.	At least 70 minutes in the first calendar month, and at least 60 minutes in subsequent calendar months of psychiatric CoCM services that is: • Furnished under the direction of the RHC or FQHC primary care practitioner; and • Furnished by an RHC or FQHC practitioner or behavioral health care manager under general supervision.
Patient Eligibility	Any mental, behavioral health, or psychiatric condition being treated by the RHC or FQHC primary care practitioner, including substance use disorders, that, in the clinical judgment of the RHC or FQHC practitioner, warrants BHI services.	Same.
Requirement Elements	Includes: • 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, pharmacotherapy, counseling and/or psychiatric consultation). Continuity of care with a designated member of the care team.	Includes: RHC or FQHC primary care practitioner: • Direct the behavioral health care manager or clinical staff; • Oversee the beneficiary's care, including prescribing medications, providing treatments for medical conditions, and making referrals to specialty care when needed; and • Remain involved through ongoing oversight, management, collaboration and reassessment. Behavioral Health Care Manager: • Provide assessment and care management services, including the administration of 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; provision of brief psychosocial interventions; ongoing collaboration with the RHC or FQHC practitioner; maintenance of the registry; acting in consultation with the psychiatric consultant;

TABLE 19—COMPARISON OF PROPOSED GENERAL BHI AND PSYCHIATRIC COCM REQUIREMENTS AND PAYMENT FOR RHCS AND FQHCS—Continued

Requirements	General BHI (proposed) (HCPCS code G0507)	Psychiatric CoCM (proposed) (HCPCS code G0502 and G0503)
		• Be available to provide services face-to-face with the beneficiary; having a continuous relationship with the patient and a collaborative, integrated relationship with the rest of the care team; and • Be available to contact the patient outside of regular RHC or FQHC hours as necessary to conduct the behavioral health care manager's duties. Psychiatric Consultant: • Participate in regular reviews of the clinical status of patients receiving CoCM services; • Advise the RHC or FQHC practitioner regarding diagnosis, options for resolving issues with beneficiary adherence and tolerance of behavioral health treatment; making adjustments to behavioral health treatment for beneficiaries who are not progressing; managing any negative interactions between beneficiaries' behavioral health and medical treatments; and • Facilitate referral for direct provision of psychiatric care when clinically indicated.
Cy 2017 PFS Non-Facility Payment.	G0507—$47.73	G0502—$142.84, G0503—$126.33.
RHC/FQHC Payment for New Psychiatric CoCM G Code.	Current: N/A Proposed: Average of CPT codes 99490, 99487, and G0507. (If using the 2017 payment amounts, this would be $61.37).	Current: N/A. Proposed: Average of HCPCS codes G0502 and G0503. (If using the 2017 payment amounts, this would be $134.58).

c. Other Options Considered

We considered allowing RHCs and FQHCs to bill for the complex CCM codes, the BHI code, and the psychiatric CoCM codes by allowing the individual CPT or HCPCS codes to be billed on an RHC or FQHC claim, in the same manner as we currently allow CPT code 99490 to be billed on a claim. We do not believe this approach is in the best interest of RHCs and FQHCs. There are now 5 separate care management codes that are applicable to RHCs and FQHCs, and more codes could be added in the future as we learn more about the benefits of non-face-to-face care management services. Each of these codes has specific time increments that must be tracked and reported for payment under the PFS. We believe that grouping the CCM and BHI codes and the psychiatric CoCM codes into 2 G codes is more consistent with the RHC and FQHC payment methodology of averaging actual costs to determine a payment rate and not paying for services based on time increments. It also requires less record keeping, monitoring, and coding expertise, while maintaining the same quality of care standards.

We also considered grouping all 5 codes together into one G code, or developing 3 G codes—one for the CCM codes, one for the BHI code, and one for the psychiatric CoCM codes. We did not choose either of these approaches because CCM and BHI are similar services that complement each other, and grouping them together is consistent with an integrated approach to care with reduced reporting requirements. We also believe that psychiatric CoCM is different enough from both CCM and BHI in its requirements, particularly in staffing and required services, that it warrants a separate G code. We believe that our proposal of creating 2 new G codes to encompass the 5 care management codes is the best option for RHCs and FQHCs now and in the future if new care management codes are developed. We welcomed comments on the proposal.

The following is a summary of the public comments received on our proposal to revise the CCM payment for RHCs and FQHCs and establish requirements and payment for general BHI and psychiatric CoCM services furnished in RHCs and FQHCs, beginning on January 1, 2018. As previously noted, the following code changes will be effective January 1, 2018, and are used in the remainder of this rule:

TABLE 20—COMPARISON OF PROPOSED AND FINAL HCPCS/CPT CODES

Description of code	Proposed or current HCPCS/CPT code	Final HCPCS/CPT code (effective January 1, 2018)
General Care Management for RHCs and FQHCs only	GCCC1	G0511
Psychiatric CoCM code for RHCs and FQHCs only	GCCC2	G0512
Psychiatric CoCM Services (first 70 min)	G0502	99492
Psychiatric CoCM Services (subsequent 60 min)	G0503	99493
Psychiatric CoCM Services (add on)	G0504	99494
General BHI Services	G0507	99484

Comment: Most commenters were supportive of our proposal. Many commenters stated that these changes will increase the availability of CCM, BHI, and psychiatric CoCM in RHCs and FQHCs and increase access for patients who need these services, especially in rural areas. Many commented that the proposal will support efforts to integrate medical and behavioral health care and encourage more primary care and behavioral health care providers to work together and coordinate care to better assist patients with complex, chronic conditions. Many commented on the role of RHCs and FQHCs as safety net providers serving the Nation's most vulnerable populations, and how important care management services are, especially for individuals with complex needs and few resources. A few commenters expressed their preference for billing each service by separate CPT codes, but most stated that the proposed methodology is administratively simple, will reduce reporting burden, and is in alignment with current RHC and FQHC billing practices. Many commenters also noted that this proposal will build upon efforts at addressing substance abuse and the opioid epidemic, increasing obesity rates, traumatic brain injury, dementia, and the health care needs of an aging population.

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

Comment: Some commenters noted that patients are often unwilling to pay the patient share of care management services and requested CMS waive cost-sharing or pursue waivers for these codes.

Response: We are aware that the copayment and/or deductible in RHCs and the copayment in FQHCs can be a barrier for some beneficiaries, but we do not have the statutory authority to waive these charges. Because these services are typically furnished non face-to-face, and therefore, are not visible to the patient, it is important that adequate information is provided during the consent process on cost-sharing responsibilities and the benefits of care management services. RHCs and FQHCs should also provide information on the availability of assistance to qualified patients in meeting their cost-sharing obligations, or any other programs to provide financial assistance, if applicable.

Comment: Several commenters asked if psychiatric mental health nurse practitioners (PMH–NPs) could serve as the psychiatric consultant to RHCs and FQHCs that are furnishing psychiatric CoCM, and recommended that they be included based on their education and training or board certification. Some commenters stated that this is especially important in rural areas where specialists are not readily available, and others stated that this would make psychiatrists more readily available for patients for which a higher degree of training may be required.

Response: The psychiatric CoCM program requires a psychiatric consultant who is a medical professional trained in psychiatry and qualified to prescribe the full range of medications. Their responsibilities include participating in regular reviews of the clinical status of patients receiving psychiatric CoCM services; advising the RHC or FQHC practitioner regarding diagnosis and options for resolving issues with beneficiary adherence and tolerance of behavioral health treatment; recommending adjustments to behavioral health treatment for beneficiaries who are not progressing; managing any negative interactions between beneficiaries' behavioral health and medical treatments; and facilitating referral for direct provision of psychiatric care when clinically indicated.

PMH–NPs are trained to provide a wide range of mental health services, including psychiatric diagnosis and medication treatment for psychiatric disorders. Although NPs are authorized to prescribe controlled substances, their practice authority varies by state and in some states they may have additional requirements or restrictions. We believe that a board-certified PMH–NP would meet the requirements to serve as a psychiatric consultant for an RHC or FQHC that is furnishing psychiatric CoCM services and would assist in making this program more widely available, especially in rural areas.

Comment: Several commenters requested clarification or removal of the requirement that the psychiatric CoCM behavioral health care manager be available to contact the patient outside of regular RHC or FQHC hours as necessary to conduct the behavioral health care manager's duties. Commenters questioned if this meant that the health care manager must be available 24/7, and if so, they noted this was an unreasonable expectation that would present a barrier to implementing this program.

Response: RHCs and FQHCs have processes for patients to contact practitioners or access care during non-RHC or FQHC hours, and it was not our intention to require or imply that the behavioral health care manager be available on a 24/7 basis. To avoid any confusion, this requirement will be removed.

Comment: Several commenters requested clarification of the qualifications for the behavioral health care manager. One commenter questioned whether a social worker could serve in this role or if a master level clinical social worker is required. Another commenter stated that some of the health care manager's duties, such as administering screening tools, scheduling meetings, and entering data for the registry, could be conducted by someone with less education, under the supervision of a licensed practitioner. Other commenters suggested that licensed clinical social workers, licensed clinical professional counsellors, licensed or bachelor level social workers, nurses who undergo mental health training or have some experience in psychiatric interviewing, certified addiction counselors, or occupational therapists should be able to serve as the behavioral health care manager.

Response: As noted in the proposed rule, the behavioral health care manager is a designated individual with formal education or specialized training in behavioral health such as social work, nursing, or psychology. A behavioral health care manager in an RHC or FQHC would be expected to have a minimum of a bachelor's degree in a behavioral health field (such as in clinical social work or psychology), or be a clinician with behavioral health training, including RNs and LPNs. Therefore, a clinical social worker is not required to have a masters degree in social work to serve as the psychiatric CoCM health manager.

It is the responsibility of the RHC or FQHC to assure that the behavioral health care manager meets the stated requirements, and to manage any delegation of duties and supervision as appropriate.

Comment: Some commenters objected to the requirement that general BHI and psychiatric CoCM services be furnished only under the direction of an RHC or FQHC primary care physician, NP, PA, or CNM, and maintained that excluding CPs and CSWs would create a barrier to effective team-based care.

Response: General BHI and psychiatric CoCM are both team-based, collaborative approaches to care that focus on integrative treatment of patients with primary care and mental or behavioral health conditions. General BHI was established to support extensive care management discussions, information-sharing, and planning between a primary care practitioner and a behavioral health specialist, while psychiatric CoCM is a specific model of care provided by a primary care team

consisting of a primary care provider and a health care manager who works in collaboration with a psychiatric consultant.

CPs and CSWs are RHC and FQHC practitioners and furnish medically-necessary, face-to-face services that may be stand-alone billable visits in RHCs and FQHCs. They can also serve as the behavioral health care manager for general BHI and psychiatric CoCM services. In order to facilitate the integration and coordination of the patient's primary care and mental or behavioral health conditions, these care management services are furnished under the direction of the RHC or FQHC primary care practitioner.

Comment: One commenter suggested that the consulting psychiatrist on the psychiatric CoCM team should be able to bill separately for this service in addition to the payment to RHCs and FQHCs. Other commenters suggested that CPs and CSWs, or the entire behavioral health workforce, be able to bill directly for these services.

Response: The consulting psychiatrist is a member of the psychiatric CoCM team, and the RHC and FQHC payment reflects the cost of their services. If the consulting psychiatrist were to bill separately, Medicare would be overpaying for this service, because the cost of the psychiatric consultant is included in the rate for the care management codes. We also note that services are billed by the RHC or FQHC, and that neither RHC, FQHC practitioners (including CPs and CSWs), nor any other clinical personnel, bill directly for services furnished in RHCs or FQHCs.

Comment: One commenter supported the proposed methodology but noted more needs to be done to create coding options and reimbursement for consultation models where a child and adolescent psychiatrist guides a primary care physician in treating behavioral and mental health conditions. The commenter stated that these models help to ensure that more children and youth in need of behavioral or mental health interventions receive the care they need and are an efficient way to address severe child and adolescent psychiatrist workforce shortages in most areas of the country.

Response: We agree that there are many children and adolescents in need of behavioral or mental health interventions and that many areas of the country do not have adequate psychiatric services for children and adolescents, but this is outside the scope of this proposal.

Comment: A commenter noted that RHCs and FQHCs would receive a higher payment for CPT 99490 services than an office-based practice, and as a result, this code should be revalued.

Response: The proposed payment methodology for general care management services furnished by RHCs and FQHCs is similar to the payment methodology for other RHC and FQHC services. In general, RHCs and FQHCs are paid a per diem rate that is based on average costs, and the payment is not adjusted for time or intensity once the requirements are met. This results in a payment rate that is sometimes less and sometimes more than the payment for the same services when it is billed by an office-based practice under the PFS. We respectfully disagree that the proposed RHC and FQHC payment for general care management is a reason to revalue CPT 99490, and note that if any of the codes that are included in G0511 (CPT codes 99490, 99487, and 99484) are revalued, the payment for G0511 would adjust accordingly.

Comment: One commenter expressed concern that RHCs and FQHCs may not offer care management services because the care management codes can be used only once per month for a beneficiary and cannot be combined with other care management codes. This commenter urged us to remove these restrictions and instead actively monitor the use of these codes to determine whether overuse occurs.

Response: While we appreciate the commenter's concern, we respectfully disagree that limiting the billing of these codes to once per month will impede an RHC or FQHC from offering these services. The payment methodology is designed to encourage the use of these services by making billing and record keeping as simple as possible while providing a favorable payment rate. Once the minimum requirements are met, RHCs and FQHCs can bill for this service and would be paid at the average rate of the applicable codes, whether or not additional time is spent furnishing these services. We believe this approach is likely to encourage RHCs and FQHCs to offer these services and is preferable to actively monitoring for overuse.

Comment: One commenter agreed with our intention to monitor the frequency of PFS billing for CPT 99487 to determine whether a weighted average would be more appropriate for future payment years, and suggested that we also monitor the extent that complex chronic care management services are provided in RHC and FQHCs.

Response: We appreciate the comment and will review all available data to determine if a weighted average would be more appropriate in the future. As we noted in the proposed rule, any changes would be undertaken through future rulemaking.

Comment: One commenter noted that for low-income or limited-English proficiency Medicare beneficiaries, care management can lead to more effective care, better health outcomes and fewer emergency department visits. This commenter suggested that the additional costs of providing appropriate care for these populations should be acknowledged and payments appropriately adjusted in future rulemaking. Another commenter was concerned that the proposed methodology may not accurately reflect and compensate RHCs and FQHCs for the additional complexity of care coordination for patients who have significant primary care needs and requested that we consider comments received from health care providers and patient advocates and consider alternative approaches if necessary. Another commenter encouraged us to monitor the use of the care management codes and any related feedback regarding the financial sustainability of the model, and address any challenges and concerns in future rulemaking.

Response: We agree that care management can lead to more effective care, better health outcomes and fewer emergency department visits and appreciate the concern raised by the commenters. As previously noted, we will monitor data as it becomes available and consider a weighted average if appropriate. We welcome RHCs, FQHCs, and others to communicate to us any information regarding the appropriateness of their care management payments as more experience is gained in implementing these services.

Comment: One commenter recommended that in order to maintain consistency and avoid confusion for providers, RHCs and FQHCs should use the PFS CPT codes for care management services. Another commenter stated that in order to avoid creating financial advantages for some medical settings over others, coding and payment should be the same for RHCs and FQHCs as for physicians billing under the PFS. This commenter maintained that creating different coding and payment protocols may lead to inequitable payments, and makes it difficult to assess differences in payment adequacy.

Response: RHCs and FQHCs differ significantly from office or hospital-based physician practices and have specific purposes, characteristics, and requirements that generally do not apply to other providers or suppliers. As

part of the nation's health care safety-net, RHCs and FQHCs are paid under a different payment methodology that reflects the costs of furnishing care in underserved rural and urban areas. We respectfully do not agree that the difference in the payment systems may lead to inequitable payments, but rather reflect the needs of these communities in providing primary health care to underserved rural and urban populations.

Comment: A commenter asked if certified EHR technology would be required for billing G0511 when BHI services are furnished.

Response: Certified EHR technology is a requirement for CCM, but it is not a requirement for general BHI or psychiatric CoCM services. To bill the new G0511 code, an RHC or FQHC must meet the requirements for either CCM (CPT 99490 or CPT 99487) or general BHI (CPT 99484). If the requirements for CPT code 99484 are met, the code can be billed and certified EHR technology is not required.

Comment: One commenter requested that we delay the denial date of January 1, 2018, for claims submitted with CPT 99490.

Response: We wish to clarify that claims with CPT 99490 for services furnished on or before December 31, 2017, will be processed and paid. Service lines reported with CPT 99490 will be denied for dates of service on or after January 1, 2018.

Comment: A few commenters requested additional information and training on the use of these new codes for RHCs and FQHCs be made available, and that CMS Connected Care Providers receive training materials.

Response: Additional information on the new care management codes for RHCs and FQHCs will be available on the CMS Web site for RHCs (*https://www.cms.gov/Center/Provider-Type/Rural-Health-Clinics-Center.html*) and FQHCs (*https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html*). This will include an MLN article for RHCs and FQHCs, and an update to the Medicare Benefit Policy Manual, Chapter 13. These changes will also be presented on the national CMS Rural Open Door Forum call, and on the Safety Net Open Door Forum call (*https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/index.html*). Information on becoming a CMS Connected Care provider to help raise awareness about the benefits of CCM services is available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/ccm/become-a-partner.html*.

Comment: Some commenters discussed issues that were outside the scope of the proposed rule.

Response: Comments received that are outside the scope of the proposed rule are not addressed in this final rule.

As a result of the public comments, we are finalizing the revisions to CCM payment for RHCs and FQHCs and establishment of requirements and payment for general BHI and psychiatric CoCM services furnished in RHCs and FQHCs, beginning on January 1, 2018, as proposed, except that we are removing the requirement that the behavioral health care manager be available to contact the patient outside of regular RHC or FQHC hours as necessary to conduct the behavioral health care manager's duties.

4. Implementation

RHCs and FQHCs will continue to receive payment for CCM services when CPT code 99490 is billed alone or with other payable services on an RHC or FQHC claim for dates of service on or before December 31, 2017. Beginning on January 1, 2018, RHCs and FQHCs must use the new General Care Management code G0511 when billing for CCM or general BHI services, and the new psychiatric CoCM code G0512 when billing for psychiatric CoCM services, either alone or with other payable services on an RHC or FQHC claim. Service lines submitted using CPT 99490 code for dates of service on or after January 1, 2018 will be denied.

Both the current RHC and FQHC payment rate for CCM, and the proposed RHC and FQHC payment rates for General Care Management and Psychiatric CoCM codes, are based on the PFS national non-facility rates. The PFS rates are updated annually, and the new G codes for RHCs and FQHCs would be updated accordingly and finalized when the PFS rates are finalized for the year. No geographic adjustment will be applied to the General Care Management or Psychiatric CoCM G codes. RHCs and FQHCs are required to submit claims for care management services on an institutional claim (electronically per the HIPAA compliant ANSI X12 837I or the Form CMS 1450, also known as the UB–04,) and are not authorized to bill care management services separately to the PFS.

5. Regulatory Changes

As previously noted, § 405.2413(a)(5) and § 405.2415(a)(5) was revised effective January 1, 2017, to state that services and supplies furnished incident to CCM and TCM services can be furnished under general supervision of an RHC or FQHC practitioner, consistent with § 410.26(b)(5), which allows CCM and TCM services and supplies to be furnished by clinical staff under general supervision when billed under the PFS. Sections 405.2413(a)(5) and 405.2415(a)(5) are now revised to state that services and supplies incident to the services of a physician, NP, PA, or CNM are furnished under the direct supervision of a physician, NP, PA, or CNM, except for TCM, General Care Management, and Psychiatric CoCM services, which can be furnished under general supervision of a physician, NP, PA, or CNM when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1).

B. Part B Drug Payment: Infusion Drugs Furnished Through an Item of Durable Medical Equipment (DME)

Section 303(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) revised the payment methodology for most Medicare-covered Part B drugs and biologicals by adding section 1847A to the Act, which established a new average sales price (ASP) drug payment methodology beginning January 1, 2005. Section 303(b) of the MMA specified payments for certain drugs using methodologies other than the ASP pricing methodology. Specifically, section 303(b) of the MMA added section 1842(o)(1)(D)(i) of the Act that required that an infusion drug furnished through an item of DME covered under section 1861(n) of the Act be paid 95 percent of the average wholesale price (AWP) for that drug in effect on October 1, 2003.

Section 5004(a) of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255, enacted on December 13, 2016) revised sections 1842(o)(1)(C) and (D) of the Act, changing the payment methodology for DME infusion drugs from being based on AWP to the methodologies in sections 1847, 1847A, 1847B, or 1881(b)(13) of the Act, as the case may be for the drug or biological. To implement the pricing changes required by section 5004(a) of Cures Act, which modifies the payment for DME infusion drugs to the amount under section 1847A of the Act (ASP drug payment methodology), by the statutorily mandated effective date of January 1, 2017, we incorporated the ASP-based infusion drug payment amounts into the January 2017 quarterly ASP drug pricing files and instructed claims processing contractors to use the updated payment limits for DME infusion drugs.

To conform regulations with the new payment requirements in section

5004(a) of the Cures Act as they pertain to section 1847A of the Act, we proposed revising § 414.904(e)(2). Currently, this describes an exception to ASP-based payments and requires pricing DME infusion drugs at 95 percent of the 2003 AWP. Consistent with section 5004(a) of the Cures Act, the proposed revision limits the exception to infusion drugs furnished before January 1, 2017. In addition, we proposed at § 414.904(e)(2) to delete the phrase ''and is not updated in 2006.'' We believe this language is not relevant since the statutory language required that the pricing of DME infusion drugs be based on the October 2003 AWP. Therefore, there was no update for pricing DME infusion drugs in 2006, and the proposed revision will serve to simplify the language. Effective January 1, 2017, payment limits for these drugs are determined under section 1847A of the Act.

Comment: We received one comment in which the commenter expressed concern that immune-compromised beneficiaries will experience access issues due to the reduction in payment for certain life-saving therapies that are paid for under Medicare Part B and administered via DME.

Response: We appreciate the commenters concern about access to infusion drugs furnished through an item of covered DME. Section 5004(a) of the 21st Century Cures Act requires the change in the payment methodology to the ASP methodology for these drugs effective January 1, 2017. This provision of the Act does not provide us with the flexibility to alter the payment methodology, implementation date or to select the drugs or patient populations that will be affected by the change.

After consideration of the public comment received, we are finalizing our proposal to revise § 414.904(e)(2) to conform with the statutory payment requirements of section 5004(a) of the Cures Act. We are also finalizing our proposal to revise § 414.904(e)(2) to delete the phrase ''and is not updated in 2006.''

C. Solicitation of Public Comments on Initial Data Collection and Reporting Periods for Clinical Laboratory Fee Schedule

1. Background on Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule

In the June 23, 2016 **Federal Register** (81 FR 41036) we issued a final rule entitled, ''Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System,'' to implement the requirements of section 1834A of the Act, which requires extensive revisions to the Medicare payment, coding, and coverage for clinical diagnostic laboratory tests (CDLTs) paid under the Clinical Laboratory Fee Schedule (CLFS).

Under the CLFS final rule, reporting entities are required to report to us certain applicable information for their component applicable laboratories. The applicable information includes, for each CDLT furnished during a data collection period, the specific HCPCS code associated with the test, each private payor rate for which final payment has been made, and the associated volume of tests performed corresponding to each private payor rate. In general, the payment amount for a test on the CLFS furnished on or after January 1, 2018, will be equal to the weighted median of private payor rates determined for the test, based on the applicable information that is collected during a data collection period and reported to us during a data reporting period.

In the CLFS final rule, we established a data collection period that is the 6 months from January 1 through June 30 during which applicable information is collected and that precedes the data collection period. We established a data reporting period that is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to us and that follows the preceding data collection period. The first data collection period was January 1, 2016 through June 30, 2016. The first data reporting period was January 1, 2017 through March 31, 2017. This 6-month data collection period and 3-month data reporting period schedule will be repeated every 3 years for CDLTs that are not advanced diagnostic laboratory tests (ADLTs), and every year for ADLTS that are not new ADLTs.

For the first data reporting period, industry feedback suggested that many reporting entities would not be able to submit a complete set of applicable information to us by the March 31, 2017 deadline, and that entities required additional time to review collected data, address any issues identified during such review, and compile the data into our required reporting format. As a result, on March 30, 2017, we announced that we would exercise enforcement discretion until May 30, 2017, with respect to the data reporting period for reporting applicable information under the Medicare CLFS and the application of the Secretary's potential assessment of civil monetary penalties for failure to report applicable information.[1] The enforcement discretion applied to entities that were subject to the data reporting requirements finalized in the CLFS final rule (81 FR 41036). We noted in the announcement that the 60-day enforcement discretion period was the maximum amount of time we could permit to still have sufficient time to calculate the CLFS payment rates scheduled to go into effect on January 1, 2018.

The announcement stated that the enforcement discretion period would not prevent reporting entities prepared to report applicable information from doing so before May 30, 2017. We explained in the announcement that we were committed to the successful implementation of the new private payor rate-based CLFS and looked forward to working with the laboratory industry to ensure accurate payment rates. In recent months, we analyzed the applicable information we received, held our Annual Laboratory Public Meeting, met with the Advisory Panel for Clinical Diagnostic Laboratory tests twice, and posted preliminary CLFS payment rates for calendar year 2018.[2]

2. Solicitation of Public Comments on Medicare Clinical Diagnostic Laboratory Tests Payment System Initial Data Collection and Reporting Periods: Summary of Public Comments

In the proposed rule, we solicited public comments from applicable laboratories and reporting entities to better understand the applicable laboratories' experiences with the data reporting, data collection, and other compliance requirements for the first data collection and reporting periods. Specifically, we sought public comment on the following questions:

- Was the CMS data reporting system easy to use? Please describe your overall experience with navigating the CMS data reporting system. For example, describe the aspects of the CMS data reporting system that worked well for your reporting entity and/or any problems the reporting entity experienced with submitting applicable information to us.
- Did the applicable laboratory (or its reporting entity) request and receive assistance from our Help Desk regarding the CMS data reporting system? Please describe your experience with receiving assistance.

[1] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf.*

[2] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html.*

• Did the applicable laboratory (or its reporting entity) request and receive assistance from the CMS CLFS Inquiries Mailbox regarding policy questions? Please describe your experience with receiving assistance.

• Did the applicable laboratory (or its reporting entity) use the subregulatory guidance on data reporting provided on the CMS CLFS Web site? [3] If so, was the information presented useful?

• Was the information that the applicable laboratory was required to report readily available in the applicable laboratory's record systems?

• Did the reporting entity have a manual, automated, or semi-automated remittance process for data reporting?

• If the reporting entity used a manual or semi-automated remittance process for data reporting, what percentage of the process was manual?

• How much time (hours) was required to assemble and report applicable information to CMS?

• Is there any other information that will inform us regarding the reporting, recordkeeping, and other compliance requirements from the first data collection and reporting periods?

We stated in the proposed rule that we were soliciting comments to better understand applicable laboratories' experiences with the data reporting, data collection, and other compliance requirements for the first data collection and reporting periods under the new private payor rate-based CLFS. We believed industry feedback on these issues would help inform us regarding potential refinements to the private payor rate-based CLFS for future data collection and reporting periods. A summary of the public comments we received on our comment solicitation, and our response to those comments, appears below.

Comment: In response to our solicitation, we received approximately 40 comments from individuals, health care providers, corporations, government agencies, and major laboratory organizations. Commenters expressed that the CMS Help Desk for the data reporting system and the subregulatory guidance on the CMS CLFS Web site were particularly helpful. Some commenters mentioned that using the data reporting system was challenging at first but became easier to navigate with more experience. One commenter stated that its laboratory organization incurred significant additional costs in collecting and reporting applicable information due to its large number of manual remittances. In addition, commenters provided the following specific recommendations:

• Improve the accessibility of the CMS data reporting system, for example, by removing certain security measures.

• A few commenters indicated that it was administratively burdensome for the reporting entity, that is the Taxpayer Identification Number (TIN) level entity, to report applicable information individually for each of its component applicable laboratories. As an alternative, they suggested that we allow the reporting entity to aggregate applicable information for its components that are applicable laboratories, and enter the aggregated applicable information in the designated column on the CMS data reporting template.

• Change the proportion of data that applicable laboratories are required to report; for example, allow applicable laboratories to report 75 to 80 percent, rather than 100 percent, of their applicable information.

• Change the requirement that applicable laboratories must report data from claims that require manual remittance processes.

• Streamline the identification of user formatting errors and permit real-time file edits in the CMS data reporting system.

• Define terms used in the data reporting system; for example, a few commenters requested CMS provide a definition for the term ''CMS Certification Number (CCN)''.

Most of the comments received were out of scope because they did not address experiences with the initial data collection and reporting periods. For example, some commenters recommended that CMS delay implementation of the new private payor rate-based CLFS payment system. A few commenters recommended that we redefine the term ''applicable laboratory'' to include hospitals, specifically to ensure hospital outreach laboratory data is included in the calculation of the new CLFS rates.

Response: We thank the commenters for their feedback and will consider the comments for potential future rulemaking or publication of subregulatory guidance pertaining to the CLFS data collection and reporting periods. No CLFS data collection or reporting changes are being proposed or finalized within this final rule. We note that a hospital outreach laboratory, that is, a hospital based laboratory that furnishes laboratory tests to patients other than inpatients or outpatients of the hospital, could be an applicable laboratory if it meets the definition of an applicable laboratory in 42 CFR 414.502.

D. Payment for Biosimilar Biological Products Under Section 1847A of the Act

In the CY 2016 Physician Fee Schedule (PFS) final rule with comment period, we finalized a proposal to amend the regulation text at § 414.904(j) to make clear that the payment amount 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 (80 FR 71096 through 71101). In general, this means that products that rely on a common reference product's biologics license application (that is, FDA's previous finding of safety, purity, and potency for the common reference product) are grouped into the same payment calculation for determining a single ASP payment limit and that a single HCPCS code is used for such biosimilar products. The regulation went into effect on January 1, 2016.

The comments received on the 2016 PFS proposed rule indicated that stakeholders had varying opinions about Medicare payment for biosimilar biological products under Part B. The commenters included individuals, pharmaceutical manufacturers, patient advocate groups, providers, insurers, and members of Congress. A number of commenters opposed a single payment amount for all biosimilars that rely on FDA's finding of safety, purity, and potency for a common reference product. Most of these commenters believed that the proposed regulation would decrease incentives for biosimilar development and that grouping payment for biosimilar biological products is inconsistent with the statute. Some commenters also expressed concerns that prescribers' choices will be limited, that tracking or pharmacovigilance activities will be impaired, and that innovation and product development will be harmed, leading to market consolidation and increased costs for biosimilar biological products. Many commenters who opposed this policy suggested that we determine a payment amount for each biosimilar biological product. These stakeholders have expressed concerns that the finalized policy restricts and threatens the viability of their business models and expressed support for a new solution. Some of these stakeholders believed that determining a payment for each biosimilar product by using individual HCPCS codes, would drive and reward innovators, producing the potential cost savings of at least 10–15

[3] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.*

percent compared to the reference biologic ASP necessary for biosimilar products to compete with the reference biological.

However, some commenters supported our proposed regulation, stating that the potential marketplace for biosimilar biological products is large and it is less risky than the marketplace for reference biologicals. Commenters also expressed concern that separate payment for each biosimilar biological product would result in less competition among manufacturers, which in turn could lead to higher payment amounts for Medicare and beneficiaries. Some commenters stated that separate billing codes could be perceived as a type of price protection and could artificially increase prices for biosimilars. Commenters who supported the proposed regulation suggested that we remain mindful of our policy as the biosimilar biological product marketplace evolves. Several commenters requested that policy decisions be delayed while issues such as naming conventions and interchangeability standards are finalized by the FDA.

In 2015, biological products accounted for the majority (65 percent) of part B spending, which totaled $26 billion including Medicare and beneficiary payments (MedPAC Report to Congress June 2017, page 37). As CMS expected, since the regulation was finalized in 2015, the biosimilar product marketplace has continued to grow, and four biosimilar biological products that are paid under Part B have been licensed, including one product approved in 2017 that is sharing a HCPCS code with another previously licensed biosimilar biological product. Based on the number of biosimilar biological products that are reported to be nearing approval and the approvals made over that past 2 years, we anticipate that several more biosimilar biological products will be licensed for use in the United States during the next year and that during the following years, the marketplace will continue to grow steadily, provided that the approved products are marketed without delay. We also anticipate that biological products will continue to be heavily utilized in Part B. At the same time, we are aware of concerns that current Medicare policy may discourage development of new biosimilars and other innovation in this area potentially resulting in higher costs over time due to a lack of competition in the market place.

In the 2016 PFS final rule, we stated that it is desirable to have fair reimbursement in a healthy marketplace that encourages product development (80 FR 71101). CMS seeks to promote innovation to provide more options to patients and physicians, and competition to drive prices down, recognizing that even though these two goals may be difficult to achieve concurrently, to delink them would be counterproductive.

Although we believe that the United States biosimilar biological product marketplace is still in an early phase (because only a few products are on the market), we are interested in assessing the effects of Medicare payment policy on this important portion of the Part B drug marketplace at this time, particularly for fostering a robust, and competitive marketplace and encouraging the innovation that is necessary to bring more of these products to the marketplace. It is essential to take a measured approach that considers all options given the significant federal spending by Medicare on Part B drugs, the effect of payment policies on program sustainability for taxpayers, health care affordability and access for beneficiaries, and the considerable investment the biosimilar industry reports to be making in the nascent market (the development cost for a biosimilar product is reported by commenters to be approximately $100–200 million). Failure to consider the available options could potentially restrict innovation in the marketplace, increase costs to the American taxpayer, and limit treatment options. With that in mind, it is CMS's goal to further evaluate our policies to be sure they allow for market forces to provide a robust and comprehensive selection of choices for providers and patients at a fair price. Additionally, we are interested in better understanding if and how the differences in biological products and their current regulatory environment should be reflected in Medicare payment policy for biosimilars, particularly as it relates to biosimilars that are licensed for fewer than all indications for which the reference product is licensed or situations where different biosimilars may be licensed for different subsets of indications for which the reference product is licensed.

Thus, in the CY 2018 PFS proposed rule we requested comments regarding our Medicare Part B biosimilar biological product payment policy. This comment solicitation sought new or updated information on the effects of the current biosimilar payment policy that is based on experience with the United States marketplace. We stated that we were particularly interested in obtaining material, such as market analyses or research articles that provide data and insight into the current economics of the biosimilar market place. This includes patient, plan, and manufacturer data both domestic and, where applicable, from European markets that may be more established than, and provide insight for, the current United States market.

We also sought data to demonstrate how individual HCPCS codes could impact the biosimilar market, including innovation, the number of biosimilar products introduced to the market, patient access, and drug spending. Finally, we also sought comment regarding other novel payment policies that would foster competition, increase access, and drive cost savings in the biological product marketplace. These novel options may include legislation, demonstrations, and administrative options. The comment solicitation did not include a proposal to change the existing payment policy.

The following is a summary of the public comments received regarding the effect of payment policies on competition, access, and cost savings in the biological product marketplace and our responses on this issue. We received more than 200 comments in response to the solicitation. In general, comments were very similar to those received during the CY 2016 PFS rulemaking period.

Comment: Most commenters opposed the current Medicare policy. These commenters believe that the policy will impair access to biosimilars, and could potentially limit the introduction of biosimilars to the US market and would fail to maximize competition and savings. Some provided updated information to support the position that greater savings will result from the use of unique codes for each biosimilar. Some commenters also believed that CMS should change its policy effective January 1, 2018.

Commenters who agreed with the current Medicare policy believed that grouping biosimilars would provide savings for beneficiaries and for the trust fund through increased competition. These commenters believe that separate billing codes do not foster price competition. The commenters pointed out that ASP-based payments for groups of potentially competing Part B drugs and biologicals remained the same or increased between 2012 and 2017. The commenters also pointed out that the use of separate billing codes would likely lead to high introductory prices. These commenters noted that Part B has already experienced a situation where the initial, WAC-based

payment amount for a biosimilar of infliximab exceeded the ASP-based payment for its reference product by about 20 percent. Also, commenters contended that the size of the United States biological market and associated revenue would provide an incentive for manufacturers to continue to introduce products in the US (even if biosimilars continued to be grouped together). Finally, some commenters believed that making a policy change at this time was not advisable because the United States marketplace had not changed significantly since 2016.

Response: We appreciate all the commenters' input, and we will discuss specific topics from the comment solicitation in the comment/response sections below. We considered these comments as we evaluated our current policy and considered changes to it.

Comment: Many commenters discussed the differences between biosimilar biological products, such as the complexity of biological molecules and how the manufacturing processes that are necessary to produce them create small differences between the products. The commenters noted that biosimilars are similar, but not identical, to their reference products, and that as a result of potentially subtle differences, they may have different therapeutic and adverse effects on patients, requiring clinical as well as payment distinctions between the products. These commenters believed that Medicare payment policy that treats biosimilars like generic drugs by grouping them for payment would lead to prescribing choices based on cost rather than clinical considerations.

Several commenters also discussed issues related to the differences between products in more detail, as well as the interchangeability of biosimilar biological products. Although none of the currently available biosimilars are approved as interchangeable (and finalized FDA guidance on the subject is not yet available), some commenters believed that grouping products for payment could be understood by clinicians and patients that the products could be interchangeable. Some commenters also pointed out that the current biosimilar approval process does not compare biosimilar biological products to each other, rather, only similarity to a reference product is established and the licensing of a biological product under the biosimilar pathway does not mean that the products are interchangeable. Also, commenters noted that biosimilar biological products may be approved for fewer indications than the reference product and that the approved indications within a group of biosimilar biological products with the same reference product may vary. Some commenters believed that blended payment for biosimilar biological products that do not have all the same indications could lead to off-label use.

Many commenters believed that differences between biosimilar biological products that share a common reference product exist and stated that such distinctions, which may affect the clinical use of a product on specific patients, support the need for separate coding and payment for biosimilars under Medicare Part B. Some commenters also associated these concerns with concerns about payment for biosimilar biological products.

Several comments discussed the relationship between costs, prices, and competition in the biologicals and biosimilars market, as follows. Because these products are likely to be expensive and may have different acquisition costs, blended payment was perceived by many commenters as a significant financial risk to the provider because the provider could not be highly certain that the products that would be the best choice for a patient would also be likely to be paid above acquisition cost. These commenters believed that separate codes would lead to more certainty about payment amounts for biosimilar biological products. Some commenters were concerned that ''race to the bottom'' pricing competition would result from shared codes and lead to prices that could not sustain educational efforts and other activities associated with marketing new and complex biological products, ultimately resulting in manufacturers leaving the United States marketplace. The commenters also noted that the development costs for these products and their manufacturing facilities are estimated to be in the hundreds of millions of dollars.

Commenters also expressed concern about the lack of competition between biosimilars and their reference product. Some commenters who disagreed with CMS's current approach of grouping biosimilar biological products for payment believed that separate codes would lead to opportunities for greater and more direct competition between the reference product and its biosimilar versions.

Other commenters who agreed with current Medicare policy, suggested that payment for biosimilars should be based on grouping the reference product with its corresponding biosimilars in the same billing and payment code and suggested that legislative authority for such a change should be sought by CMS. These commenters opined that combining reference products and corresponding biosimilar biological products into the same billing and payment code would maximize competition for items with similar effects. In the absence of authority to expand grouped payment to include the reference product, most of these commenters agreed with the current approach of grouping biosimilar biological products of the same reference product into the same billing and payment code.

Response: We appreciate the commenters' wide range of concerns about the differences between biosimilar biological products and how payment approaches may influence clinical decisions.

Many of these concerns were brought up in comments on biosimilars made in response to the CY 2016 PFS final rule with comment period. We discussed these issues, including differences between small molecule drugs and biologicals (including biosimilars), generic drugs, and interchangeability in the 2016 final rule. However, as we have further considered the Part B biosimilar biological payment policy and this year's comments, we have become increasingly concerned about the relationship between cost, prices and competition; specifically, many commenters' continued unease regarding the effects of our payment policy on patient and provider choices, as well as the biosimilar marketplace. We have also considered how the payment policy could affect market entry of new biosimilar manufacturers. If payment amounts limit manufacturers' willingness to invest in the development of new biosimilars, it could in the long term, decrease the number of biosimilar biological products that are available to prescribe and thus impair price competition. Given that the United States' biosimilar biological product marketplace is still relatively new, we believe that it is important to maintain a payment policy innovation as well as reasonable pricing for consumers.

We agree that current statutory authority does not permit the inclusion of the reference product in a payment determination calculation for biosimilar biological products paid under Medicare Part B.

Comment: Some commenters did not believe that separate coding for each biosimilar product would lead to greater competition or savings. These commenters noted that ASP-based payment amounts for biological drugs, even those with other comparable products on the market, continue to

increase. Also, they provided specific examples where the payment amount for reference products filgrastim and infliximab, which are currently paid under Part B (and are coded and paid separately from corresponding biosimilar products) have not decreased; these commenters expressed concern about a potential lack of competition within the Part B marketplace. Some of these commenters also expressed concern about the United States experience with high launch prices for biosimilars, particularly one situation where the Part B payment amount for a biosimilar significantly exceeded the payment amount for a reference product. The commenters pointed out that in situations where each product has a unique code, high launch prices, particularly while a product is paid using Wholesale Acquisition Cost (WAC), would lead to higher costs for Medicare and beneficiaries. One commenter also stated that combining payment for biosimilar products is consistent with the concept of similar payment for similar services.

Response: We note that section 1847A(c)(4) of the Act authorizes WAC based payment during the first quarter of sales and this subject has been discussed in rulemaking previously (75 FR 73465). In most cases WAC exceeds ASP. However, the duration of a WAC based payment amount is limited, and generally, once a full quarter of ASP data is available, payments made under section 1847A are based on ASP.

Comment: Several commenters provided materials that were previously submitted with comments on the CY 2016 PFS proposed rule, in response to our solicitation of new or updated information on the effects of our biosimilars payment policy on the United States marketplace.

One commenter also provided a revised industry estimate from the Biosimilars Forum that projected $50 billion in savings to the Medicare program over 10 years under the existing policy and an additional $15 billion in savings over 10 years if separate codes were used. This estimate, which was referenced by a number of other commenters, assumes higher uptake of biosimilars (up to 65 percent at 10 years, compared to 35 percent with current policy) if separate codes are implemented. Commenters stated that they believe the separate coding approach would create competition and lower prices for the long term. The main reasons for this were: Increased physician confidence (mainly associated with certainty about the payment amount), a number of manufacturers and products in the marketplace, and resources (from the manufacturers) that would encourage uptake.

Response: We thank commenters for the updated estimates.

Comment: Several commenters also discussed the European biosimilar product market. Commenters who support current Medicare policy pointed out that the European market as a whole has grown and includes nearly 30 biosimilar biological products. Another commenter referenced a report on the European biosimilar market (The Impact of Biosimilar Competition in Europe. QuintilesIMS. May 2017) and described the report as indicating that competition reduces prices, and that government policies could influence both manufacturer participation in a market as well as uptake of products. The report and other commenters who do not support current Medicare policy pointed out a specific European example from Austria where a tiered pricing policy treats biosimilar biological products exactly as generic drugs. A significant payment reduction associated with this policy is thought to have contributed to low biosimilar biological product utilization and limited access in this country.

Response: We appreciate the examples of approaches used to pay for biosimilars in Europe. In general, we believe that the European examples provided by commenters help confirm that savings can be expected in the United States marketplace with a variety of policy approaches because payments for biosimilar products used in Europe are determined in a several ways. In other words, several payment approaches for biosimilars have yielded savings. We also agree that the introduction of new products and savings may be influenced by a government's payment policies. We note that payment methodologies for drugs and biologicals in many European countries differ, sometimes significantly, from payment methodologies for drugs and biologicals in the United States. For example, a number of European countries utilize a single payer system and some have the authority to set prices, so some of these examples may not provide information that is fully applicable to the United States market. For example, the description of Austria's payment policy for biosimilar biological products is not similar to our pricing policy for several reasons. First, Austria uses a single payer system that we understand to include mandatory payment reductions in certain circumstances. We do not use a tiered pricing strategy in Part B and, under the payment methodology in section 1847A of the Act, we cannot mandate 40 to 50 percent reductions in payment for biosimilar biological products by deeming them generic drugs as Austria has done. We believe that many commenters continue to misunderstand our position on the relationship between biosimilar biological products and generic drugs, that is, we distinguish between the two. As we noted in the CY 2016 PFS final rule with comment period, our payment policy does not address whether a biosimilar is completely or partially analogous to its reference product as a clinical matter (80 FR 71100). We have communicated that we appreciated the complexity of these products and the potential differences in the clinical utilization of biosimilar biological products when they are being used to treat individual patients. In summary, we believe that most of the examples provided by commenters include helpful information to consider as the United States marketplace develops.

Comment: We also sought comment regarding other novel payment policies, legislation, demonstrations, and administrative options that would foster competition, increase access, and drive cost savings in the biological product marketplace.

As discussed earlier in this section, several commenters discussed code consolidation where reference and corresponding biosimilar products would be included in a shared code. Commenters also suggested that value based purchasing models, including outcomes-based pricing and pricing based on negotiations between a vendor and manufacturers, be considered for biosimilar biological products (as well as other drugs). One commenter also stated that paying differently for biosimilars and interchangeable products may create incentives for growth in the marketplace. One manufacturer suggested that the ASP add on percentage could be increased to the 15–20 percent range to encourage uptake.

We also received comments that encouraged consistency between Part B, Part D and Medicaid, and comments that encouraged streamlining and simplification of price reporting, as well as comments on HCPCS coding schedules and deadlines, the use of NDCs on claims, pharmacy substitution activities, coverage, and the FDA naming conventions for biosimilars.

Response: We appreciate these comments and we plan to consider them for future policy decisions. Regarding the ASP add-on percentage for biosimilar products, we note that the statute requires the ASP add-on to be 6 percent of the reference product. We

note that some of these issues are generally outside the scope of Part B payment policy and that statutory requirements may also constrain flexibility to modify or conform policies.

Comment: Some commenters also noted that the use of a modifier to track the manufacturer of a biosimilar biological product was perceived as burdensome and suggested that unique codes were more desirable and more convenient for tracking. However, several commenters stated that the use of modifiers is an acceptable method of tracking biosimilars. Both groups appeared to agree that tracking the use of these new and complex products was necessary.

Response: We agree that tracking the use of these new and complex products is important. We believe that either method, code and modifier combinations or unique codes, can be used for this purpose. We plan to continue to monitor Part B biosimilar payment and utilization, particularly as they relate to access, including the number of products available to beneficiaries with Part B and cost savings associated with Medicare and beneficiary payments.

Comment: Many commenters requested that a change in policy be made as soon as possible so that manufacturers would be incentivized to enter the United States marketplace as soon as possible. Several commenters, including most who supported continuing the current policy and others who did not explicitly support either changing or not changing policy at this time, believed that there is insufficient experience with the United States marketplace to warrant making a change in policy at this time, but they suggested that CMS continue to examine its policy, and that changes should consider effects on patients, providers and manufacturers.

Response: We appreciate the broad range of possibilities that commenters have provided during this rulemaking cycle. We agree that it is important to consider and effect policy changes early, as this portion of the drug marketplace develops, in order to support a robust marketplace that provides choices for providers and patients while maximizing savings.

Comment: Several commenters urged CMS to change the regulation text to indicate that separate payment for each biosimilar biological product is required, and to do so in this final rule. Some commenters believe that there is sufficient legal basis to do so despite the fact that CMS did not make a proposal.

Response: We have not proposed to make a regulation change and we will not be doing so in this final rule. We continue to believe, as we stated in the CY2016 PFS final rule with comment period, that the existing regulation text provides flexibility to accommodate policy changes in a new and evolving environment. Specifically, we stated in the CY 2016 PFS rule that current regulation text at § 414.904(j) would not preclude us from separating some, or all, of a group of biosimilars for payment (and the creation of one or more separate HCPCS codes) should a program need to do so arise (80 FR 71098). As we have stated earlier in this rule, we are particularly concerned about the commenters' continuing unease regarding the effects of our payment policy on patient and provider choices, and the interaction between the payment policy, choice, and the marketplace. In an effort to support a more competitive marketplace and greater choice and value for beneficiaries, CMS is taking immediate action on this issue. We will discuss our reasons further in the paragraphs below.

We appreciate the many responses that we received to our comment solicitation. Comments received about the issue of grouping or separating payment for biosimilars of the same reference product were sharply divided, and information provided as support for a given position was also subject to interpretation. For example, a commenter who is opposed to the current policy cited a report (Scott Morton F, Boller LT. Enabling Competition in Pharmaceutical Markets. Hutchins Center. May 2017as evidence that robust competition could reduce costs in the long-term; however, another portion of the report supported MedPAC's June 2017 recommendation to pay biosimilars and reference products under the same code (which CMS does not have the authority to do). We are acknowledging that opinions on the issue of how Part B should pay for biosimilar biological products vary, however, as discussed below, we believe that the solution discussed in the paragraphs below is superior to existing policy.

As we stated previously, we seek to promote innovation, to provide more options to patients and physicians, and to encourage competition to drive prices down. We also stated that our goal for the comment solicitation was to further evaluate our policies to be sure they allow for market forces to provide a robust and comprehensive selection of choices for patients at a fair price. Based on the review of the comments that are summarized above, we are persuaded that changing the Part B biosimilar payment policy to provide for the separate coding and payment for products approved under each individual abbreviated application, rather than grouping all biosimilars with a common reference product into codes, will meet the stated goal. We believe that this policy change will encourage greater manufacturer participation in the marketplace and the introduction of more biosimilar products, thus creating a stable and robust market, driving competition and decreasing uncertainty about access and payment. First, as we have discussed, we anticipate that this policy change will provide physicians with greater certainty about biosimilar payment. We are persuaded that, in turn, this will affect utilization of these products, creating more demand that would help increase competition (compared to the policy that is currently in place). As a result of the policy change we anticipate greater access to biosimilar biological products and we anticipate that more price competition between more products will occur because there will be more products available. The change in policy could lead to additional savings for Medicare and its beneficiaries over the long-term by increasing the utilization of products that are less expensive than reference biologicals. Further, carrying out this policy change as early as possible, rather than waiting, would maximize the benefits described in this paragraph and would bring more certainty to the new and developing marketplace promptly.

In summary, we are persuaded that that there is a program need for assigning Part B biosimilar biological products into separate HCPCS codes, specifically that this policy change will address concerns about a stronger marketplace, access to these drugs in the United States marketplace, provider and patient choice and competition. We also believe that the change in policy will encourage innovation needed to bring more products to the market. We remind readers that our preamble language in the CY 2016 PFS rule with comment period (80 FR 71096) indicated that policy changes could be forthcoming (80 FR 71098).

Thus, in this final rule, we are finalizing the policy to separately code and pay for biological biosimilar products under Medicare Part B; we are not changing regulation text at § 414.904(j). Effective January 1, 2018, newly approved biosimilar biological products with a common reference product will no longer be grouped into the same HCPCS code. We will issue detailed guidance on coding, including

instructions for new codes for biosimilars that are currently grouped into a common payment code and the use of modifiers. Completion of these changes, which will require changes to the claims processing systems, is planned to occur as soon as feasible, but should not be expected to be complete by January 1, 2018. We anticipate that this will be done by mid-2018 and we plan to issue instructions using subregulatory means, such as change requests/transmittals to contractors and the ASP Web site.

As suggested by commenters who supported both policy approaches, we plan to continue to monitor Part B biosimilar payment and utilization, particularly as they relate to access, including the number of products available to beneficiaries with Part B and cost savings associated with Medicare and beneficiary payments. We also appreciate the comments on novel payment policies that would foster competition, increase access, and drive cost savings in the biological product marketplace.

E. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of the Protecting Access to Medicare Act (PAMA) amended Title XVIII of the Act to add section 1834(q) of the Act directing us to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. The CY 2016 PFS final rule with comment period addressed the initial component of the new Medicare AUC program, specifying applicable AUC. In that rule (80 FR 70886), we established an evidence-based process and transparency requirements for the development of AUC, defined provider-led entities (PLEs) and established the process by which PLEs may become qualified to develop, modify or endorse AUC. The first list of qualified PLEs was posted on the CMS Web site at the end of June 2016 at which time their AUC libraries became specified applicable AUC for purposes of section 1834(q)(2)(A) of the Act. The CY 2017 PFS final rule addressed the second component of this program, specification of qualified clinical decision support mechanisms (CDSMs). In that rule (81 FR 80170), we defined CDSM, identified the requirements CDSMs must meet for qualification including an opportunity for preliminary qualification for mechanisms still working toward full adherence, and established a process by which CDSMs may become qualified. We also defined applicable payment systems under this program, specified the first list of priority clinical areas and identified exceptions to the requirements that ordering professionals consult specified applicable AUC when ordering applicable imaging services. The first list of qualified CDSMs was posted on the CMS Web site in July 2017.

The CY 2018 PFS proposed rule proposed the start date of January 1, 2019 for the Medicare AUC program for advanced diagnostic imaging services. It is on and after this date that ordering professionals must consult specified applicable AUC using a qualified CDSM when ordering applicable imaging services and furnishing professionals must report consultation information on the Medicare claim. This rule also proposed to modify the policy related to significant hardship exceptions and requested public feedback on details regarding how AUC consultation information must be included on the Medicare claim. To further this iterative process of implementation, we also discussed briefly the potential for alignment with other Medicare quality programs.

1. Background

AUC present information in a manner that links: A specific clinical condition or presentation, one or more services and, an assessment of the appropriateness of the service(s). For purposes of this program AUC is a set or library of individual appropriate use criteria. Each individual criterion is an evidence-based guideline for a particular clinical scenario. Each scenario in turn starts with a patient's presenting symptoms or condition. Evidence-based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients based on their individual clinical presentation.

AUC need to be integrated as seamlessly as possible into the clinical workflow. CDSMs are the electronic portals through which clinicians access the AUC during the patient workup. While CDSMs can be standalone applications that require direct entry of patient information, they may be more effective when they automatically incorporate information such as specific patient characteristics, laboratory results, and lists of co-morbid diseases from Electronic Health Records (EHRs) and other sources. Ideally, practitioners would interact directly with the CDSM through their primary user interface, thus minimizing interruption to the clinical workflow.

Consistent with descriptions of clinical decision support by the Agency for Healthcare Research and Quality (AHRQ) (*http://www.ahrq.gov/professionals/prevention-chronic-care/decision/clinical/index.html*), and the Office of the National Coordinator for Health Information Technology (ONC) (*https://www.healthit.gov/policy-researchers-implementers/clinical-decision-support-cds*), within health IT applications, a CDSM is a functionality that provides persons involved in care processes with general and person-specific information, intelligently filtered and organized, at appropriate times, to enhance health and health care.

2. Statutory Authority

Section 218(b) of the PAMA added a new section 1834(q) of the Act entitled, ''Recognizing Appropriate Use Criteria for Certain Imaging Services,'' which directs the Secretary to establish a new program to promote the use of AUC. Section 1834(q)(4) of the Act requires ordering professionals to consult with a qualified CDSM for applicable imaging services furnished in an applicable setting and paid for under an applicable payment system; and for the furnishing professional to include on the Medicare claim information about the ordering professional's consultation with a qualified CDSM.

3. Discussion of Statutory Requirements

There are four major components of the AUC program under section 1834(q) of the Act, and each component has its own implementation date: (1) Establishment of AUC by November 15, 2015 (section 1834(q)(2) of the Act); (2) identification of mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3) of the Act); (3) AUC consultation by ordering professionals, and reporting on AUC consultation by furnishing professionals by January 1, 2017 (section 1834(q)(4) of the Act); and (4) annual identification of outlier ordering professionals for services furnished after January 1, 2017 (section 1834(q)(5) of the Act). We did not identify mechanisms for consultation by April 1, 2016. Therefore, we did not require ordering professionals to consult CDSMs or furnishing professionals to report information on the consultation by the January 1, 2017 date.

a. Establishment of AUC

In the CY 2016 PFS final rule with comment period, we addressed the first component of the Medicare AUC program under section 1834(q)(2) of the Act—the requirements and process for establishment and specification of applicable AUC, along with relevant aspects of the definitions under section 1834(q)(1) of the Act. This included

defining the term PLE and finalizing requirements for the rigorous, evidence-based process by which a PLE would develop AUC, upon which qualification is based, as provided in section 1834(q)(2)(B) of the Act and in the CY 2016 PFS final rule with comment period. Using this process, once a PLE is qualified by CMS, the AUC that are developed, modified or endorsed by the qualified PLE are considered to be specified applicable AUC under section 1834(q)(2)(A) of the Act. We defined the term PLE to include national professional medical societies, health systems, hospitals, clinical practices and collaborations of such entities such as the High Value Healthcare Collaborative or the National Comprehensive Cancer Network. Qualified PLEs may collaborate with third parties that they believe add value to their development of AUC, provided such collaboration is transparent. We expect qualified PLEs to have sufficient infrastructure, resources, and the relevant experience to develop and maintain AUC according to the rigorous, transparent, and evidence-based processes detailed in the CY 2016 PFS final rule with comment period.

In the same rule we established a timeline and process under § 414.94(c)(2) for PLEs to apply to become qualified. Consistent with this timeline the first list of qualified PLEs was published at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/PLE.html* (OMB Control Number 0938–1288).

b. Mechanism for AUC Consultation

In the CY 2017 PFS final rule, we addressed the second major component of the Medicare AUC program—the specification of qualified CDSMs for use by ordering professionals for consultation with specified applicable AUC under section 1834(q)(3) of the Act, along with relevant aspects of the definitions under section 1834(q)(1) of the Act. This included defining the term CDSM and finalizing functionality requirements of mechanisms, upon which qualification is based, as provided in section 1834(q)(3)(B) of the Act and in the CY 2017 PFS final rule. We included an opportunity for mechanisms still working toward full adherence to these requirements to receive preliminary qualification during the preliminary qualification period that begins June 30, 2017, and ends when the AUC consulting and reporting requirements become effective. The preliminarily qualified CDSMs must meet all requirements by that time. We defined CDSM as an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient's specific clinical condition. Tools may be modules within or available through certified EHR technology (as defined in section 1848(o)(4) of the Act) or private sector mechanisms independent from certified EHR technology or established by the Secretary.

In the CY 2017 PFS final rule we established a timeline and process in § 414.94(g)(2) for CDSM developers to apply to have their CDSMs qualified. Consistent with this timeline, the first list of qualified CDSMs was published at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html* in conjunction with this rule in July 2017 (OMB Control Number 0938–1315).

c. AUC Consultation and Reporting

The third major component of the Medicare AUC program is in section 1834(q)(4) of the Act, Consultation with Applicable Appropriate Use Criteria. This section establishes, beginning January 1, 2017, the requirement for an ordering professional to consult with a qualified CDSM when ordering an applicable imaging service that would be furnished in an applicable setting and paid for under an applicable payment system; and for the furnishing professional to include on the Medicare claim information about the ordering professional's consultation with a qualified CDSM. The statute distinguishes between the ordering and furnishing professional, recognizing that the professional who orders an applicable imaging service is usually not the same professional who bills Medicare for that service when furnished. Since a list of qualified CDSMs was not available by January 1, 2017, we did not require ordering professionals to meet the consultation requirement by that date.

Section 1834(q)(4)(C) of the Act provides for certain exceptions to the AUC consultation and reporting requirements including in the case of certain emergency services, inpatient services paid under Medicare Part A, and ordering professionals who obtain an exception due to a significant hardship. In the CY 2017 PFS final rule, we identified the circumstances specific to ordering professionals under which consulting and reporting requirements are not required. These include orders for applicable imaging services: (1) For emergency services when provided to individuals with emergency medical conditions as defined in section 1867(e)(1) of the Act; (2) for an inpatient and for which payment is made under Medicare Part A; and (3) by ordering professionals who are granted a significant hardship exception to the Medicare EHR Incentive Program payment adjustment for that year under 42 CFR 495.102(d)(4), except for those granted such an exception under § 495.102(d)(4)(iv)(C). We discuss changes to the significant hardship exceptions later in this preamble.

Section 1834(q)(4)(D) of the Act specifies the applicable payment systems for the AUC consultation and reporting requirements, and, in the CY 2017 PFS final rule we defined them as: (1) The physician fee schedule established under section 1848(b) of the Act; (2) the prospective payment system for hospital outpatient department services under section 1833(t) of the Act; and (3) the ambulatory surgical center payment system under section 1833(i) of the Act.

d. Identification of Outliers

The fourth component of the Medicare AUC program is in section 1834(q)(5) of the Act, Identification of Outlier Ordering Professionals. The identification of outlier ordering professionals under this paragraph facilitates a prior authorization requirement for outlier professionals beginning January 1, 2020, as specified under section 1834(q)(6) of the Act. Given that we proposed a program start date of January 1, 2019, we anticipate that implementation of the prior authorization component would be delayed. We expect to discuss details around outlier calculations and prior authorization in the CY 2019 PFS proposed rule. However, we did finalize in the CY 2017 PFS final rule the first list of priority clinical areas to guide identification of outlier ordering professionals as follows:

- Coronary artery disease (suspected or diagnosed).
- Suspected pulmonary embolism.
- Headache (traumatic and non-traumatic).
- Hip pain.
- Low back pain.
- Shoulder pain (to include suspected rotator cuff injury).
- Cancer of the lung (primary or metastatic, suspected or diagnosed).
- Cervical or neck pain.

As established in § 414.94(e)(4) of our regulations, priority clinical areas may be used in the identification of outlier ordering professionals. By starting to identify these areas now, we believe ordering professionals will have the opportunity to become familiar with

AUC within identified priority clinical areas prior to Medicare claims for those services being part of the input for calculating outlier ordering professionals.

We did not include proposals to expand or modify the list of priority clinical areas in the CY 2018 PFS proposed rule.

4. Proposals for Continuing Implementation

In the CY 2018 PFS proposed rule, we proposed to amend § 414.94 of our regulations, ''Appropriate Use Criteria for Certain Imaging Services,'' to reflect the following policies.

a. Consultation by Ordering Professional and Reporting by Furnishing Professional Timeline

We proposed that ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on or after January 1, 2019. We proposed this effective date for the consulting and reporting requirements to allow time for ordering practitioners who are not already aligned with a qualified CDSM to research and evaluate the qualified CDSMs so they may make an informed decision. Although there will be an additional rulemaking cycle before the consulting and reporting requirement is effective, we are establishing the date through rulemaking this year because we expect practitioners and other stakeholders to begin preparing themselves to report and we want to ensure all impacted parties have sufficient time to prepare to meet the requirements of this program.

After proposing the timeline and process for qualification of CDSMs in the CY 2017 PFS proposed rule (81 FR 46392), we anticipated that furnishing professionals may begin reporting as early as January 1, 2018. However, we received comments that these timelines did not allow enough time to address the needs of different stakeholder groups. Some commenters requested that we delay the timeline and process to give practitioners sufficient time to obtain a qualified CDSM. Other commenters cited insufficient time for CDSMs to incorporate requirements between the release of the final CDSM requirements and January 1, 2018, and requested that we fully implement the program at a later date. Additionally, in the CY 2017 PFS final rule (81 FR 80411) we discussed commenters' recommendations that we develop and launch an educational campaign, including a Town Hall meeting. Some commenters requesting additional time suggested that, for purposes of both CDSM vendor readiness and practitioner readiness, consulting and reporting requirements should not go into effect for an additional 12–18 months after the initial list of CMS-qualified CDSMs is posted.

By proposing that the consulting and reporting requirements begin on January 1, 2019, we intended to allow needed time for education and outreach efforts, time for practitioners and stakeholders to prepare, and time for CDSMs to continue current strides in being more user-friendly and less burdensome. We note that the statute required publication of qualified CDSMs by April 1, 2016, and required AUC consultation and reporting by January 1, 2017; therefore, our proposal substantially lags the statutory requirements. As noted earlier and in previous rulemaking, a delay in the statutory timeline is necessary to maximize the opportunity for public comment and stakeholder engagement, which is also a statutory requirement, and allow for adequate advance notice to practitioners, beneficiaries, AUC developers, and CDSM developers. This delay is also important to allow time to test and ensure Medicare claims processing systems are ready to accept and process claims that include the necessary AUC consultation information. Failure to test our own processes could result in claims being denied inappropriately or, conversely, being paid inappropriately.

The following is a summary of the public comments received on the proposed effective date for consulting and reporting requirements:

Comment: Some commenters strongly supported the proposal to begin the AUC consultation and reporting requirement in January 2019 and further stated that additional delays beyond 2019 are not warranted. They asserted that physicians need certainty that the AUC program will move forward on a predictable timeline and will not be subject to continued changes. Some commenters stated that they are prepared for this program to begin and that others will be prepared within one year. In contrast, other commenters do not want this AUC program implemented in 2019 or at any point in the future. These commenters wanted the program to be delayed indefinitely, discontinued or modified to the extent that participation be only voluntary as opposed to mandatory. Some of these commenters stated that the quality goals of the AUC program are duplicative of the quality goals of the Quality Payment Program and that the AUC program runs counter to the agency's goal of reducing administrative burden for practitioners and providers. Some suggested that the Quality Payment Program could serve as a less burdensome approach to achieving the same goals. Commenters disagreed with the premise behind the AUC consultation and reporting requirement that the furnishing professional claim should not be paid when the ordering professional failed to perform an AUC consultation.

Response: We recognize the interest from commenters in better understanding our separate and distinct efforts to improve quality, and note that such efforts are the result of the distinct statutory requirements for the AUC program required in section 1834(q) of the Act as added by section 218(b) of the statute and the Quality Payment Program required in section 1848(q) of the Act as added by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10). We agree that the goals of the Quality Payment Program are consistent with those of the AUC program. In addition, the AUC program promotes AUC to ensure the patient gets the right test at the right time and reduces inappropriate imaging. We are required by separate statutory authority provisions to implement the AUC program and the Quality Payment Program. Section 1834(q) of the Act requires AUC consultation information to be included on the furnishing professional's claim in order for that claim to be paid; we do not have discretion with respect to that requirement.

Comment: There are commenters that supported the AUC program but suggested that CMS participate in further stakeholder engagement. These commenters suggested an advisory panel be created to identify a reasonable program start date based on the readiness of practitioners, facilities, EHRs and CDSMs. Commenters also recommended listening sessions, town hall meetings and open door forums for stakeholders to share information with CMS about minimizing burden and communicating the state of stakeholder readiness.

Response: We agree that we would benefit from additional stakeholder engagement. Over the coming months we will establish opportunities for this type of interaction.

Comment: Although some commenters very clearly expressed strong, clear positions either for or against the proposed effective date for the AUC consultation and reporting requirements, as well as the AUC program more generally, the majority of commenters were more nuanced in their

comments and gave additional opinions regarding not only the start date but options as to how the program should begin.

Response: We will summarize and respond to these comments in a later section of this preamble within the relevant sections that discuss the voluntary participation and educational and operations testing periods we are finalizing in this rule.

Comment: Numerous commenters requested clarification regarding who is required to perform the consultation of AUC through a qualified CDSM. Commenters questioned whether a designee within an ordering professional's practice could consult on behalf of the ordering professional and whether an ordering professional could delegate consultation authority to another individual, a third party vendor or contracted agent. Several commenters supported this notion, noting that state laws allow professionals to delegate to qualified individuals in practice under the supervision of a physician the ability to assist advanced imaging orders, and URAC states that an organization conducting utilization review must accept information from any reasonably reliable source that will assist in the certification process. One commenter recommended that CMS reinforce the requirement that the ordering professional responsible for the order must meaningfully interact with AUC at the time of order, but allow the market to develop compliant approaches that ensure the educational effect of AUC is achieved. Some commenters supported delegation only to the ordering professional's staff while other commenters opposed allowing consultation by anyone other than the ordering professional, which they understand as the clear requirement under section 1834(q) of the Act and the current AUC regulations, and are concerned that other types of individuals and stakeholders are preparing to circumvent this requirement by performing consultations on behalf of ordering professionals.

Response: Section 1834(q)(4)(A)(i) of the Act requires an ordering professional to consult with a qualified CDSM. We appreciate the varying opinions presented by stakeholders and the number of commenters who raised these questions. We will consider developing policy to address this issue.

Comment: Some commenters requested that we clarify how imaging replacement orders, where the furnishing professional or radiology technician updates or modifies an order based on new information at the time of imaging, are handled under the AUC program. Commenters questioned whether the furnishing professional can update the order as necessary or if they need to consult with the ordering professional or AUC again to generate a new determination of appropriateness. One commenter requested that CMS provide guidance for situations where the furnishing professional performs different or additional tests than ordered in accordance with guidance in Medicare publication 100–02, Chapter 15, sections 80.6.2–4. Some commenters recommended that furnishing professionals have the flexibility to adjust exam parameters or modify orders without consulting AUC, submit orders themselves if they have relevant patient clinical information, and occasionally use AUC as appropriate to demonstrate that a test was warranted.

Response: We understand that in certain situations updates or modifications to orders for advanced diagnostic imaging services may be warranted once the beneficiary is under the care of the furnishing professional. As a commenter noted, the Medicare Benefit Policy Manual (Pub. L. 100–02) addresses rules around these situations in Chapter 15, sections 80.6.2–4. We do not believe it was the intent of section 218(b) of the PAMA to reverse these rules, and we expect furnishing professionals and facilities to continue to adhere to them so as to avoid additional burden, workflow interruptions and delays in medically necessary services.

In instances when the furnishing professional must update or modify the order for an advanced diagnostic imaging service, the AUC consultation information provided by the ordering professional with the original order should be reflected on the Medicare claim to demonstrate that the requisite AUC consultation occurred. In future rulemaking, we expect to establish a means to account for instances when the order must be updated or modified. We anticipate addressing this issue in rulemaking to develop policies relating to the identification of outlier ordering professionals, and in order to inform the prior authorization component of this program.

In response to public comments we are further delaying the effective date for the AUC consultation and reporting requirements for this program from January 1, 2019 as proposed to January 1, 2020. We are also finalizing a voluntary period during which early adopters can begin reporting limited consultation information on Medicare claims from July 2018 through December 2019. During the voluntary period there is no requirement for ordering professionals to consult AUC or furnishing professionals to report information related to the consultation. On January 1, 2020, the program will begin with an educational and operations testing period and during this time we will continue to pay claims whether or not they correctly include such information. Ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on or after January 1, 2020, and furnishing professionals must report the AUC consultation information on the Medicare claim for these services ordered on or after January 1, 2020.

Reporting

Consistent with section 1834(q)(4)(B) of the Act, we also proposed that furnishing professionals report the following information on Medicare claims for applicable imaging services, furnished in an applicable setting, paid for under an applicable payment system as defined in § 414.94(b), and ordered on or after January 1, 2019: (1) Which qualified CDSM was consulted by the ordering professional; (2) whether the service ordered would adhere to specified applicable AUC, 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).

We believe that, unless a statutory exception applies, an AUC consultation must take place for every order for an applicable imaging service furnished in an applicable setting and paid under an applicable payment system. We further believe that section 1834(q)(4)(B) of the Act accounts for the possibility that AUC may not be available in a particular qualified CDSM to address every applicable imaging service that might be ordered; and thus, the furnishing professional can meet the requirement to report information on the ordering professional's AUC consultation by indicating that AUC is not applicable to the service ordered. We remind readers that, as required under § 414.94(g)(1)(iii), qualified CDSMs must make available, at a minimum, AUC that reasonably address common and important clinical scenarios within all priority clinical areas. As discussed in the CY 2017 PFS final rule (81 FR 80170), the current list of priority clinical areas represents about 40 percent of advanced diagnostic

imaging services paid for by Medicare in 2014. We also remind readers that consistent with section 1834(q)(4)(A) of the Act, ordering professionals must consult AUC for every advanced diagnostic imaging service ordered. Although section 1834(q)(4)(B) of the statute does not prohibit qualified CDSMs to return a response of ''not applicable'' if a qualified CDSM does not contain specified applicable AUC for the service ordered, we expect these situations to be limited in scope and number, and to decrease over time. The ''not applicable'' responses should decrease as qualified PLEs continue to build out their AUC libraries and qualified CDSMs update their content and potentially collaborate with more qualified PLEs so as to make available highly comprehensive tools.

Section 1834(q)(4)(B) requires that payment may only be made if the claim for the advanced diagnostic imaging service includes the specific information discussed in this final rule. This information, to the extent feasible, is required across claim types (including both the furnishing professional and facility claims) and across all three applicable payment systems (PFS, hospital outpatient prospective payment system and ambulatory surgical center payment system). In other words, we would expect this information to be included on the practitioner claim that includes the professional component of the imaging service and on the hospital outpatient claim for the technical component of the imaging service. Claims for services for which payment is not made under the three identified payment systems would not be required to include consultation related information.

To implement this requirement we proposed to establish a series of HCPCS level 3 codes. These G-codes would describe the specific CDSM that was used by the ordering professional. Ultimately there would be one G-code for every qualified CDSM with the code description including the name of the CDSM. However, because the claims processing system can only recognize new codes quarterly, we may not be able to update the G-code descriptors simultaneously with the announcement of any new qualified CDSMs which is expected to occur in June of each year. To ensure that there is a code available to immediately describe newly qualified CDSMs, we proposed to establish a generic G-code that would be used to report that a qualified CDSM was consulted, but would not identify a specific qualified CDSM; clinicians would only be permitted to use this code if a more specific named code did not yet exist for that clinician's CDSM. Furnishing professionals would report this code temporarily until a specific G-code describing the newly qualified CDSM by name becomes available. We also proposed to establish a G-code to identify circumstances where there was no AUC consultation through a qualified CDSM. The description of this code would indicate that a qualified CDSM was not consulted by the ordering professional.

G-codes would be a line-item on both practitioner claims and facility claims. We would expect that one AUC consultation G-code would be reported for every advanced diagnostic imaging service on the claim. If there are two codes billed for advanced imaging services on the claim then we would expect two G-codes. Each G-code would be expected, on the same claim line, to contain at least one new HCPCS modifier. We proposed to develop a series of modifiers to provide necessary information as to whether, when a CDSM is used to consult AUC: (1) The imaging service would adhere to the applicable appropriate use criteria; (2) the imaging service would not adhere to such criteria; or (3) such criteria were not applicable to the imaging service ordered. We proposed to create additional modifiers to describe situations where an exception applies and a qualified CDSM was not used to consult AUC: (1) The imaging service was ordered for a patient with an emergency medical condition or (2) the ordering professional has a significant hardship exception. Based on this proposal we specifically sought comments on any additional HCPCS modifiers that might be needed to separately identify allowable scenarios for which a qualified CDSM was not consulted by the ordering professional.

The following is a summary of the public comments received on our proposals for the information furnishing professionals must report on the Medicare claim:

Comment: Some commenters agreed with the proposed approach of using a combination of G-codes and HCPCS modifiers to capture AUC consultation information on Medicare claims. Numerous commenters, however, stated that the creation of new G-codes and modifiers will excessively burden practitioners and their systems. Practitioners and facilities will have to dedicate significant staff time and in some cases additional full-time staff positions to translating this new information into the appropriate codes and ensuring such information is appended to Medicare claims. Others noted that CDSMs, EHRs and systems that create electronic orders will require additional programming and testing. There was also concern that CMS would not be able to keep up with timely issuing of G-codes to keep up with newly qualified CDSMs.

Commenters provided various recommendations to CMS that would avoid the combination of reporting through G-codes and modifiers. A commenter suggested that only one G-code be developed to generically identify that a CDSM consultation occurred without identifying the specific mechanism. Another comment pointed out that when the modifiers for consultation exceptions are reported (for example, emergency medical conditions or hardship exceptions) that the modifier should be reporting on the same line as the CPT code for the imaging service as opposed to reporting a G-code.

Many commenters suggested CMS require the unique consultation identifier be appended to the Medicare claim instead of using G-code and modifier combinations. They suggested CMS, along with stakeholders, standardize the identifier to have embedded meaning that is consistent across CDSMs. They further supported the reporting of this identifier on claims so CMS can match the claim with the richer, more robust consultation data that is collected within the CDSM. It is with this more complete information that they suggested that outlier ordering professionals be identified rather than rely solely on information reported on the claim. Commenters generally supported use of the unique identifier as the least administratively burdensome approach to collecting AUC consultation information on Medicare claims.

Other commenters suggested a registry to hold all AUC consultation information across CDSMs and that the information be available to CMS directly from the registry rather than having furnishing professionals report information on the claim. They further suggested that a registry would also include information about consultations that do not result in imaging.

Response: We agree with many of the commenters in that a less burdensome approach to reporting AUC consultation information on Medicare claims should be considered. Reporting the unique consultation identifier would still be a new burden on the ordering and furnishing professionals; however, we are pleased to learn from commenters that it is a less burdensome and preferred approach when compared to the proposed G-code and modifier combinations. We also agree that

capturing this identifier on the claim provides the best opportunity to access the robust data contained within qualified CDSMs.

In response to these comments we will not move forward with the G-code and modifier combinations for reporting which CDSM is consulted, adherence, non-adherence or situations where AUC are not applicable. We will further explore and pursue use of the unique consultation identifier for reporting on Medicare claims. However, in order to use such an identifier we must work with stakeholders to develop a standard taxonomy. We expect to conduct stakeholder outreach during 2018 so that such standardization can be accomplished and will discuss such changes in future rulemaking ahead of the 2020 consulting and reporting effective date. We do not anticipate including these identifiers on claims before then. We will conduct outreach to better explore options of where to place such an identifier on practitioner and facility claims for advanced imaging services. We will also explore mechanisms for CMS and qualified CDSMs to share data.

Since we intend to move forward to implement the AUC consultation and reporting requirement under section 1834(q)(4) using the unique AUC consultation identifier, we will not pursue the use of G-codes to identify the consulted CDSM. It is our expectation that the information required for Medicare claims processing and, ultimately, identification of outlier ordering professionals, will be embedded within a standardized unique identifier. AUC adherence, non-adherence and not applicable responses should also be embedded. Therefore, we will not move forward with the creation of modifiers to identify each of those AUC consultation result conditions. We do expect that limited use of modifiers will be required in the future to identify certain exceptions to AUC consultation requirements.

In another section of this preamble we discuss the voluntary reporting period that we proposed to be available from July 2018 through December 2018, and we are extending in this final rule through CY 2019. During the voluntary reporting period, ordering professionals are not required to consult AUC and furnishing professionals are not required to report consultation information on their Medicare claims. Furnishing professionals and facilities reporting AUC consultation information during the voluntary reporting period will have one HCPCS modifier available to them to report on the line level with the CPT code for the advanced diagnostic imaging service. This modifier identifies only that AUC was consulted and not the result of the consultation. We expect this type of limited reporting will be temporary as we move forward to implement the AUC consultation and reporting requirements using the unique AUC consultation identifier.

Comment: A commenter asked whether claims for physicians billing Medicare Part B services for advanced imaging services will require AUC consultation when the patient is an inpatient.

Response: When the patient is in an inpatient setting and advanced diagnostic imaging services are paid under Medicare Part A, the physician's Part B professional claim would not require reporting of an AUC consultation. Under section 1834(q)(1)(D) of the Act, the AUC consultation and reporting requirements apply only in an ''applicable setting'' which includes a physicians' office, hospital outpatient department, ambulatory surgical center, or other ''provider-led outpatient setting,'' but does not include any inpatient setting. The ordering practitioner, in this example, would not be required to consult a qualified CDSM.

Comment: A few commenters asked if orders for advanced diagnostic imaging services for patients in critical access hospitals (CAHs) are subject to the AUC consultation and reporting requirement.

Response: Any advanced imaging service furnished within a CAH would not be furnished in an applicable setting. Applicable settings currently include physician offices, hospital outpatient departments and ambulatory surgical centers. CAH patients who are furnished an advanced diagnostic imaging service in an applicable setting but the claim for that imaging service is not paid under one of the applicable payment systems would not require consultation and reporting of the AUC consultation. This may apply in situations when a CAH has elected Method II billing.

In response to the public comments, we are not moving forward with requiring reporting of AUC consultation information on Medicare claims using a combination of G-codes and modifiers. Rather, we will evaluate a simplified method of reporting during the voluntary reporting period using a single modifier while we work with stakeholders to explore using a standardized unique AUC consultation identifier.

The following is a summary of public comments received on communication of AUC consultation information between the ordering and furnishing professionals:

Comment: Commenters suggested options be made available to report situations when the furnishing professional attempted to obtain AUC consultation information from the ordering professional but the information was ultimately not made available. These commenters sought an option to report on the furnishing professional claim that the information was not provided. Some commented that furnishing professionals should not be required to report the ordering professional's compliance with the AUC program. They stated that this unfairly punishes the furnishing professional.

Response: We understand that there is a burden placed on furnishing professionals since it is their claims that ultimately will not be paid if AUC consultation information is not included on the claim form. However, section 1834(q)(4)(B) of the Act specifically requires that this information be reported on the furnishing professional's claim. We will continue to seek opportunities to reduce the reporting burden, including use of the unique AUC consultation identifier.

Comment: Commenters widely requested further timely and detailed guidance, clarification, and education on claims processing requirements for reporting, certification and documentation. Commenters requested specific information and examples on requirements and new codes, and on how to report information such as hardship exception information on the claim.

Commenters also requested clarification around a number of specific issues. One commenter requested CMS provide instructions on how to handle orders written prior to the effective date for the AUC consultation and reporting requirement when services are furnished after the effective date. One commenter requested clarification around claims processing issues if the imaging test ordered does not match the test performed because the furnishing professional modifies the order. Several commenters requested clarification regarding the obligations on ordering and furnishing professionals along with the consequences during the educational and operations testing period, and specifically asked whether claims will be paid during this period. Commenters also requested clarification on which professional is responsible for the accuracy of reporting, how CMS will ensure this, and the consequences on furnishing professionals if the required information is not obtained after the

educational and operations testing period. Some commenters requested clarification on orders for repeat tests (for example, for the same test to be performed every three months) and whether the same decision support number could be used on each order or if a unique number was required for each. One commenter requested we clarify that, when CMS qualifies a PLE and their AUC development method, we are also accepting the way the resulting level of appropriateness is translated to one of the three options identified in our regulations (whether the service ordered would adhere to specified applicable AUC, whether the service ordered would not adhere to specified applicable AUC, or whether the specified applicable AUC consulted was not applicable to the service ordered) for the purposes of claims reporting. This commenter noted that this is important to assure consistent translation (or mapping) regardless of who performs the mapping.

Response: These comments and requests for clarification are helpful and important as we develop and build out our outreach and education strategies. We hope to engage in continuous communications with stakeholders to address these and other questions that arise. As discussed earlier, the AUC consultation and reporting requirements begin for services furnished on or after January 1, 2020; so orders placed for services that are furnished prior to this date are not subject to the AUC consultation and reporting requirement. We are exploring claims-reporting options for situations when the imaging service is ordered before January 1, 2020 but furnished after January 1, 2020 and AUC consultation information is not available for inclusion on the claim. During the educational and operations testing period, beginning January 1, 2020 and continuing through December 31, 2020, claims will be paid regardless of whether AUC consultation information is correctly included on the claim. We hope practitioners will use this time to make good faith efforts to accurately report information on the claim so we can learn, adjust, and improve these processes and ordering and furnishing professionals can learn and grow accustomed to consulting AUC and reporting consultation information. Furnishing professionals should expect ordering professionals to communicate accurate information about their AUC consultations, so that such information is reflected on the Medicare claim beginning January 1, 2020. We will continue to consider implementation of the exceptions to AUC consultation during the voluntary reporting period and in response to stakeholder feedback. We continue to explore options for reporting this information in the least burdensome and most efficient manner and will release specific instructions prior to January 1, 2020.

Voluntary and Educational and Operations Testing Periods

There are aspects of the AUC program that are novel for ordering and furnishing professionals. An AUC consultation by an ordering professional and reporting by a furnishing professional has never before been required under Medicare Part B with such a broad application (all professionals ordering and furnishing advanced diagnostic tests). Additional considerations are warranted for the complex communication that is required to convey AUC consultation information from the ordering professional to the furnishing professional and facility that must include that information when billing for the service. Billing systems for furnishing professionals will also need to include the AUC consultation information onto Medicare claims forms. These processes are new for many professionals, and there are many areas for potential missteps and errors. For these reasons an educational and operations testing period is needed. During this period, ordering professionals would consult AUC and furnishing professionals would report AUC consultation information on the claim, but we would continue to pay claims whether or not they correctly include such information. This educational and operations testing period allows professionals to actively participate in the program while avoiding claims denials during the learning curve. It also gives us an opportunity to make any needed claims processing adjustments before payments are impacted.

We believe it is preferable to begin implementation with an educational and operations testing period of a year. We do not expect to continue this educational and operations testing period beyond the first year of the AUC program.

We sought public comments on all aspects of our proposal, and specifically, whether the AUC program requirements should be delayed beyond the proposed start date of January 1, 2019. Although our proposal to start the AUC program with an educational and operations testing period beginning on January 1, 2019 was based in part on comments received in prior rulemaking cycles, it was important to receive comments to help us understand the current readiness of stakeholders. In addition, we proposed that the program begin with an educational and operations testing period and were interested in comments regarding how long, if longer than one year, such a period should be available.

In our proposals, we expected a voluntary reporting period to be available prior to the beginning of the educational and operations testing period and anticipated such voluntary period will begin in July 2018. When the voluntary period becomes available we will make announcements through our educational channels such as the CMS Web site and listservs. It is important to note that the educational and operations testing period is separate from the voluntary reporting period. During the voluntary reporting period, AUC consultation and reporting are not required. However, for applicable imaging services ordered on and after January 1, 2019, we proposed that ordering professionals would be required to consult specified applicable AUC and furnishing professionals would be required to report AUC consultation information on the Medicare claim. We proposed further that the initial year of the AUC consultation and reporting requirement would be an educational and operations testing period during which we would continue to pay claims whether or not they correctly include the required information.

The following is a summary of the public comments received on the proposed start date of January 1, 2019, our proposal to begin with a year long educational and operations testing period, and the inclusion of a voluntary reporting period ahead of the required AUC consultation and reporting start date; and our responses to the comments:

Comment: Of the commenters supporting a 2019 start date the majority also supported an educational and operations and testing period. Some of those commenters further supported extending the educational and operations testing period to two years, indicating that two years is necessary for us to learn from the testing and make adjustments before fully implementing the AUC program. Other commenters supported starting the program in 2020 with the first two years being for education and testing. Of the commenters that agreed with including an initial period of educational and operations testing, or delaying the first year of the program to 2020 or beyond, many cited concerns of infrastructure

readiness, high administrative burden, lack of standards across CDSM and EHR vendors, need to educate the affected professionals, time for those professionals to overcome technical and workflow challenges, and additional time for CMS to provide needed guidance including establishing vendor standards for communication between the ordering and furnishing professionals. Specifically, some commenters identified concern over the lack of interoperability across CDSMs and the lack of available CDSMs that are embedded within EHRs as a reason for delaying the program start date. Also, they recommended CMS work with ONC to establish applicable standards for AUC, CDSMs and their EHR integration.

Although commenters pressed the need for predictability in the start of the program and asserted that numerous professionals are ready to begin, or are very close to beginning, to use CDSMs, other commenters focused on the increased burden associated with this program. Those commenters identified the Quality Payment Program as a new program that is currently requiring extra resources and has recently increased burden on the same practitioners and facilities that will be burdened by the AUC program.

Some commenters suggested that, instead of beginning to implement the AUC program broadly, we should begin smaller with focused pilots, or a staged or incremental rollout.

Response: We understand that the AUC program is a new requirement that increases the administrative burden on practitioners and facilities that order and furnish advanced diagnostic imaging services. For example, practitioners that do not have access to a qualified CDSM within their EHR may experience greater interruptions to their clinical workflows due to issues of interoperability or availability than practitioners that do not have to leave their EHR environment to consult a qualified CDSM. Allowing additional time for CDSMs and EHRs to work together to improve workflow for practitioners may ease some of the burden. In addition, we agree that there is value in ONC having a role establishing standards for CDSMs and their EHR integration.

We believe this program can be implemented in a manner that would minimize burden, but this will require additional stakeholder outreach, collaboration and time. For practitioners and facilities that are ready to use qualified CDSMs or that are new to CDSMs and want to practice and refine their workflow, we are providing a voluntary period starting in July of 2018 that runs through CY 2019.

Taking into account the comments related to burden and readiness, we agree with the commenters recommending that the program begin in 2020 with an educational and operations testing period. Providing a start date for implementation of the AUC consultation and reporting requirement will also give some predictability and assurance to practitioners. Given our intention to use the educational and operations testing period to make needed adjustments to the program as well as identify any needs for further guidance and education, we will evaluate whether a second educational and operations testing year is necessary. We believe it is appropriate to retain this option in the event that, to be responsive to stakeholder feedback and the lessons we learn, it is expedient to take additional time to fully implement the AUC consultations and reporting requirements. However, since we currently have qualified PLEs and qualified CDSMs, we expect to be prepared to quickly begin a voluntary participation period. Since the educational and operations testing period will not start until 2020, we are extending the voluntary participation period to 18 months from July 2018 through December 2019.

Comment: Of the commenters that referenced the proposal to begin the program with a voluntary reporting period, the majority stated their support. However, some commenters expressed confusion about the voluntary period and the educational and operations testing period. They requested clarification regarding what is required of ordering and furnishing professionals during those two periods.

Response: During the voluntary reporting period, consulting specified AUC through a qualified CDSM and reporting AUC consultation information will be completely optional. AUC consultation information will not be required on Medicare claims for advanced diagnostic imaging services during the voluntary reporting period. We intend to develop a single HCPCS modifier to be used on claims during this period so the furnishing professional may use the modifier when AUC consultation information is provided by the ordering professional. Currently, we expect that the use of the HCPCS modifier will be the extent of reporting we can accommodate during the voluntary period. However, we anticipate that more specific reporting of AUC consultation information will be required when the educational and operations testing period begins on January 1, 2020. Since the first year of required AUC consultation and reporting will be an educational and operations testing period, we will not deny claims that fail to properly include AUC consultation information. We expect to adopt and communicate additional details and expectations for AUC consultation and reporting during the educational and operations testing period through further rulemaking and guidance before January 1, 2020.

Comment: Commenters inquired about the responsibilities of the ordering professional and requested guidance on how AUC consultation information is to be communicated to the furnishing professional and what must be included in the communication. Some commenters recommended we require this information to be communicated using a unique consultation identifier and require that information to be included on the order from the ordering professional to the furnishing professional.

Response: It is the responsibility of the ordering professional to consult specified applicable AUC through a qualified CDSM and communicate information on that consultation to the furnishing professional. We recognize that there are many ways to communicate orders (paper, fax, telephone) for advanced diagnostic imaging services between ordering and furnishing professionals and we expect that the information related to the AUC consultation would be communicated as part of the order. If we adopt a policy to require reporting of the unique AUC consultation identifier on the furnishing professional's claim, then we would expect the ordering professional to include that identifier on the order for the advanced diagnostic imaging service. We understand that commenters are looking to us to provide prescriptive guidance about how AUC consultation information is communicated between the ordering and furnishing professionals; however, a first step may be to fulfill the need to standardize the taxonomy of the unique consultation identifier before we determine the extent to which we will establish guidance.

Comment: Some commenters suggested that CMS establish a proactive mechanism to review issues that arise during the voluntary and educational and operations testing periods and develop solutions. One commenter cited the way CMS handled the ICD–9 to ICD–10 coding transition as a suggestion for how to implement AUC coding and claims processing. Commenters also suggested using the voluntary reporting

and the educational and operations testing periods for CMS to offer feedback to practitioners, develop targeted education and release data to the public.

Response: We agree with commenters that it would be mutually beneficial to develop a learning and feedback loop, so we will explore a plan to provide feedback and education to practitioners during the voluntary and educational and operations testing periods. We will explore this further through additional stakeholder outreach. It is unlikely that we will have the same level of resources to devote to this program that were available for the ICD–9 to ICD–10 transition, but we will consider and work toward developing the ability to monitor these claims and provide feedback in a more real-time manner.

In response to the public comments, and in addition to delaying the effective date for requiring AUC consultation and reporting as described earlier in this section, we are extending the voluntary period through 2019, so it will begin in July 2018 and end at the end of December 2019. The voluntary period will then be immediately followed by the educational and operations testing period in 2020 during which claims will not be denied for failure to include proper AUC consultation information.

b. Alignment With Other Medicare Quality Programs

The CY 2017 Merit-based Incentive Payment System and Alternative Payment Model final rule with comment period (Quality Payment Program final rule) (81 FR 77008) finalized policies to implement a new approach to payment for physicians and other eligible clinicians, enacted by the MACRA, that rewards the delivery of high-quality patient care through two avenues: Advanced Alternative Payment Models (APMs) and the Merit-Based Incentive Payment System (MIPS) under the PFS. We expect the Quality Payment Program to evolve over multiple years and to continue iterating on these policies. We also believe the AUC program has the potential to provide new opportunities to improve care delivery by supporting and rewarding clinicians as they find new ways to engage patients, families and caregivers as well as improving care coordination and patient health management.

Therefore, we proposed in the CY 2018 Updates to the Quality Payment Program proposed rule (82 FR 30010) to develop a direct tie between MIPS and the AUC program. In that rule, we proposed to give MIPS credit in the improvement activities performance category to ordering professionals for consulting specified AUC using a qualified CDSM as a high-weight improvement activity for the performance period beginning January 1, 2018 (82 FR 30484). We believe this will incentivize early use of qualified CDSMs to consult AUC by motivated eligible clinicians looking to improve patient care and to better prepare themselves for the AUC program. Although we proposed that the AUC program consultation and reporting requirements would not officially begin until January 1, 2019, we are able to adopt this proposed improvement activity because the first qualified CDSMs were announced in conjunction with the CY 2018 PFS proposed rule; therefore, ordering professionals will be able to begin consulting specified, applicable AUC using those tools.

We also considered how the AUC program could serve to support a quality measure under the MIPS quality performance category, and sought feedback from the public regarding feasibility and value of pursuing this idea further.

The following is a summary of the public comments received on how the AUC program could serve to support a quality measure under the MIPS quality performance category, and feedback regarding feasibility and value of pursuing this idea further; and our responses:

Comment: Commenters were supportive of the proposed improvement activity described in the CY 2018 Quality Payment Program proposed rule. Most commenters directly stated that this proposed activity should be finalized and maintained as a high weight activity for the 2018 MIPS performance period and also future years by making the improvement activity and associated weight permanent. A few commenters simply stated agreement with the proposal to make AUC consultation an improvement activity, while other commenters noted that the proposal only ties the MIPS improvement activity points to the ordering physician, which seems like a step in the correct direction but, alone, is unlikely to prompt a significant increase in use of AUC. Commenters offered additional proposals to expand the scope of the proposed improvement activity including suggestions that: (1) Eligible clinicians could receive credit for AUC consultation through both the MIPS quality and improvement activities performance categories; (2) we should further incentivize the electronic ordering of advanced diagnostic imaging services; (3) credit would be awarded if the rate of consultation with AUC is 60 percent for first year, or 75 percent for the second year similar to IA _PSPA _ 6 ''Consultation of the Prescription Drug Monitoring program''; (4) we should award credit for consultation with AUC through CDSMs that have not been qualified; (5) we should provide credit to those eligible clinicians providing radiological consultative services; (6) credit should be given for reporting of the AUC consultation by furnishing professionals; and (7) MIPS credit should be awarded to those clinicians directly involved in AUC development. One commenter did not support providing a high-level improvement activity credit under the MIPS for mandatory clinical decision support use stating that such credit is intended for voluntary improvement efforts by clinicians, and thus is not appropriate for mandated activities. One commenter suggested that it is not appropriate to incentivize CDS program adoption with MIPS before at least January 1, 2019.

Response: We agree with recommendations that we work closely to align quality improvement mechanisms in the Medicare program. The improvement activity proposal is addressed in rulemaking for the Quality Payment Program. We note that we continue to believe this proposal is useful to encourage early adoption of, and maximize the movement to, voluntary AUC consultation and reporting as the AUC program moves towards full implementation. We recognize that there are further opportunities for alignment between the AUC program and the Quality Payment Program, but did not propose additional policies in rulemaking for CY 2018. Therefore, we will consider these suggestions further as we continue to collaborate with other quality improvement programs and engage in future rulemaking.

Comment: Many commenters noted that current AUC program policies and proposals are not yet tied to the MIPS quality or cost categories in the CY 2018 Quality Payment Program proposed rule. However, commenters were divided on the extent to which the AUC program could feasibly align with MIPS beyond the proposed improvement activity performance category. A few commenters believed that use of a qualified CDSM should be incorporated into MIPS only as an improvement activity. One commenter noted that, at best, any proposed AUC program quality measure would be a process measure, suggesting that measures of outcomes are preferable. A few commenters discouraged creation of quality measures around the consultation of AUC based on

administrative claims. Other commenters stated that creating a quality measure would be moving closer to more directly tying AUC consultation to payment for the ordering professional, potentially through MIPS performance scoring, which runs contrary to the statutory requirement that the furnishing professionals' claims and payment are directly impacted.

A few commenters stated they look forward to working with us to develop and implement appropriate measures that will further align the AUC program with the Quality Payment Program. Several commenters submitted additional proposals to better align the AUC program to additional MIPS performance categories. One commenter believed that if the certified EHR technology (CEHRT) requirements were expanded to include the requirement for CDSM functionality within computerized physician order entry modules, the alignment between the AUC program and the MIPS ACI performance category would be further reinforced. A few commenters noted the currently available appropriate use measures, including measures for cardiac imaging, and suggested that such measures could be leveraged as models for applying AUC to more areas of advanced diagnostic imaging, which the commenters believed to be responsive to the request to align the AUC program with the Quality Payment Program. One commenter recommended that any potential quality measure developed around AUC would have to meet the standards set for other quality measures—reliability, validity, and testing. Specific suggestions from commenters also included the framework for creation of a new quality measure. For example, commenters suggested that a quality measure could assess whether a clinician consults specified, applicable AUC using a qualified CDSM or other tool. Another proposal included an optional quality measure or bonus points in MIPS if physicians provide feedback to PLEs and CDSMs about why they decided to proceed with ordering an applicable imaging service when it does not adhere to the specified applicable AUC consulted, thus enabling PLEs and CDSMs to learn from user experience. Another commenter recommended that CDSMs could support such feedback and improvement efforts by including applications for practitioners to download to mobile devices, thus allowing ordering professionals to consult AUC using an intuitive flow-chart based interface. One commenter asked that any AUC-related measure provide two points for reporting on appropriate use, suggesting that such a proposal would further incentivize reporting on an appropriate use measure. One commenter suggested that greater alignment with the quality performance category of MIPS could be achieved through utilization of a Qualified Clinical Data Registry (QCDR) that incorporates CDSMs and reports information on the physician's behalf. The commenter believed that a registry approach would be simpler, provide essential data, and potentially avoid clinician burden as a result. Finally, a few commenters strongly urged full alignment of the AUC program with the MIPS cost or quality performance categories and complete discontinuation of the AUC program and its regulatory burden.

Response: We thank all the commenters for their consideration and feedback about additional MIPS performance categories that could be better aligned with the AUC consulting and reporting requirements. We appreciate the thoughtful comments on ways we could connect the AUC program with the Quality Payment Program in order to reach a less burdensome approach to the AUC program, and will also consider these suggestions.

In response to public comments, we have finalized this improvement activity in the CY 2018 Updates to the Quality Payment Program final rule and note here that the description was updated such that clinicians attest that they are consulting specified applicable AUC through a qualified CDSM 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.

c. Significant Hardship Exceptions to Consulting and Reporting Requirements

We proposed to modify § 414.94(i)(3) of our regulations to reflect the conclusion of application of the payment adjustments under the Medicare EHR Incentive Program and to substitute an alignment with the advancing care information (ACI) performance category of MIPS. In the CY 2017 PFS final rule, for purposes of the AUC program significant hardship exceptions, we included the following categories from § 495.102(d)(4):

- Insufficient Internet Connectivity (as specified in § 495.102(d)(4)(i)).
- Practicing for less than 2 years (as specified in § 495.102(d)(4)(ii)).
- Extreme and Uncontrollable Circumstances (as specified in § 495.102(d)(4)(iii)).
- Lack of Control over the Availability of CEHRT (as specified in § 495.102(d)(4)(iv)(A)).
- Lack of Face-to-Face Patient Interaction (as specified in § 495.102(d)(4)(iv)(B)).

In addition, in the CY 2017 Quality Payment Program final rule, we finalized a policy (81 FR 77240–77243) to reweight the ACI performance category to zero in the MIPS final score for the year for MIPS eligible clinicians who meet the criteria in one of the listed categories of § 495.102(d)(4), with the exception of the category for clinicians practicing for less than 2 years. Under section 1848(q)(1)(C)(v) of the Act, eligible clinicians who first enroll in Medicare during the performance period for a year and have not previously submitted claims under Medicare are not considered MIPS eligible clinicians, and thus are excluded from MIPS. Therefore, many clinicians who have been practicing for less than 2 years would be excluded from MIPS on the basis that they are new Medicare-enrolled MIPS eligible clinicians as defined in § 414.1305. Because these clinicians are not MIPS eligible clinicians, they would never meet the criteria for re-weighting of their MIPS ACI performance category for the year. Therefore, to implement a hardship exception for purposes of the AUC program that is both operationally consistent and administratively efficient, we proposed to remove as a criterion for a significant hardship exception for the AUC program the criterion specified in § 495.102(d)(4)(ii) of our regulations for those practicing for less than 2 years. We proposed to keep the remaining listed categories including insufficient internet connectivity, extreme and uncontrollable circumstances, lack of control over availability of CEHRT and lack of face to face patient interaction. We noted that section 1843(q)(4)(C)(iii) of the Act only allows the ordering professional to seek a significant hardship exception, not the furnishing professional.

As such, we proposed to amend the AUC significant hardship exception regulation to specify that ordering professionals who are granted re-weighting of the ACI performance category to zero percent of the final score for the year under MIPS per § 414.1380(c)(2) due to circumstances that include the criteria listed in § 495.102(d)(4)(i), (iii), (iv)(A) and (iv)(B) would be excepted from the AUC consultation requirement during the same year that the re-weighting applies for purposes of the MIPS payment adjustment.

There will be scenarios when a clinician's experience of a significant hardship or extraordinary circumstance does not align with the prospective identification of these ordering professionals with reference to MIPS criteria and processes. However, we believe the prospective identification process allows us to apply exceptions in real-time for claims submitted for advanced imaging services. There are timing differences between the MIPS and the AUC program (the MIPS payment adjustment year is based on performance in a prior year while the Medicare AUC program requires real-time AUC consultation and claims-based reporting). In addition to the timing, there will be instances when a clinician who is not a MIPS eligible clinician will need to seek a significant hardship exception to the Medicare AUC program. To accommodate these two separate scenarios, we proposed to establish a process to identify ordering professionals in need of a significant hardship exception to the Medicare AUC program requirements that is outside the MIPS re-weighting process. For purposes of these scenarios, we proposed to use the criteria for clinicians seeking an AUC significant hardship exception described under § 495.102(d)(4) to include (i), (iii), (iv)(A) and (iv)(B) of our regulations. We proposed these criteria to align with the criteria used under MIPS for re-weighting under the ACI performance category, and to provide predictability and consistency to the determination of significant hardship. We further proposed that a significant hardship exception from the Medicare AUC program requirements would be granted for no longer than 12 months, and that we could establish an exception for a shorter period where warranted by the circumstances.

Therefore we proposed that ordering professionals who have not received a re-weighting to zero for the MIPS ACI performance category for the year, but experience one of the circumstances described in § 495.102(d)(4) to include (i), (iii), (iv)(A) and (iv)(B), may be granted an AUC significant hardship exception for no longer than one year.

In addition to these proposals, we invited the public to comment on additional circumstances for which it may be appropriate for an ordering professional to be granted a significant hardship exception under the AUC program.

The following is a summary of the public comments received on our proposed modifications to the AUC program significant hardship regulation language, proposal to grant a significant hardship exception for no longer than 12 months, and additional circumstances for which it may be appropriate for an ordering professional to be granted a significant hardship exception under the AUC program; and our responses:

Comment: Many commenters thanked us for adopting policies to provide for significant hardship exceptions for the AUC program in the CY 2017 PFS final rule, and for working to align AUC program significant hardship exceptions with those under the MIPS as proposed in the CY 2018 PFS proposed rule. These commenters supported alignment between the proposed changes to the AUC significant hardship exception policy and the significant hardship exceptions proposed in the CY 2018 Updates to the Quality Payment Program proposed rule. Several commenters requested that CMS finalize these hardships for the AUC program as proposed. These commenters further believed that identifying ordering professionals with significant hardship exceptions creates challenging workflows for furnishing professionals. The furnishing professionals must have this information so they are aware which of the claims require AUC consultation information to be reported and which do not. One commenter expressed specific concern about the increased resources and burden of identifying, tracking, and reporting which ordering professionals have significant hardship exceptions. One commenter explicitly concurred with the proposed AUC program hardship exceptions available for certain eligible clinicians as outlined in the proposed rule, and with providing for exceptions for periods of no longer than 12 months at a time.

In contrast, a few commenters did not understand why such hardship exceptions were proposed within two different programs (the AUC program and the MIPS). These same commenters opposed our proposal to exclude from the hardship exception categories under the AUC program the category for clinicians who have been practicing for fewer than 2 years. Other commenters expressed concern that under our proposals all radiologists who meet the lack of face-to-face patient interaction threshold would be excepted from consulting AUC if they order applicable imaging services. In addition, many commenters believed that certain hardships may justifiably last longer than 12 months and the circumstances leading to the initial request for a significant hardship may be uncontrollable by the physician. These commenters opposed the 12-month cap on hardship exemptions and further stated that such an approach is unfair, unjustified, and disproportionately affects rural providers.

A few commenters believed it was unreasonable to recognize eligible clinicians who have their MIPS ACI performance category re-weighted to zero for the reason that the ordering professional practices at multiple locations, without also considering an exception for other practitioners that face challenges to controlling their CEHRT such as ASC-based eligible clinicians. Those commenters support these categories as qualifying for a significant hardship exception under the AUC program. A few commenters believed that we must also include an exception for hospital-based physicians because emergency physicians and practitioners could not purchase a CDSM platform or adopt a free CDSM platform, for implementation in the hospital because they do not have the appropriate authority to make such purchases or to implement a new CDSM for the delivery of emergency medical care provided in the hospital emergency department setting. To this end, commenters urged inclusion of the statutory references to hospital-based physicians and ASC-based MIPS eligible clinicians into existing exceptions from AUC requirements for MIPS eligible clinicians who have their ACI Performance Category reweighted to zero.

Response: We appreciate the views of commenters that agreed with our proposals and those that questioned the extent of alignment we proposed with the MIPS re-weighting policies for the ACI performance category. In response to public comments that varied widely in content and tone, we are not finalizing the proposed changes to the significant hardship exceptions in this final rule. Commenters offered extensive suggestions for modifications to our proposed updates to the significant hardship exceptions under the AUC program. After considering these comments, we have decided further evaluation is needed before making changes to the significant hardship exception regulatory language. We will reflect further on both the public comments on our proposals, as well as the policies adopted in the CY 2018 Quality Payment Program final rule with comment period, before proposing any revisions to the significant hardship exceptions for the AUC program. In rulemaking for CY 2019, we intend to address policies on significant hardship exceptions for the AUC program that take into account points raised in public comments, as well as the requirements

of the statute and the goal to align as closely as possible with other quality program exceptions and mechanisms for seeking and obtaining exceptions so as to avoid unnecessary administrative burdens. As such, we are not revising our regulation at section 414.94(i)(3) in this final rule.

We provide responses to the comments below to inform commenters of our current thoughts despite not finalizing the changes we proposed to the significant hardship exception under the AUC program.

Comment: Many commenters encouraged expansion of the scope of available significant hardship exceptions. Commenters suggested the following additional circumstances for which an ordering professional should be granted a significant hardship exception under the AUC program: (1) Imaging services ordered as part of clinical research; (2) emergency clinicians attempting to meet the current exclusion criteria; (3) physicians nearing retirement or dealing with hardships who may not have data systems, capital, or the desire to invest in a qualified CDSM system necessary to consult AUC; (4) any time when a PLE or CDSM is de-qualified; (5) for complex medical systems; (6) any physician who does not have access to free integrated CDSMs; and (7) physicians whose EHR cannot integrate into an existing qualified registry.

To support some of these requests for additional exceptions, commenters noted that a CDSM is a form of health information technology that is routinely incorporated into EHR systems, and that costs are associated with such integration. Commenters also stated that a free tool is an impractical solution for those practices focused on investing in upgrading to certified 2015 Edition EHR technology or unable to afford acquisition of a CDSM that integrates with an EHR system. More than one commenter cited the GAO's 2015 evaluation of the Medicare Imaging Demonstration which reported frustration on the part of ordering professionals when decision support was not integrated with their EHRs. This demonstration was authorized by Congress to test whether clinicians would change their ordering patterns (for example, reducing inappropriate imaging) as a result of using appropriateness guidelines for advanced imaging services through decision support systems.

Response: We appreciate the additional context the commenters provided about the rationale to support additional categories of significant hardship exceptions under the AUC program. We will take these comments into account for future rulemaking. We are not finalizing our proposed significant hardship exceptions policies in this final rule, and instead intend to address significant hardship exceptions for the AUC program through rulemaking for CY 2019.

Comment: Commenters took interest in the proposed identification of a re-weighting policy under the ACI performance category of MIPS for MIPS eligible clinicians in small practices. Some commenters noted that small, rural, and independent practices are not ready for AUC program implementation, adding that AUC features within EHRs will be costly, and using these features will take additional time away from patient care. One commenter stated that modifications to either the EHR environment or the CDSM capabilities may be challenging, even for large organizations with greater resources, but especially for small entities or practices. Although a few commenters recognized that while the statute did not authorize a significant hardship exception category for ordering professionals that order a low-volume of advanced imaging services, these same commenters also believed that the statute did give the Secretary discretion on a case-by-case basis to establish hardship exemptions under which low-volume ordering professionals could qualify for significant hardship.

Some commenters requested consideration for exempting ordering professionals based on a low-volume threshold of services. One commenter requested that if the proposed threshold for what constitutes low volume under the CY 2018 Updates to the Quality Payment Program is finalized, that these eligible clinicians also be excluded from the AUC program. Another commenter submitted an alternative proposal that instead of using the same low volume threshold proposed for MIPS a threshold that more closely reflects advanced diagnostic imaging services and billing would be an acceptable threshold calculation for such an exception. Another commenter recommended adaptation of an exception similar to those used in the Medicare e-prescribing (eRx) program, which allowed individual eligible professionals who had been successful electronic prescribers in 2011, and had reported the G8553 code via claims for less than 10 billable Medicare Part B PFS services provided January 1, 2012 through June 30, 2012 to avoid the 2013 eRx payment adjustment. In addition, one commenter requested a significant hardship exception category for furnishing professionals that furnish a low-volume of advanced imaging services, and supported this request with the statement that it would be unreasonable to forgo any payment for advanced diagnostic imaging services furnished under this program.

Response: We appreciate the suggestions for additional opportunities to align the AUC program with the Quality Payment Program. Section 1834(q)(4)(C)(iii) of the Act authorizes the Secretary, on a case-by-case basis, to determine, subject to annual renewal, that consultation with applicable AUC for an applicable imaging service ordered by and ordering professional would result in a significant hardship, such as in the case of a professional who practices in a rural area without sufficient Internet access. In the CY 2018 Quality Payment Program proposed rule (82 FR 30076), we proposed to re-weight the ACI performance category in MIPS to zero to recognize that eligible clinicians who would have struggled to satisfy the requirements of meaningful use would also struggle to report within the ACI performance category on their CEHRT, for instance if they cannot afford or have not adopted EHRs. In contrast, the AUC program did not include such considerations, and further made available mechanisms independent from CEHRT and free of charge. Therefore we will continue to examine the significant hardship exceptions allowed under the statute in order to identify appropriate areas of future alignment with the Quality Payment Program as applicable to the AUC program.

Comment: Commenters sought clarification on the processes and procedures for the hardship application and approval. Some commenters requested a process by which MIPS eligible clinicians could apply for an AUC program hardship exemption following the ACI hardship exemption application deadline. One commenter requested implementation of a year-round application process that will cover both the AUC program for the ordering professional, and the ACI performance category of MIPS for eligible clinicians.

Response: We thank these commenters for their suggestions and considerations for a hardship application and approval process. We agree that it is important for a process to be available throughout the year. It is important to note that, since publication of our proposals in the CY 2018 PFS proposed rule, the 2017 Quality Payment Program hardship exception application was posted at: *https://cmsqualitysupport.service-now.com/exception_application.do*. We look

forward to working to align our AUC program significant hardship exception process with existing processes through future rulemaking.

Comment: A few commenters observed that all significant hardship exceptions include the additional burden furnishing professionals face to verify that ordering physicians have in place a significant hardship exception at the time a service is ordered. Therefore, commenters requested a unique identifier for ordering professionals that have obtained a hardship exception and requested such information be prospectively publicly available. Commenters noted that this proposal would allow significant hardship exceptions to apply in real-time for claims submitted for advanced diagnostic imaging services, and requested that the furnishing professional's claim should not be denied payment if the ordering professional did not in fact have in place a significant hardship exception from the AUC consultation requirement. Another commenter requested that information on ordering professionals' significant hardship status should be published no less frequently than every two weeks. One commenter sought clarification about the situation where an ordering professional is in the process of applying for a hardship but has not yet received a significant hardship exception. Another commenter sought clarity as to whether the hardship exception applies to the clinician's NPI or the clinician's NPI and TIN.

Response: We agree that the communication about a significant hardship exception from an ordering professional to a furnishing professional introduces potential challenges. We will continue to explore opportunities to use a more automated process for providing additional information to ordering and furnishing professionals in a timely manner in order to facilitate such communication and make the information readily accessible.

As stated earlier we will not move forward with the proposed significant hardship exceptions and will maintain our regulations at § 414.94(i)(3). This current policy provides exceptions from consulting and reporting requirements for orders for applicable imaging services made by ordering professionals who are granted a significant hardship exception to the Medicare EHR Incentive Program payment adjustment for that year. The basis for granting a significant hardship exception to the ordering professional are identified under § 495.102(d)(4) of this chapter, and include the following as discussed in CY2017 PFS final rule: Lacking sufficient Internet access; practicing for less than 2 years, facing extreme and uncontrollable circumstances; practicing at multiple locations and demonstrating inability to control the availability of CEHRT; and, lacking face-to-face or telemedicine interaction with patients and a lack of need for follow up with patients. We believe that during the voluntary reporting period, we will continue to develop our understanding of the workflows of both ordering and furnishing professionals, and in particular how we can apply section 1834(q)(4)(C)(iii) of the Act to support those ordering professionals whose consultation would result in a significant hardship.

5. Summary

Section 1834(q) of the Act includes rapid timelines for establishing a Medicare AUC program for advanced diagnostic imaging services. The impact of this program is extensive as it will apply to every physician or other practitioner who orders or furnishes advanced diagnostic imaging services (for example, magnetic resonance imaging (MRI), computed tomography (CT) or positron emission tomography (PET)). This crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite broad. Stakeholders have expressed concern that program requirements may inadvertently encourage physicians to order imaging services that they do not believe are right for their patients. The goal of evidence-based AUC is to assist clinicians in ordering the most appropriate imaging service for their patients' specific clinical scenarios. However, to ensure we are implementing the program effectively, we requested public comment on such potential unintended consequences. Additionally, as we continue to develop the AUC program, we continue to engage a variety of stakeholders interested in participating in the development of AUC. We sought comment about how we can continue to engage interested participants, consistent with statutory requirements at section 1834(q) of the Act, in developing AUC in a transparent and scientifically robust manner. We are particularly interested in how qualified PLEs develop or modify AUC in collaboration with non-PLE entities and what additional challenges such entities might face.

The following is a summary of the public comments received on issues we solicited including potential unintended consequences of the AUC program requirements as well as how we can continue to engage interested participants, particularly qualified PLEs in collaboration with non-PLEs, consistent with statutory requirements at section 1834(q) of the Act, in developing AUC in a transparent and scientifically robust manner and our responses:

Comment: Many commenters shared their thoughts on potential unintended consequences that may result from implementation of the AUC program. Some commenters noted issues of patient access and delivery of care. Commenters warned of the risk of decreased patient access or choices, inappropriate underutilization of imaging studies and harm to patients because of such a reduction, inappropriate testing to avoid AUC requirements, delays in beneficiaries receiving needed tests or even denial of services by furnishing professionals and facilities if AUC is not consulted or information is not provided by the ordering professional, and healthcare rationing. Commenters also warned that the AUC program requirements could result in a shift in referral patterns among primary care physicians and cardiologists and cautioned that the program requirements could lead to disruptions in physicians' practices and workflows and a reduction in patient facing time for providers. Commenters also noted the potential for unwarranted financial penalties for imaging facilities and increases in the cost of tests as CDSMs may recommend higher cost imaging. Commenters noted a risk of impeding clinical research involving imaging, particularly research on new imaging decision rules, which would dramatically slow the generation of relevant published evidence and limit the ability of qualified PLEs to expand the scope of coverage and improve the quality of evidence-based AUC. One commenter stated that there is no evidence that an unintended consequence of AUC consultation is the ordering of imaging services that ordering professionals do not believe are right for their patients.

Response: We appreciate the time and energy commenters and stakeholders have dedicated to share ideas, suggestions, feedback and critiques of our progress in implementing the AUC program. Throughout this preamble, we discuss ways to avoid these unintended consequences as identified by commenters. We appreciate being alerted to these potential unintended consequences so that we can closely monitor and mitigate these issues should they arise during the voluntary

and educational and operations testing as we proceed to implement this program.

Comment: Some commenters expressed concerns regarding the definition of PLE codified in § 414.94(b) of our regulations in the CY 2016 PFS final rule with comment period and the avenues by which entities not meeting the definition PLE can participate in the AUC program. These commenters reiterated their previously expressed opposition to the regulatory definition of PLE and requested revisions to allow participation by more organizations, inclusive of independent content developers, which they deem to be more reflective and in the spirit of the language in the statute describing a PLE.

One commenter noted that organizations where practitioners are involved in day-to-day management or providing strategic direction and can deploy a rigorous evidence-based process for developing AUC should be included. Another commenter stated that CMS prioritizes content developed by clinicians who see patients over those who specialize in reviewing science and developing guidelines so the definition does not account for the fact that clinicians who spend most of their time seeing patients do not have the capacity to develop and regularly update comprehensive care guidelines. One commenter recommended revising the definition to include organizations that develop AUC under the leadership of a structured group of providers who are actively engaged in the practice and delivery of healthcare as the regulatory definition is inappropriately restrictive and limits the organizations that may contribute to provider-developed AUC.

Response: We appreciate these comments and recommendations. We understand the disagreement with the regulatory definition established in the CY 2016 PFS final rule with comment period, but continue to believe it is an accurate and appropriate interpretation of the provisions added by the statute. We believe there are feasible options for AUC content developers to participate in the AUC program regardless of organizational structure, and thus, do not believe a modification to the regulatory definition of PLE is warranted. Moreover, we did not propose to modify the definition of PLE in the CY 2018 PFS proposed rule. Therefore, we are making no changes to the definition of PLE this year.

Comment: These commenters also questioned the endorsement pathway codified in § 414.94(d) of our regulations in the CY 2016 PFS final rule with comment period whereby qualified PLEs may endorse the AUC of other qualified PLEs, under agreement by the respective parties, to enhance an AUC set. Commenters stated that this pathway is inconsistent with statutory language and Congressional intent because the law was meant to allow content developers other than national medical professional specialty societies and PLEs to participate in the AUC program when a national medical professional specialty society or PLE endorsed the organization's AUC content. Under the current regulatory definition, commenters stated that independent content developers and third party entities cannot participate in the AUC program. One commenter stated that the endorsement pathway should enable practitioners to use third party criteria to comply with the AUC program requirements. These commenters requested that the regulations be revised to reflect the intent and language in the statute, and to allow PLEs to endorse AUC from any author or developer. Another commenter recommended that CMS reiterate that each qualified PLE that endorses another qualified PLE's AUC must document that it obtained the organization's agreement, as some organizations are endorsing AUC without an agreement.

Response: We understand the commenters' views in relation to the AUC program statutory provisions and the endorsement pathway, and agree that AUC developed by independent content developers, third parties or non-PLE authors can play a valuable role under the AUC program. However, we do not believe that AUC endorsed by any organization that could meet the definition of PLE should be considered specified AUC under this program. Rather, we have established specific requirements for PLEs to be qualified in order to ensure that any AUC developed, modified or endorsed by these organizations are scientifically valid, transparent and are created using an evidence based methodology. To ensure this requirement of section 1834(q)(2)(B) of the Act is fulfilled, we must understand the processes PLEs use to develop or modify AUC and are consistent with statutory requirements.

Comment: One commenter specifically stated that collaboration, as discussed in the preamble of the CY 2016 PFS final rule with comment period, between an organization that meets the regulatory definition of PLE and third-party content developers that do not is unworkable because it places unreasonable burdens on the PLEs who are responsible for the associated legal, regulatory and compliance burden. In their experience, this commenter noted that these issues have prevented collaborations from moving forward.

Another commenter recommended that the efforts of PLEs be monitored over the next four years before CMS takes action to establish new directives regarding specific AUC and its development. This commenter stated that PLEs are expected to establish new methods for collaboration over this period of time.

Another commenter noted that there is benefit to collaboration between qualified PLEs and non-qualified PLEs as well as between qualified PLEs. This commenter also stated that collaborations with non-qualified PLEs have highlighted the anxiety of these organizations in being forced to adopt practices that may conflict with established local best practices and reinforce that we should focus on eliminating unnecessary imaging and construct AUC that acknowledge local differences in care settings, expertise and best practices. One commenter states that non-PLEs can bring significant, relevant experience to the AUC development process and support for physicians engaged in medical practice; and that relationships between PLEs and non-PLEs can create significant value leading to improved care provided they are clearly defined and transparent.

One commenter recommended that PLEs should be allowed to delegate the AUC development process to third parties that demonstrate adherence to the AUC program requirements for deploying a multidisciplinary team with the requisite expertise, transparency and managing conflicts of interest.

Response: As stated earlier, we strongly agree that non-PLE organizations can play a valuable role under the AUC program. We have already seen this demonstrated by collaboration arrangements between qualified PLEs and third party organizations such as independent content developers, and expect these collaborations to continue to grow and evolve. We encourage stakeholders to explore options for collaboration under the guidelines of this policy.

Comment: Some commenters expressed their opposition to the transparency requirements for qualified PLEs codified in § 414.94(c)(1) of our regulations in the CY 2016 PFS final rule with comment period. Commenters stated that the transparency requirements are inappropriate because they require developers to place their intellectual property in the public domain and that the statute does not include such transparency requirements. One commenter warned

that if guidelines are made available to the public for free, authors will have less incentive to invest resources to keep guidelines updated and participation of independent, evidence-based guideline authors with no financial stake in the actual delivery of care will be limited. Commenters recommended instead that we allow alternative methods for making AUC information available upon request. For example, commenters suggested that requirements can be met by granting access to providers, beneficiaries and CMS to AUC on an as-needed basis or to customers through password protected portals.

Response: We thank commenters for communicating concerns regarding transparency and protecting intellectual property. We recognize the importance and value of AUC that are developed by all authors and, as discussed in previous responses, believe there are opportunities for the participation by all content developers. Among other requirements, the statute requires that we consider whether criteria (1) have stakeholder consensus; (2) are scientifically valid and evidence based; and (3) are based on studies that are published and reviewable by stakeholders. We believe that to assure the public that all the statutory considerations are taken into account, transparency of the process is essential. This includes making publicly available the people, methodologies, and evidence used by developers. Failing to be transparent calls into question the degree to which AUC are indeed evidence based. AUC developed using non-evidence based sources could result in physicians and patients making the wrong decisions to guide care. Transparency allows AUC to be vetted by all stakeholders, including the patient and his/her physician, therefore allowing them to make informed decisions.

Because transparency is a critical element of this program, we established specific requirements for qualified PLEs to make information publicly available through their Web sites. We believe qualified PLEs may fulfill transparency requirements and still keep track of who is accessing the information on their Web sites, for example, some qualified PLEs require users to enter basic information and register through the Web site to gain access to AUC information.

Comment: Most commenters recommended that we undertake increased education efforts on the AUC program as a whole, as well as on more specific elements, to enable professionals who order and furnish advanced diagnostic imaging services to learn about and comply with the program. Commenters suggested using a ''town hall'' approach to provide further education and engage in listening sessions during the educational and operations testing period to understand concerns and challenges ordering and furnishing professionals experience. Commenters recommended that during the voluntary period, codes and modifiers should be adjusted based on solicited feedback from providers and feedback on billing practices should be provided including the identification of what must be fixed and confirmation when it is fixed.

Some commenters recommended direct communications with ordering professionals to encourage program compliance as well as focused education and outreach targeting ordering professionals who may not be complying with program requirements during the educational and operations testing period. Citing the lack of awareness of the AUC program and requirements, one commenter suggested CMS leverage existing communication channels to promote awareness as soon as possible and allow professionals sufficient time to adopt workflows that can reduce administrative burden.

Response: We thank commenters for the suggestions and recommendations regarding outreach and education considerations and strategies. This information will assist and inform our planning as we move forward with the AUC program and focus more heavily on outreach and education efforts. In particular, we look forward to exploring opportunities for town halls, listening sessions and ways to leverage communication channels and strategies already used successfully by other CMS programs.

We continue to believe the best implementation approach is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for adequate advance notice to physicians and practitioners, beneficiaries, AUC developers, and CDSM developers. It is for these reasons we proposed to continue a stepwise approach, adopted through notice and comment rulemaking. In summary, we proposed policies to implement the third component of the AUC program—the consulting and reporting requirements and the effective date on which these requirements would begin. We proposed that ordering professionals must begin consulting specified applicable AUC through qualified CDSMs for applicable imaging services ordered on and after January 1, 2019, and furnishing professionals must begin reporting AUC consultation information on Medicare claims for advanced diagnostic imaging services for which payment is made under an applicable payment system as defined in § 414.94(b) and ordered on or after January 1, 2019. We also proposed modifications to the significant hardship exception to better align these exceptions under the AUC program with those under existing quality programs. We invited the public to submit comments on these proposals.

We believe the changes we are adopting to the policies we proposed in the CY 2018 PFS proposed rule in response to public comments are important to provide more time for ordering and furnishing professionals, qualified PLEs, qualified CDSMs, CMS and other stakeholders to prepare for and support successful participation in the Medicare AUC program. These changes include the following: (1) Extending the voluntary reporting period to 18 months starting July 2018 and continuing through CY 2019; and (2) making the AUC consultation and reporting requirements effective for an educational and operations testing period beginning on January 1, 2020, instead of January 1, 2019 as proposed, to last through CY 2020. We are not finalizing the changes to the significant hardship exceptions in this final rule as we have decided further evaluation is necessary before making changes to our regulations at section 414.94(i)(3). We intend to take into consideration the public comments on our proposals, as well as policies adopted in CY 2018 rulemaking for the Quality Payment Program, and to address significant hardship exceptions for the AUC program in rulemaking for CY 2019. We will reevaluate the proposals regarding what information must be reported on the Medicare claim and will further explore opportunities for stakeholder engagement.

We will continue to post information on our Web site for this program accessible at *www.cms.gov/Medicare/Quality-Initiatives/Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program*.

F. Physician Quality Reporting System (PQRS) Criteria for Satisfactory Reporting for Individual EPs and Group Practices for the 2018 PQRS Payment Adjustment

1. Background

Section 1848(a)(8) of the Act provides that for covered professional services furnished by an EP during each of 2015 through 2018, if the EP does not satisfactorily report data on quality

measures for covered professional services for the reporting period for the year, the PFS amount for services furnished by such professional during the year (including the PFS amount for purposes of determining a payment based on such amount) shall be equal to the applicable percent of the PFS amount that would otherwise apply to such services. For 2016 through 2018, the applicable percent is 98.0 percent. Thus, individual EPs and group practices who did not satisfactorily report data on quality measures for the CY 2016 reporting period are subject to a downward payment adjustment of 2.0 percent to the PFS payment amount for covered professional services they furnish in 2018.

2. Previously Finalized Satisfactory Reporting Criteria for Individual EPs and Group Practices for the 2018 PQRS Payment Adjustment

We previously finalized the satisfactory reporting criteria for individual EPs and group practices for the CY 2016 reporting period to avoid the 2018 PQRS payment adjustment in the CY 2016 PFS final rule (80 FR 71140 through 71250) at § 414.90(j)(8) and (9) and § 414.90(k)(5).

Table 18 in the proposed rule summarized the previously finalized satisfactory reporting criteria for individual EPs (see 82 FR 34097) at § 414.90(j)(8) and § 414.90(k)(5).

Table 19 in the proposed rule summarized the previously finalized satisfactory reporting criteria for group practices via the group practice reporting option (GPRO) (see 82 FR 34098 through 34099) at § 414.90(j)(9) and § 414.90(k)(5).

3. Modifications to the Satisfactory Reporting Criteria for Individual EPs and Group Practices for the 2018 PQRS Payment Adjustment

Since we finalized these requirements, we have heard from stakeholders that EPs have had difficulty with the previously finalized satisfactory reporting criteria for the CY 2016 reporting period, which was the final reporting period for the PQRS. Specifically, we have heard from stakeholders through written communications to CMS that EPs have found the requirements complex, and had difficulty in understanding the requirements to be a satisfactory reporter for PQRS. Stakeholders have also requested that the requirements for the CY 2016 reporting period be aligned with those of the Quality Payment Program, specifically the Merit-based Incentive Payment System (MIPS). In particular, we have heard requests to lower the previously finalized requirement from 9 measures across 3 NQS domains, where applicable, to only 6 measures with no domain requirement associated with these measures. While the PQRS and the MIPS are separate programs, we understand that stakeholders would like to see greater continuity between the final year of the PQRS and the beginning of the MIPS.

The final reporting period for the PQRS was CY 2016. The Quality Payment Program, authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), consolidates and replaces three existing programs (the Medicare EHR Incentive Program for EPs, the PQRS, and the Value-Based Payment Modifier (VM)). There are two ways eligible clinicians can participate in this program: (1) Through the MIPS; and (2) through Advanced Alternative Payment Models (APMs). The initial performance period for the MIPS began on January 1, 2017. Under MIPS, there are four connected pillars that affect how MIPS eligible clinicians will be paid by Medicare: Quality; Improvement Activities; Advancing Care Information; and Cost. For more information on the Quality Payment Program, see *https://qpp.cms.gov/*.

Although we understand that the data submission period for the CY 2016 reporting period has already ended and that all data that has been submitted to CMS is based on the previously finalized satisfactory reporting criteria for the CY 2016 reporting period, we revisited our previously finalized policy because we wanted individual EPs and groups to be assessed for purposes of the 2018 PQRS payment adjustment based on satisfactory reporting criteria that are simpler, more understandable, and more consistent with the beginning of MIPS. We believe that such criteria will help clinicians more accurately gauge their readiness for the beginning of MIPS and transition into the Quality Payment Program successfully. Additionally, we want to be responsive to the concerns of the clinician community. Therefore, although we did not propose to collect any additional data for the CY 2016 reporting period, we proposed to modify the criteria we would apply to the data already submitted for the CY 2016 reporting period to determine whether an individual EP or group practice has satisfactorily reported for purposes of avoiding the 2018 PQRS payment adjustment (82 FR 34099).

a. Individual EPs

Specifically, we proposed to revise the previously finalized satisfactory reporting criteria for the CY 2016 reporting period to lower the requirement from 9 measures across 3 NQS domains, where applicable, to only 6 measures with no domain or cross-cutting measure requirement (82 FR 34099). For individual EPs, this would apply to the following reporting mechanisms: Claims, qualified registry (except for measures groups), QCDR, direct EHR product and EHR data submissions vendor product. This would not affect the criteria used to determine whether an individual EP or group practice has satisfactorily reported for purposes of avoiding the 2017 PQRS payment adjustment, with the exception of the criteria applicable to individual EPs and group practices reporting using the secondary reporting period established under § 414.90(j)(1)(ii) for the 2017 PQRS payment adjustment (hereinafter referred to as the ''ACO Secondary Reporting Period''), as discussed in section III.F.4. of this final rule.

Table 20 in the proposed rule summarized our proposed modifications to the previously finalized satisfactory reporting criteria for individual EPs to avoid the 2018 PQRS payment adjustment, based on data previously submitted for the CY 2016 reporting period (82 FR 34100). We did not propose to collect any additional data for the CY 2016 reporting period, as the data submission period for the CY 2016 reporting period had already ended. As summarized in Table 20 of the proposed rule, the NQS domain requirement would no longer apply (82 FR 34100). No changes were proposed for the measures groups criteria.

Additionally, we also proposed that individual EPs and group practices reporting via claims or qualified registry, as applicable, would no longer be required to report a cross-cutting measure and that individual EPs and group practices reporting via QCDR would no longer be required to report an outcome or ''high priority'' measure (that is, for purposes of PQRS, a resource use, patient experience of care, efficiency/appropriate use, or patient safety measure) (82 FR 34100). We note that what is considered to be a ''high-priority'' measure in PQRS is different from what is considered a ''high-priority'' measure in MIPS, and we did not propose to align this requirement with MIPS for the last year of PQRS as this could cause confusion. Although certain MIPS eligible clinicians are required to report at least one outcome or other high-priority measure (see § 414.1335(a)(1)(i)), we are also not aligning the PQRS requirements with that MIPS requirement because, although we agree that outcome and

high-priority measures are valuable for reporting, we want to revise the satisfactory reporting criteria for the last year of PQRS to be less complex for individual EPs and groups to understand.

Lastly, where we proposed to lower the requirement to only 6 measures, if less than 6 measures apply to the individual EP or group practice, each measure that is applicable would need to have been reported. We define ''applicable'' to mean measures relevant to a particular individual EP's or group practice's services or care rendered. As previously finalized, individual EPs and group practices would continue to be subject to the measure application validity (MAV) process (80 FR 71140 through 71145). The MAV process seeks to identify clinically similar measures and creates clusters of measures that can be reported if one of the measures in the cluster is reported. We will maintain the requirement that each required measure be reported for at least 50 percent of the individual EP's or group practice's patients to which the measure applies.

Accordingly, we proposed to revise § 414.90(j)(8) and (k)(5) (82 FR 34101). We believe these proposals will result in fewer individual EPs being subject to the 2018 PQRS payment adjustment, and will impose no additional burden on individual EPs because this data has already been submitted to CMS. We requested comment on these proposals.

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

Comment: The majority of commenters supported our proposal to revise the previously finalized satisfactory reporting criteria for the CY 2016 reporting period to lower the requirement from 9 measures across 3 NQS domains, where applicable, to only 6 measures with no domain or cross-cutting measure requirement, primarily for its alignment with MIPS reporting criteria.

Response: We appreciate the commenters' feedback, and agree that the proposed changes to the reporting criteria are simpler, more understandable, and more consistent with the MIPS quality reporting requirements, and we are finalizing these changes as proposed.

Comment: Some commenters supported the proposed changes but urged further reduction to reporting criteria, such as considering any attempt of reporting to be satisfactory for purposes of avoiding a downward payment adjustment.

Response: While recommendations to further reduce reporting criteria were considered, we are finalizing the changes as proposed to maintain alignment with MIPS quality reporting requirements. We believe that requiring at least 6 measures provides a more accurate reflection of the quality of care provided by an individual EP or group practice.

Comment: A few commenters opposed the proposed changes, as time and resources have already been placed into reporting on the previously finalized satisfactory reporting criteria for the CY 2016 reporting period. Commenters also expressed that changing the requirements from the previously finalized satisfactory reporting criteria would reward those who did not originally report according to the finalized satisfactory reporting criteria, as well as reduce the standard of quality that the program was meant to represent.

Response: We appreciate the commenters' feedback on this proposal. While all of the recommendations and rationale provided were considered, we are finalizing our proposed modifications to the previously finalized satisfactory reporting criteria for CY 2016 as proposed to maintain alignment with MIPS quality reporting requirements. Based on feedback we received from some stakeholders, we believe that these modifications will simplify the requirements for some clinicians, as well as provide consistency with the first year of MIPS.

Comment: One commenter supported the proposed changes, but recommended the creation of a hardship exemption to relieve satisfactory reporters, of any number of measures, from the 2018 downward payment adjustment.

Response: We can appreciate the commenter's recommendation. However, section 1848(a)(8), (k), and (m) of the Act, which direct us to create and implement the PQRS, do not provide for a hardship exemption process, nor did we propose to implement such a process. We note, however, that individual EPs or group practices may seek an informal review of their satisfactory reporting or satisfactory participation determination in accordance with § 414.90(m). For detailed information about submitting an informal review request, please refer to the PQRS Payment Adjustment Information Web page at *https://www.cms.gov/;Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Payment-Adjustment-Information.html*.

After consideration of the public comments, we are finalizing the proposal to revise the previously finalized satisfactory reporting criteria for the CY 2016 reporting period to lower the requirement from 9 measures across 3 NQS domains, where applicable, to only 6 measures with no domain or cross-cutting measure requirement. Please see Table 21 for a summary of our final policies. We are also finalizing the revisions at § 414.90(j)(8) and (k)(5) as proposed.

TABLE 21—SUMMARY OF THE FINALIZED MODIFICATIONS TO THE REQUIREMENTS FOR THE 2018 PQRS PAYMENT ADJUSTMENT: INDIVIDUAL REPORTING CRITERIA FOR THE SATISFACTORY REPORTING OF QUALITY MEASURES DATA VIA CLAIMS, QUALIFIED REGISTRY, AND EHRS AND SATISFACTORY PARTICIPATION CRITERION IN QCDRS

Reporting period	Measure type	Reporting mechanism	Satisfactory reporting criteria
12-month (Jan 1–Dec 31, 2016)	Individual Measures	Claims	Report at least 6 measures, AND report each measure for at least 50 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the EP, the EP must report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).

TABLE 21—SUMMARY OF THE FINALIZED MODIFICATIONS TO THE REQUIREMENTS FOR THE 2018 PQRS PAYMENT ADJUSTMENT: INDIVIDUAL REPORTING CRITERIA FOR THE SATISFACTORY REPORTING OF QUALITY MEASURES DATA VIA CLAIMS, QUALIFIED REGISTRY, AND EHRS AND SATISFACTORY PARTICIPATION CRITERION IN QCDRS—Continued

Reporting period	Measure type	Reporting mechanism	Satisfactory reporting criteria
12-month (Jan 1–Dec 31, 2016)	Individual Measures	Qualified Registry	Report at least 6 measures, AND report each measure for at least 50 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the EP, the EP must report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).
12-month (Jan 1–Dec 31, 2016)	Individual Measures	Direct EHR Product or EHR Data Submission Vendor Product.	Report at least 6 measures. If an EP's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the EP must report all of the measures for which there is Medicare patient data. An EP must report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1–Dec 31, 2016)	Measures Groups	Qualified Registry	No changes.
12-month (Jan 1–Dec 31, 2016)	Individual PQRS measures and/or non-PQRS measures reportable via a QCDR.	QCDR	Report at least 6 measures available for reporting under a QCDR AND report each measure for at least 50 percent of the EP's patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the EP, the EP must report on each measure that is applicable, AND report each measure for at least 50 percent of the EP's patients.

b. Group Practices

As discussed previously, although we did not propose to collect any additional data for the CY 2016 reporting period, we proposed to modify the satisfactory reporting criteria for the CY 2016 reporting period for purposes of the 2018 PQRS payment adjustment (82 FR 34101). Specifically, we proposed to lower the requirement from 9 measures across 3 NQS domains, where applicable, to only 6 measures with no domain or cross-cutting measure requirement. For group practices, this would apply to the following reporting mechanisms: Qualified registry; QCDR; direct EHR product; and EHR data submissions vendor product. This proposal would not affect the criteria used to determine whether an individual EP or group practice has satisfactorily reported for purposes of avoiding the 2017 PQRS payment adjustment, with the exception of the criteria applicable to individual EPs and group practices reporting using the ACO Secondary Reporting Period, as discussed in section III.F.4. of this final rule.

Table 21 in the proposed rule summarized our proposed modifications to the previously finalized satisfactory reporting criteria for group practices to avoid the 2018 PQRS payment adjustment, based on data previously submitted for the CY 2016 reporting period (82 FR 34101 through 34102). We did not propose to collect any additional data for the CY 2016 reporting period, as the data submission period for the CY 2016 reporting period has already ended. As summarized in Table 21 of the proposed rule, the NQS domain requirement would no longer apply (82 FR 34101 through 34102). No changes were proposed for the Web Interface criteria.

Additionally, as discussed previously, we proposed that individual EPs and group practices reporting via claims and qualified registry, as applicable, would no longer be required to report a cross-cutting measure and that individual EPs and group practices reporting via QCDR would no longer be required to report an outcome or high priority measure. We note that what is considered to be a ''high-priority'' measure in PQRS is different from what is considered a ''high-priority'' measure in MIPS, and we did not propose to align this requirement with MIPS for the last year of PQRS as this could cause confusion. Although certain MIPS eligible clinicians are required to report at least one outcome or other high-priority measure (see § 414.1335(a)(1)(i)), we are also not aligning the PQRS requirements with that requirement because, although we agree that outcome and high-priority measures are valuable for reporting, we want to revise the satisfactory reporting criteria for the last year of PQRS to be less complex for individual EPs and groups.

Where we proposed to lower the requirement to only 6 measures, if less than 6 measures apply to the individual EP or group practice, each measure that is applicable would need to have been reported. We define ''applicable'' to mean measures relevant to a particular individual EP's or group practice's services or care rendered. As previously finalized, individual EPs and group practices would continue to be subject to the MAV process (80 FR 71140 through 71145). The MAV process seeks to identify clinically similar measures and creates clusters of measures that can be reported if one of the measures in the cluster is reported. We would maintain the requirement that each required measure be reported for at least 50 percent of the individual EP's or group practice's patients to which the measure applies.

Lastly, for purposes of the 2018 PQRS payment adjustment, § 414.90(j)(9)(viii) currently provides that if the CAHPS for PQRS survey is applicable to the practice, group practices comprised of 100 or more EPs that register to participate in the GPRO must administer the CAHPS for PQRS survey, regardless of the GPRO reporting mechanism selected. For the reasons discussed previously, we proposed to revise § 414.90(j)(9)(viii) to provide that such group practices may administer the CAHPS for PQRS survey, regardless of the GPRO reporting mechanism selected, but are not required to do so. This change would be consistent with the data submission criteria for the MIPS quality performance category, under which groups may voluntarily elect to participate in the CAHPS for MIPS survey (see § 414.1335(a)(3)(i)). As summarized in Table 21 of the proposed rule (82 FR 34101 through 34102), the previously finalized satisfactory reporting criteria for group practices

administering the CAHPS for PQRS survey would continue to apply to group practices that elected to administer the survey.

Accordingly, we proposed to revise § 414.90(j)(9) and (k)(5) (82 FR 34102). We believe these proposals will result in fewer group practices being subject to the 2018 PQRS payment adjustment, and will impose no additional burden on group practices because this data has already been submitted to CMS. We requested comment on these proposals.

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

Comment: The majority of commenters supported our proposal to lower the requirement from 9 measures across 3 NQS domains, where applicable, to only 6 measures with no domain or cross-cutting measure requirement for group practices using the following reporting mechanisms: Qualified registry; QCDR; direct EHR product; and EHR data submissions vendor product.

Response: We appreciate these commenters' support and are finalizing these requirements as proposed.

Comment: A commenter supported the proposed changes but recommended reopening of the 2016 PQRS submissions.

Response: We are not reopening 2016 PQRS data submissions as it is technically not feasible while maintaining our program deadlines.

After consideration of the public comments, we are finalizing the proposed changes as proposed. We refer readers to Table 22 to view a summary of our final policies. We are also finalizing revisions to § 414.90(j)(9) and (k)(5) as proposed.

TABLE 22—SUMMARY OF FINALIZED MODIFICATIONS TO THE REQUIREMENTS FOR THE 2018 PQRS PAYMENT ADJUSTMENT: GROUP PRACTICE REPORTING CRITERIA FOR SATISFACTORY REPORTING OF QUALITY MEASURES DATA VIA THE GPRO

Reporting period	Group practice size [4]	Measure type	Reporting mechanism	Satisfactory reporting criteria
12-month (Jan 1–Dec 31, 2016).	25+ EPs	Individual GPRO Measures in the Web Interface.	Web Interface	No changes.
12-month (Jan 1–Dec 31, 2016).	25+ EPs that elect CAHPS for PQRS.	Individual GPRO Measures in the Web Interface + CAHPS for PQRS.	Web Interface + CMS-Certified Survey Vendor.	No changes.
12-month (Jan 1–Dec 31, 2016).	2+ EPs	Individual Measures	Qualified Registry	Report at least 6 measures AND report each measure for at least 50 percent of the group's Medicare Part B FFS patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the group, the group practice must report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).
12-month (Jan 1–Dec 31, 2016).	2+ EPs that elect CAHPS for PQRS.	Individual Measures + CAHPS for PQRS.	Qualified Registry + CMS-Certified Survey Vendor.	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report at least 3 additional measures using the qualified registry AND report each measure for at least 50 percent of the group's Medicare Part B FFS patients seen during the reporting period to which the measure applies. If less than 3 measures apply to the group practice, the group practice must report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).
12-month (Jan 1–Dec 31, 2016).	2+ EPs	Individual Measures	Direct EHR Product or EHR Data Submission Vendor Product.	Report 6 measures. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

TABLE 22—SUMMARY OF FINALIZED MODIFICATIONS TO THE REQUIREMENTS FOR THE 2018 PQRS PAYMENT ADJUSTMENT: GROUP PRACTICE REPORTING CRITERIA FOR SATISFACTORY REPORTING OF QUALITY MEASURES DATA VIA THE GPRO—Continued

Reporting period	Group practice size [4]	Measure type	Reporting mechanism	Satisfactory reporting criteria
12-month (Jan 1–Dec 31, 2016).	2+ EPs that elect CAHPS for PQRS.	Individual Measures + CAHPS for PQRS.	Direct EHR Product or EHR Data Submission Vendor Product + CMS-Certified Survey Vendor.	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report at least 3 additional measures using the direct EHR product or EHR data submission vendor product. If less than 3 measures apply to the group practice, the group practice must report all of the measures for which there is patient data. Of the additional 3 measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice must report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1–Dec 31, 2016).	2+ EPs	Individual PQRS measures and/or non-PQRS measures reportable via a QCDR.	QCDR	Report at least 6 measures available for reporting under a QCDR AND report each measure for at least 50 percent of the group practice's patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable, AND report each measure for at least 50 percent of the group practice's patients.

4. Accountable Care Organization (ACO) Participants Who Report PQRS Quality Measures Separately During the Secondary Reporting Period

As discussed in the CY 2017 PFS final rule (81 FR 80441 through 80445), individual EPs and group practices who bill under the TIN of an ACO participant may report separately from the ACO, if the ACO failed to report on behalf of such individual EPs or group practices for the applicable reporting period, during the CY 2016 reporting period for purposes of the 2017 and 2018 PQRS payment adjustments, as applicable. Please note that, in accordance with our previously established policies for the ACO Secondary Reporting Period, our finalized modifications to the satisfactory reporting criteria for individual EPs and group practices for the CY 2016 reporting period would apply to such individual EPs and group practices for purposes of the 2017 PQRS payment adjustment. We did not receive comments on this aspect of the proposal. These modifications will not affect the 2017 PQRS payment adjustment for any other individual EP or group practice.

5. Physician Compare Downloadable Database—Addition of Value Modifier (VM) Data

We previously finalized in the CY 2016 PFS final rule (80 FR 71129 through 71130) a decision to publicly report three data points for the 2018 VM based on 2016 data in the Physician Compare downloadable file in late 2017:

- 2018 VM quality tiers for cost and quality, based on the 2016 data, noting if the EP or group is high, low, or average on cost and quality per the VM.
- A notation of the payment adjustment received based on the cost and quality tiers—upward, downward, or neutral—for each EP or group.
- An indication if the EP or group was eligible to but did not report quality measures to CMS for CY 2016 under PQRS.

In light of the proposals to change the 2016 reporting criteria to avoid the 2018 payment adjustment for PQRS (see section III.F. of this final rule) and subsequent VM proposed policies to hold all physician groups and solo practitioners who met minimum quality reporting requirements harmless from downward payment adjustments for performance under quality-tiering for the last year of the program (see section III.I. of this final rule), and because the revised policies for PQRS and VM in this rule will change the nature of how the PQRS data will be used under the VM, we proposed not to report this data specific to the VM (82 FR 34103). Given the fact that VM data would have been available for posting in the Physician Compare downloadable database for only 1 year and the VM data may not reflect an EP or group's actual performance or payment adjustment given they could have chosen to report fewer measures, we believe that proceeding with the posting of this data could be confusing for the public.

Additionally, we have created other VM data files intended to promote transparency. For each VM performance year, we will publish a Public Use File (PUF) that contains VM performance results of de-identified practices. Supporting documentation for each PUF contains the field name, length, type, label, description, and notes for each variable included in the PUF. The Value Modifier program years 2015 and 2016 (performance year 2013 and 2014) are currently available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/VMPUF/Value-Modifier-PUF.html*. In addition, three Research Identifiable Files (RIFs) for Value Modifier program years 2015 and 2016 (performance year 2013 and 2014) are available through the Research Data Assistance Center (ResDAC) and will be made available for each program year. These files include a practice-level, an NPI-practice level, and a beneficiary-level file, as described at: *https://www.resdac.org/news/cms-creates-set-rif-data-files-support-value-based-payment-modifier-program/2017/06*.

All other previously finalized policies related to 2016 PQRS data available for public reporting on Physician Compare in late 2017 remain unchanged (80 FR 71116 through 71132). Appreciating this, we believe the best course of action is to not move forward with publicly reporting this VM data for 2016. All data required to be reported by law will remain available for public reporting as previously finalized (80 FR 71116

[4] Please note that the group practice size descriptions have been revised for greater consistency with our policy of making the CAHPS for PQRS survey voluntary.

through 71132). For more information on the public reporting policies previously finalized and proposed for MIPS, we refer readers to the following two rules: The Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models final rule with comment period (81 FR 77390 through 77399); and Medicare Program; CY 2018 Updates to the Quality Payment Program proposed rule (82 FR 30163 through 30170). We requested comment on this proposal not to move forward with publicly reporting the VM information in the downloadable database and specifically, if we were to release this data, how it could be used by the public.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Almost all commenters who specifically addressed the proposal not to move forward with reporting the VM data in the Physician Compare downloadable database supported this proposal. Overwhelmingly, commenters indicated it would be best not to report these data, understanding that the policy changes for both PQRS and the VM changed the nature of the data available for public reporting. Commenters also noted including these data would be confusing for both clinicians and patients. And, they also commented that it would be best not to include these data for just 1 year.

Response: We appreciate the comments received and agree with the large majority of commenters that indicated these data would potentially confuse the public and not add significant value given the changes to the PQRS and VM policies. And, we agree that because this would be the first and only year the data were available for public reporting, it is best to not publicly report the information.

Comment: A few commenters opposed this proposal and asked CMS to move forward with publicly reporting these VM data to support transparency and specifically so clinicians could get value from the tiering data.

Some other commenters did question if this type of data was consistent with the goals of Physician Compare, generally, and others questioned if this type of data was useful for decision-making. For transparency purposes, many of these commenters noted the available aggregated, de-identified data was sufficient.

Response: For transparency purposes, as previously noted, these data are already available in a PUF that contains VM performance results of de-identified practices. Clinicians could use the PUF files to evaluate the tiering information as that is included and already public. As noted, we agree these data are not the data most likely to be evaluated by Physician Compare users when looking to make a decision about their health care. But, we anticipate that the audience for the downloadable database will be composed primarily of third party data users, as well as the clinicians and groups themselves, rather than patients and their caregivers. As a result, we appreciate the comment regarding usefulness and alignment with Physician Compare goals, but also note that the primary goal of the downloadable database is to promote transparency. Again, we believe the PUF file is appropriate for this purpose.

As a result of the public comments, we are finalizing this proposal, and, as a result, we will not be including VM data in the Physician Compare downloadable database related to the 2018 payment adjustment.

G. Clinical Quality Measurement for Eligible Professionals Participating in the Electronic Health Record (EHR) Incentive Program for 2016

1. Background

Sections 1848(o), 1853(l) and (m), 1886(n), and 1814(l) of the Act provide the statutory basis for the Medicare incentive payments made to eligible professionals (EPs), Medicare Advantage (MA) organizations (for certain qualifying EPs and hospitals), subsection (d) hospitals, and critical access hospitals (CAHs) that demonstrate meaningful use of certified electronic health record (EHR) technology (CEHRT). Sections 1848(a)(7), 1853(l) and (m), 1886(b)(3)(B), and 1814(l) of the Act also establish downward adjustments to Medicare payments, beginning with calendar or fiscal year (FY) 2015, for EPs, MA organizations, subsection (d) hospitals, and CAHs that are not meaningful users of CEHRT for certain associated reporting periods. Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for the Medicaid incentive payments made to EPs and eligible hospitals for the adoption, implementation, upgrade, and meaningful use of CEHRT. We have implemented these statutory provisions in prior rulemakings to establish the Medicare and Medicaid EHR Incentive Programs.

Under these statutory provisions and the regulations at 42 CFR 495.4, one of the requirements of being a meaningful EHR user is successfully reporting the clinical quality measures selected by CMS to CMS or the states, as applicable, in the form and manner specified by CMS or the states, as applicable. Section 1848(o)(2)(B)(iii) of the Act requires that in selecting clinical quality measures (CQMs) for EPs to report under the EHR Incentive Program, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required, including reporting under section 1848(k)(2)(C) of the Act (the Physician Quality Reporting System). As such, we have taken steps to establish alignments among various quality reporting and payment programs that include the submission of CQMs.

2. Clinical Quality Measure (CQM) Requirements for Meaningful Use in 2016

Under sections 1848(o)(2)(A)(iii) and 1903(t)(6)(C)(i)(II) of the Act and the definition of ''meaningful EHR user'' at § 495.4, EPs must report on CQMs selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare and Medicaid EHR Incentive Programs. In the final rule titled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017,'' we finalized the options for CQM submission for EPs in the Medicare EHR Incentive Program in 2016 as follows (80 FR 62888 through 62889):

- EP Options for Medicare EHR Incentive Program Participation (single program Participation—EHR Incentive Program only):

++ *Option 1:* Attest to CQMs through the EHR Registration & Attestation System.

++ *Option 2:* Electronically report CQMs through Physician Quality Reporting System (PQRS) Portal.

- EP Options for Electronic Reporting for Multiple Programs (for example: EHR Incentive Program plus PQRS participation):

++ *Option 1:* Report individual EP's CQMs through PQRS Portal.

++ *Option 2:* Report group's CQMs through PQRS Portal.

(**Note:** Under option 2, this may include an EP reporting using the group reporting option, either electronically using QRDA, or via the GPRO Web Interface.)

For the Medicaid EHR Incentive Program, we specified (80 FR 62888) that states would continue to be responsible for determining whether and how electronic reporting of CQMs would occur, or if they wish to allow reporting through attestation. Any

changes that states make to their CQM reporting methods must be submitted through the state Medicaid Health IT Plan (SMHP) process for our review and approval prior to being implemented.

We maintained a requirement that EPs report 9 CQMs covering at least 3 NQS domains (80 FR 62888 through 62889). This requirement was established in the final rule titled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2'' (77 FR 54058).

We also continued (80 FR 62888 through 62889) our existing policy that under Medicare, healthcare providers in any year of participation for the EHR Incentive Program for 2015 through 2017 may electronically report CQM data using the options previously outlined for electronic reporting either for single program participation in the Medicare EHR Incentive Program, or for participation in multiple programs if the requirements of the aligned quality program are also met.

We noted that an EHR certified for CQMs under the 2014 Edition certification criteria does not need to be recertified each time it is updated to a more recent version of the eCQMs (80 FR 62889).

3. CQM Requirements for EPs and Groups Under the Medicare EHR Incentive Program in 2016

As we discussed in section III.F. in this final rule, since we finalized these requirements, we have heard from stakeholders through written communications that EPs and groups have found the previously finalized reporting criteria for the CY 2016 reporting period to be complex and had difficulty in understanding the requirements to be a satisfactory reporter, and these same EPs and groups subsequently requested that the CQM reporting requirements for EPs and groups participating in the Medicare EHR Incentive Program in 2016 who chose to report CQMs electronically through the Physician Quality Reporting System (PQRS) Portal be aligned with those of the Quality Payment Program, specifically the Merit-based Incentive Payment System (MIPS).

Therefore, although we did not propose to collect any additional data for 2016, we proposed to change the reporting criteria for EPs and groups who chose to electronically report CQMs through the PQRS Portal for purposes of the Medicare EHR Incentive Program. Specifically, we proposed to change the reporting criteria from 9 CQMs covering at least 3 NQS domains to 6 CQMs with no domain requirement. We proposed this change so that the reporting criteria for the Medicare EHR Incentive Program would be in alignment with the modified requirement that we proposed for the final PQRS reporting period (2016) in section III.F. of the proposed rule, as well as the transition year of the Quality Payment Program. We proposed that an EP or group who satisfies the proposed reporting criteria may qualify for the 2016 incentive payment under section 1848(o) of the Act and may avoid the downward payment adjustment in 2017 and/or 2018 under section 1848(a)(7)(A) of the Act, depending on the EP or group's applicable EHR reporting period for the payment adjustment year. This proposed change would help maintain alignment with PQRS per the requirement under section 1848(o)(2)(B)(iii) of the Act for the Secretary to seek to avoid redundant or duplicative reporting otherwise required, including reporting under section 1848(k)(2)(C) of the Act (the PQRS).

We did not propose to change the previously finalized requirements for CQM reporting in 2016 for eligible hospitals and CAHs; or the previously finalized requirements for EPs who chose to report CQMs through attestation in 2016 for the Medicare EHR Incentive Program (80 FR 62888). Our reasoning for not proposing to change the eligible hospital or CAH requirements for CQM reporting is because the changes proposed for PQRS in section III.F. of the proposed rule and the policies established for the transition year of the Quality Payment Program would only affect clinicians and groups, and therefore, there is no reason to change the established policy for eligible hospitals or CAHs. We did not propose to change the requirements for EPs who reported CQMs through attestation because those who attested were successful; therefore, we believe there is no need to change the requirement. Additionally, the Registration and Attestation portal was phased out on October 1, 2017, and is no longer available for use.

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

Comment: The majority of commenters supported CMS' proposal to revise the reporting criteria for EPs for the CY 2016 reporting period, from 9 measures across 3 NQS domains, to 6 measures with no domain requirement for EPs and groups who chose to electronically report CQMs through the PQRS Portal for purposes of the Medicare EHR Incentive Program in order to align with the changes proposed for PQRS reporting requirements for 2016.

Response: We appreciate the commenters' support for our proposal.

Comment: One commenter supported the proposed changes but requested that CMS establish a new ''Administrative Burden'' category of hardship exception for the 2016 meaningful use reporting period.

Response: We appreciate the commenter's support. We did not consider or propose any changes to our existing policy on significant hardship exceptions under the Medicare EHR Incentive Program, and comments on this topic are outside of the scope of this rulemaking. We note, however, that for the 2016 program year, we offered multiple categories of hardship exceptions, covering a number of issues that participants in the EHR Incentive Program might experience. However, the application deadline for EPs requesting a hardship exception closed on July 1, 2017. We also note that the policy we are finalizing decreases the number of CQMs required for reporting if reported electronically through the PQRS portal. Given that both the reporting period and the deadline for submission of applications for a hardship exception have closed for the CY 2016 reporting year, we are not adding additional hardship exceptions at this time.

Comment: A few commenters opposed the proposed changes, as time and resources have already been invested in order to meet the previously finalized reporting criteria for the CY 2016 reporting period.

Response: We appreciate the commenters' feedback on this proposal and acknowledge that many EPs have invested time and resources into meeting the reporting requirements for the CY 2016 reporting period. Under this proposal, there would be no change in status for those who successfully met the previously finalized reporting requirements—they would continue to be successful reporters.

After consideration of the public comments, we are finalizing the proposal to revise the CQM reporting criteria for EPs from 9 measures across 3 NQS domains to 6 measures with no domain requirement for EPs and groups who chose to electronically report CQMs through the PQRS Portal for purposes of the Medicare EHR Incentive Program in order to align with the proposed PQRS reporting requirements for 2016. An EP or group who satisfies these revised reporting criteria (as well as other EHR Incentive Program requirements) may qualify for the 2016 incentive payment under section

1848(o) of the Act and may avoid the downward payment adjustment in 2017 and/or 2018 under section 1848(a)(7)(A) of the Act, depending on the EP or group's applicable EHR reporting period for the payment adjustment year.

Lastly, we also did not propose to change the previously finalized requirements for 2016 for EPs participating in the Medicaid EHR Incentive Program. At the time that we published the proposed rule, we had already proposed in ''Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices'' that, for 2017, Medicaid EPs would be required to report on any six CQMs that are relevant to the EP's scope of practice (82 FR 20135). On August 14, 2017, we finalized that proposal (82 FR 38487). In proposing and finalizing that change, we indicated that it is our intention to align CQM requirements for Medicaid EPs with the requirements of Medicare quality improvement programs, to the extent practicable. However, due to the timing of this rulemaking and when any proposed changes for 2016 would take effect (if finalized), we were concerned that the benefits of proposing to extend the policy proposed for Medicare EPs for 2016 to Medicaid EPs for 2016 would not be realized, and the burden on states to implement such a policy would be significant. There is no negative payment adjustment for not participating in the Medicaid EHR Incentive Program, so we explained that it was likely that applying the proposed policy for Medicare EPs to Medicaid EPs for 2016 would benefit Medicaid EPs only if they were able to submit new data to states for a Medicaid EHR incentive payment for 2016. Because we anticipated that most states would have completed processing and paying 2016 Medicaid EHR incentive payments by the time such a proposal (if finalized) would take effect, we explained that we believed that applying this change to the Medicaid EHR Incentive Program for 2016 would significantly burden states. We sought comment on our assessment of the difficulty states might face implementing this policy for 2016 for Medicaid EPs, and on the number of Medicaid EPs who might benefit if we instead decided to apply this policy in the Medicaid EHR Incentive Program for 2016, to the extent that doing so would be legally permissible.

We did not receive any comments related to our request for comment, and are not changing the previously finalized CQM reporting requirements for 2016 for EPs participating in the Medicaid EHR Incentive Program.

H. Medicare Shared Savings Program

Under section 1899 of the Act, we established the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among health care providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. Eligible groups of providers and suppliers, including physicians, hospitals, and other health care providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). A subsequent major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). A final rule addressing changes related to the program's financial benchmark methodology appeared in the June 10, 2016 **Federal Register** (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 (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule'')). We have also made use of the annual calendar year (CY) Physician Fee Schedule (PFS) rules to address quality reporting and certain other issues. In addition, in the CY 2017 Quality Payment Program final rule (81 FR 77255 through 77256), we finalized policies related to the Alternative Payment Model (APM) scoring standard under the Merit-Based Incentive Payment System (MIPS), which reduces the reporting burden for MIPS eligible clinicians who participate in MIPS APMs, such as the Shared Savings Program, by: (1) Using the same quality data reported by the ACO using the CMS Web Interface for purposes of the Shared Savings Program to score the MIPS quality performance category for these eligible clinicians and (2) automatically awarding MIPS eligible clinicians a minimum of one-half of the total points in the improvement activities performance category; and (3) not assessing MIPS eligible clinicians on the cost performance category because, through their participation in the ACO, they are already being assessed on cost and utilization under the Shared Savings Program.

In the CY 2018 PFS proposed rule (82 FR 34105 through 34110), we proposed two modifications to the Shared Savings Program beneficiary assignment methodology for performance years beginning on or after January 1, 2019: (1) Revisions to the assignment methodology under 42 CFR part 425, subpart E to reflect the requirement under section 17007 of the 21st Century Cures Act (Pub. L. 114–255, December 13, 2016), that the Secretary determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of services furnished by rural health clinics (RHCs) or federally qualified health centers (FQHCs), and (2) addition of new chronic care management (CCM) and behavioral health integration (BHI) service codes to our definition of primary care services. In addition, we proposed to revise the methodology used in our quality measure validation audits and the way the results of these audits may be used to adjust an ACO's sharing rate (82 FR 34113 through 34114). We also proposed to reserve the discretion to redesignate a measure reported through the CMS Web Interface as pay-for-reporting when substantive changes are made to the measure under the Quality Payment Program (82 FR 34110 through 34113).

We also addressed proposals intended to reduce application burden for stakeholders by reducing certain documentation submission requirements included in the initial Shared Savings Program application and the application for use of the Skilled Nursing Facility (SNF) 3-Day Rule Waiver (82 FR 34114 through 34120). We also proposed to establish specific procedures to address situations where a Taxpayer Identification Number (TIN) that is an ACO participant in more than one ACO begins to submit claims for services used in the beneficiary assignment process and becomes out of

compliance with the ''exclusivity'' requirement in § 425.306(b)(2) (82 FR 34120 through 34122). Finally, we proposed that, for performance year 2018 and subsequent years, we would only include individually beneficiary identifiable payments made under a demonstration, pilot or time limited program that are final and not subject to further reconciliation in financial calculations related to establishing and updating benchmarks and determining performance year expenditures under the Shared Savings Program (82 FR 34122 through 34123).

1. Modifications to the Shared Savings Program Beneficiary Assignment Methodology

a. Assignment of Beneficiaries to ACOs That Include RHCs and/or FQHCs

(1) Background

(a) General Shared Savings Program Assignment Methodology

As originally enacted in the Affordable Care Act, section 1899(c) of the Act requires us to assign FFS beneficiaries to an ACO participating in the Shared Savings Program based on the beneficiary's utilization of primary care services rendered by physicians participating in the ACO. We refer readers to the CY 2018 PFS proposed rule (82 FR 34105 through 34108) for an overview of existing policies for assigning beneficiaries to ACOs under the Shared Savings Program consistent with the requirements of section 1899(c) of the Act. The regulations governing the assignment methodology under the Shared Savings Program are in part 425, subpart E. Briefly, in the November 2011 final rule we adopted a claims-based hybrid approach (called preliminary prospective assignment with retrospective reconciliation) for assigning beneficiaries to an ACO (76 FR 67851 through 67870), which is currently applicable to ACOs participating under Track 1 or Track 2 of the Shared Savings Program. Under this approach, beneficiaries are preliminarily assigned to an ACO, based on a two-step assignment methodology, at the beginning of a performance year and quarterly thereafter during the performance year, but the final beneficiary assignment is determined after each performance year based on where beneficiaries chose to receive a plurality of their primary care services during the performance year. Subsequently, in the June 2015 final rule, we implemented an option for ACOs to participate in a new two-sided performance-based risk track, Track 3 (80 FR 32771 through 32781). Under Track 3, beneficiaries are prospectively assigned to an ACO at the beginning of the performance year using the same two-step methodology used in the preliminary prospective assignment approach, based on where the beneficiaries have chosen to receive a plurality of their primary care services during a 12-month assignment window offset from the calendar year that reflects the most recent 12 months for which data are available prior to the start of the performance year. The ACO is held accountable for beneficiaries who are prospectively assigned to it for the performance year. Under limited circumstances, a beneficiary may be excluded from the prospective assignment list during or after the performance year, such as if the beneficiary enrolls in Medicare Advantage during the performance year or no longer lives in the United States or U.S. territories and possessions.

Finally, in the CY 2017 PFS final rule (81 FR 80501 through 80510), we further enhanced the claims-based beneficiary assignment methodology by finalizing a policy under which beneficiaries, beginning in performance year 2017, may designate a ''primary clinician'' they believe is responsible for coordinating their overall care using *MyMedicare.gov*, a secure, online, patient portal. (We would note that although we previously used the term ''main doctor'' in the CY 2017 PFS final rule, we are using the more comprehensive term ''primary clinician'' in this final rule for consistency with *MyMedicare.gov* and to reflect that beneficiaries can designate healthcare provider types other than physicians as responsible for coordinating their overall care.) Notwithstanding the assignment methodology in § 425.402(b), beneficiaries who designate an ACO professional whose services are used in assignment as responsible for their overall care will be prospectively assigned to the ACO in which that ACO professional participates, provided the beneficiary meets the eligibility criteria established at § 425.401(a) and has had at least one primary care service during the assignment window with an ACO professional in the ACO who is a primary care physician or a physician with one of the primary specialty designations included in § 425.402(c). Such beneficiaries will be added prospectively to the ACO's list of assigned beneficiaries for the subsequent performance year.

(c) Special Assignment Conditions for RHCs and FQHCs

As we noted in the November 2011 final rule, RHC and FQHC claims contain very limited information concerning the individual practitioner, or even the type of health professional (for example, physician, PA, or NP) who provided the service to the beneficiary because this information is not necessary to determine payment rates for services in RHCs and FQHCs (76 FR 67858 through 67861). Therefore, unlike physician fee schedule claims, there is no direct way for us to determine if an RHC or FQHC claim was for a service furnished by a physician at the RHC or FQHC. Despite this difference in claims billing for RHCs and FQHCs, we established a process that allows primary care services furnished in RHCs and FQHCs to be considered in the assignment process for any ACO that includes an RHC or FQHC as an ACO participant. This process is set forth in § 425.404. The special procedures that we have established for using RHC and FQHC services in the assignment methodology are discussed in detail in the June 2015 final rule (80 FR 32755 through 32756). We assign beneficiaries to ACOs that include RHCs or FQHCs as ACO participants in a manner generally consistent with how we assign beneficiaries to other ACOs based on primary care services performed by certain physicians and non-physician practitioners who are ACO professionals in the ACO. However, to address the requirement under section 1899(c) of the Act that beneficiaries be assigned to an ACO based on their use of primary care services furnished by physicians, we require ACOs that include RHCs or FQHCs to identify, through an attestation, the physicians that directly provide patient primary care services in their ACO participant RHCs or FQHCs (see §§ 425.204(c)(5)(iii) and 425.404(a)). We use the combination of the RHC or FQHC ACO participant TIN (and another unique identifier, such as a CCN, when appropriate) and the NPIs of the RHC or FQHC physicians provided to us through the attestation process to identify those beneficiaries who received a primary care service from a physician in the RHC or FQHC and who are therefore eligible to be assigned to the ACO.

This required attestation process for submitting physician identifiers requires more effort to ensure the accuracy of the ACO participant list (including the attestation that includes the physician identifiers) than the level of effort required for ACOs that do not include RHCs and FQHCs. In addition,

we have recognized that the required attestation process for submitting physician identifiers is prone to error because some RHCs and FQHCs (particularly rural FQHCs) have multiple locations with potentially hundreds of NPIs to report which, in turn, increases the likelihood that ACOs that include RHCs or FQHCs as ACO participants will make inadvertent clerical errors, such as transposing digits, in submitting the required information. Errors that are not identified and corrected by the specified deadline for additions to the ACO participant list may result in fewer claims being considered for purposes of determining eligibility for assignment under the Shared Savings Program than would otherwise occur.

(2) Proposals

Section 17007 of the 21st Century Cures Act amended section 1899(c) of the Act (42 U.S.C. 1395jjj(c)) to require the Secretary to assign beneficiaries to ACOs participating in the Shared Savings Program based not only on their utilization of primary care services furnished by physicians but also on their utilization of services furnished by RHCs and FQHCs, effective for performance years beginning on or after January 1, 2019. The statute provides the Secretary with broad discretion to determine how to incorporate services provided by RHCs and FQHCs into the Shared Savings Program beneficiary assignment methodology.

As explained in the proposed rule (82 FR 34108), we believe that the amendments to section 1899(c) made by 21st Century Cures Act enable us to revise the assignment methodology to address the concerns expressed by certain stakeholders regarding the burdens placed on ACOs that include RHCs and FQHCs as ACO participants. Accordingly, in implementing section 17007 of the 21st Century Cures Act, we indicated that we believe it would be appropriate to reduce operational burdens for ACOs that include RHCs or FQHCs as ACO participants and bring greater consistency to the operational method of using claims to assign beneficiaries to ACOs. To promote participation of RHCs and FQHCs under the Shared Savings Program, we proposed to remove the burdensome attestation requirement and instead treat a service reported on an RHC or FQHC institutional claim as a primary care service furnished by a primary care physician for purposes of the step-wise assignment methodology under 42 CFR part 425, subpart E described in the proposed rule (82 FR 34105 through 34106). Consistent with the 21st Century Cures Act, under this proposal: (1) The requirement for an attestation identifying physicians who directly provide primary care services in each RHC or FQHC that is an ACO participant and/or ACO provider/supplier in the ACO would be removed; (2) all RHC and FQHC claims would be used to establish beneficiary eligibility to be assigned to the ACO; and (3) all RHC and FQHC claims would be included in step 1 of the stepwise assignment methodology. We noted that in considering all services billed under the TIN of the ACO participant RHC or FQHC, we would include services that do not meet the definition of primary care services, and such services would not be limited to those provided by a primary care physician, as defined under program rules. This means that under the proposal, a beneficiary could be furnished any service in an RHC or FQHC only by a nurse practitioner, physician assistant, clinical nurse specialist, or any other practitioner in the RHC or FQHC and still be eligible for assignment to the ACO in which the RHC or FQHC is participating.

More specifically, we proposed the following changes to our regulations: (1) Remove § 425.204(c)(5)(iii) in its entirety; (2) revise § 425.404; and (3) make conforming changes to the definition of primary care physician found at § 425.20. Under our proposal, for performance year 2019 and subsequent performance years, ACOs with ACO participants that are RHCs and FQHCs would no longer be required to submit NPIs or other identifying information for physicians who directly provide primary care services in the ACO participant RHCs and FQHCs as indicated in § 425.204(c)(5)(iii)(A) and § 425.404(a). Therefore, we proposed to remove § 425.204(c)(5)(iii) in its entirety. Additionally, we proposed revisions to § 425.404 to reflect that for performance year 2019 and subsequent performance years, we would assign beneficiaries to ACOs based on services furnished in RHCs or FQHCs consistent with the general assignment methodology in § 425.402, by treating a service reported on an RHC or FQHC institutional claim in the same way as a primary care service performed by a primary care physician. We also proposed to remove revenue center codes from the definition of primary care services (§ 425.20) for performance year 2019 and subsequent performance years because all RHC and FQHC services will be used for purposes of assignment for benchmark and performance years; therefore, it is appropriate to modify our definition of primary care services for performance year 2019 and subsequent years to no longer include revenue center codes. Additionally, because the requirement for an attestation under § 425.404 is also referenced in the definition of primary care physician in § 425.20, we proposed to make a conforming revision to that definition to remove the reference to the attestation requirement for performance year 2019 and subsequent years.

Consistent with how we have implemented other changes to the assignment methodology (see, for example, 80 FR 32757 through 32758), we proposed to adjust all ACO benchmarks at the start of the first performance year in which the new assignment rules are applied so that the ACO benchmarks reflect the use of the same assignment rules as will apply in the performance year. Also, 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 purposes of performance year 2019, including using the new methodology in late CY 2018 to determine the eligibility of ACOs wishing to enter into or renew a participation agreement beginning January 1, 2019.

We sought comments on these proposals. We also invited suggestions on how we might further support participation of RHCs and FQHCs in the Shared Savings Program.

Comment: Nearly all commenters strongly supported the proposals, agreeing that the proposed revisions would decrease administrative burdens for ACOs that include RHCs and FQHCs as ACO participants. One commenter indicated support for the proposals only in situations where the plurality of services is provided by an RHC or FQHC. A few commenters appreciated the attempt to reduce burden for ACOs that include RHCs and FQHCs as ACO participants but expressed concerns that treating all RHC and FQHC claims as primary care services and/or including certain specialty services furnished by non-physician practitioners (NPPs) could result in unanticipated beneficiary assignment results. One of these commenters suggested instituting an optional attestation process in which RHCs/FQHCs and NPPs could voluntarily attest they furnish specialty services (and not primary care services) for purposes of beneficiary assignment and the exclusivity requirement under § 425.306(b)(2).

Response: We appreciate the supportive comments on these proposals. We believe these revisions to the assignment methodology will reduce

administrative burden for ACOs that include RHCs or FQHCs as ACO participants and support our policy goal of assigning beneficiaries to the entity that is primarily responsible for the beneficiary's overall care. Notably, section 1899(c) of the Act, as amended by section 17007 of the 21st Century Cures Act, does not restrict the RHC and FQHC services that may be used in assignment for performance years beginning on or after January 1, 2019 to primary care services. Although most services provided by RHCs and FQHCs are primary care services, in view of the broad statutory reference in section 1899(c)(2) to RHC and FQHC ''services,'' rather than ''primary care services,'' we believe it is appropriate to include all services furnished by RHCs or FQHCs to establish beneficiary eligibility to be assigned to an ACO and in the stepwise assignment methodology . We recognize the unique needs and challenges of rural and underserved communities and the key role played by providers and suppliers serving these communities in assuring access to health care. RHCs, FQHCs, and other providers furnishing care in rural and underserved communities play an important role in the nation's health care delivery system by serving as safety net providers of primary care and other health care services, and we believe these changes will enhance their ability to participate in the Shared Savings Program, while also helping to ensure that a beneficiary is assigned to an ACO when the ACO participants in that ACO are responsible for the beneficiary's overall care. We appreciate the additional suggestions on how to assess NPP claims and will continue to consider whether services provided in RHCs/FQHCs by NPPs who provide primary care should be treated differently for purposes of beneficiary assignment than those provided by NPPs who supplement or support specialty practices.

We are finalizing the revisions to our assignment policies for services furnished in FQHCs and RHCs as proposed. Specifically, we are finalizing our proposals to: (1) Remove § 425.204(c)(5)(iii) and modify § 425.404 to eliminate the requirement, for performance year 2019 and subsequent performance years, for ACOs that include an RHC or FQHC as an ACO participant to provide an attestation identifying physicians who directly provide primary care services in each RHC or FQHC that is an ACO participant and/or ACO provider/supplier in the ACO, and make conforming changes to the definition of primary care physician at § 425.20; and (2) for performance year 2019 and subsequent performance years, to: (a) Treat a service reported on an RHC or FQHC claim as if it were a primary care service performed by a primary care physician under the assignment methodology in § 425.402, and (b) remove revenue center codes from the definition of primary care services.

b. Revisions to the Definition of Primary Care Services

(1) Background

Except as discussed previously in this section of the final rule, for services furnished by RHCs and FQHCs for performance years beginning on or after January 1, 2019, section 1899(c) of the Act requires the Secretary to assign beneficiaries to an ACO ''based on their utilization of primary care services'' provided by a physician. We currently define primary care services for purposes of the Shared Savings Program in § 425.20 as the set of services identified by the following HCPCS/CPT codes: 99201 through 99215, 99304 through 99318 (excluding claims including the POS 31 modifier), 99319 through 99340, 99341 through 99350, 99495, 99496, 99490, the Welcome to Medicare visit (G0402), and the annual wellness visits (G0438 and G0439). In addition, we have established a cross-walk for these codes to certain revenue center codes used by RHCs and FQHCs (for services furnished prior to January 1, 2011) so that their services can be included in the beneficiary assignment process. Lastly, we include G0463 for services furnished in electing teaching amendment (ETA) hospitals.

(2) Proposals

In the proposed rule (82 FR 34110), we proposed to revise the definition of primary care services currently located in § 425.20 to include three additional CCM service codes 99487, 99489, and G0506, and four BHI service codes G0502, G0503, G0504 and G0507, beginning in 2018 for performance year 2019 and subsequent performance years and to include these codes when performing beneficiary assignment under § 425.402. The three additional CCM codes reflect the changes in medical practice toward advanced primary care and differ from each other only in the amount of clinical staff service time provided; the complexity of medical decision-making as defined in the Evaluation and Management guidelines (determined by the problems addressed by the reporting practitioner during the month); and the nature of care planning that was performed (establishment or substantial revision of the care plan for complex CCM versus establishment, implementation, revision, or monitoring of the care plan for non-complex CCM). The BHI codes reflect important enhancements in primary care to support improvement and integration of care provided for patients receiving behavioral health treatment.

In addition, we proposed to move the list of primary care service codes currently listed in the definition of ''primary care services'' in § 425.20 to § 425.400(c). We believe § 425.400, which specifies general requirements related to the assignment methodology and currently contains a cross-reference at § 425.400(c) to the definition of primary care services under § 425.20, is the more appropriate place to specify the particular primary care codes that will be considered in the assignment methodology. We also proposed to reorganize the list of service codes, grouping HCPCS codes, G codes, and revenue center codes together, respectively, by relevant performance year(s). We sought comments on this proposal. In addition, we sought comments as to whether there are any additional existing HCPCS/CPT codes that we should consider adding to the definition of primary care services in future rulemaking for purposes of assignment of beneficiaries to ACOs under the Shared Savings Program. Finally, we also proposed to remove paragraph (3) from the definition of primary care services, rather than move it to § 425.400(c) along with the other paragraphs making up the definition of primary care services. Paragraph (3) indicates that we will include additional codes designated by us as primary care services, including new HCPCS/CPT and revenue center codes and any subsequently modified or replacement codes for the HCPCS/CPT and revenue center codes identified in the definition. We explained that, because we always have the flexibility to propose these changes through rulemaking, this provision is unnecessary.

Comment: Nearly all commenters strongly supported this proposal to add the specified CCM and BHI codes to the definition of primary care services. However, one commenter disagreed with the proposal to include CCM as a primary care service, stating that the value of CCM services is highly disputed in the ACO community and that CCM services are often provided by outside companies with little connection between the primary care provider and the beneficiary.

Response: We appreciate the comments supporting our proposed

changes to the definition of primary care services. We respectfully disagree with the commenter who believes that value of CCM services is highly disputed in the ACO community, and note that other commenters, including ACOs and ACO stakeholders, expressed strong support for the proposal to add the CCM and BHI codes to the definition of primary care service. These CCM services are characteristic of the changes in medical practice toward advanced primary care, and, therefore, we believe that these services should be considered in determining where a beneficiary received the plurality of their primary care, and thus in determining whether an ACO should be responsible for the overall care of that beneficiary.

Comment: A commenter encouraged CMS to continue to refine the primary care codes used in assignment ''in a timely manner as codes are finalized for inclusion in the PFS.'' One commenter recommended that CMS consider including the advance care planning codes, CPT codes 99497 and 99498, in the definition of primary care services in future rulemaking.

Response: We appreciate receiving thoughtful suggestions from stakeholders regarding our assignment methodology and will consider whether CPT codes 99497 and 99498 or any additional existing HCPCS/CPT codes should be added to the definition of primary care services in future rulemaking for purposes of assignment of beneficiaries to ACOs under the Shared Savings Program.

Comment: One commenter recommended exclusion of the costs of new codes such as for CCM from the financial settlements of ACOs. The commenter requested that CMS establish a ''revenue neutral threshold for the existing codes at the time of the base determination'' so that billing CCM and other new patient centered care management codes would not impact the ACO's financial performance.

Response: Section 1899(d)(1)(B) of the Act requires us to consider all expenditures for Part A and Part B services in determining an ACO's performance year expenditures. At this time, we are not persuaded by the commenter's suggestion for the need to adjust expenditures to account for CCM or other patient care management codes. As previously discussed in the June 2015 Shared Savings Program final rule (80 FR 32794), we believe that adjusting benchmark and performance year expenditures for the effect of all policy changes, including coding changes, would create an inaccurate and inconsistent picture of ACO spending and may limit innovations in ACOs' redesign of care processes or cost reduction strategies. Therefore, we will continue to include the costs associated with all Parts A and B claims for assigned beneficiaries when determining an ACO's financial performance.

We are finalizing the policies in this section as proposed, except for the minor corrections to § 425.400(c)(1)(iii) and (iv) described below. Specifically, we are finalizing our proposals to: (1) Revise the definition of primary care services currently located in § 425.20 to include three additional CCM service codes 99487, 99489, and G0506, and four BHI service codes G0502, G0503, G0504 and G0507, beginning in 2018 for performance year 2019 and subsequent performance years and to include these codes when performing beneficiary assignment under § 425.402; (2) move the list of primary care service codes currently included in the definition of primary care services in § 425.20 to § 425.400(c); (3) reorganize the list of service codes, grouping HCPCS codes, G codes, and revenue center codes together, respectively, by relevant performance year(s); and (4) remove paragraph (3) from the definition of primary care services at § 425.20.

Finally, we note that in the proposed rule, we made a typographical error in the proposed regulatory text for § 425.400(c)(1)(iv). Consistent with the discussion in the preamble to the proposed rule, we had intended the listed primary care codes to apply not only ''for performance year 2019,'' but also for subsequent performance years.'' In addition, in the proposed regulatory text for § 425.400(c)(1)(iii), we inadvertently referenced ''performance year 2017 and 2018'' rather than ''performance years 2017 and 2018.'' We are making these minor corrections in this final rule.

2. ACO Quality Reporting

a. Changes to the Quality Measure Set Used in Establishing the Quality Performance Standard

(1) Background

Section 1899(b)(3)(A) of the Act requires the Secretary to determine appropriate measures to assess the quality of care furnished by ACOs, such as measures of clinical processes and outcomes; patient and, wherever practicable, caregiver experience of care; and utilization, such as rates of hospital admission for ambulatory sensitive conditions. Section 1899(b)(3)(B) of the Act requires ACOs to submit data in a form and manner specified by the Secretary on measures that the Secretary determines necessary for ACOs to report to evaluate the quality of care furnished by ACOs. 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. We designate the quality performance standard that will apply for each performance year. The quality performance standard is the overall standard the ACO must meet to be eligible for shared savings.

In the November 2011 final rule (76 FR 67973), we initially established a quality performance standard consisting of 33 measures across 4 domains (see § 425.502(d)), including patient experience of care, care coordination/patient safety, preventive health, and at-risk population and a methodology for scoring the measures (see § 425.502(e)). Through the annual rulemaking for the PFS we have reviewed and updated the quality measures reported by ACOs, including adding new measures and retiring measures that had become redundant or no longer met the goals for group reporting, and ensuring that the quality measures reported by ACOs through the CMS Web Interface align with the measures reported through the CMS Web Interface by group practices in other CMS initiatives such as PQRS and the Quality Payment Program. The quality measure set currently includes 31 quality measures (see Tables 42 and 43 at 81 FR 80488 and 80489). We refer readers to the 2018 PFS proposed rule for a detailed discussion of ACO quality reporting requirements and the process we follow under the Shared Savings Program to account for changes to the quality measure set used in establishing the quality performance standard (82 FR 34110 through 34111). To avoid confusion and duplication of rulemaking, and reduce provider burden, we also finalized a policy in the 2017 PFS final rule that future changes to the CMS Web Interface measures will be made through rulemaking for the Quality Payment Program and will be applicable to ACO quality reporting under the Shared Savings Program (81 FR 80499 and 80500). Lastly, we finalized a policy in the CY 2016 PFS final rule with comment period (80 FR 71269) under which we reserve the right to maintain a measure as pay-for-reporting or revert a pay-for-performance measure to pay-for-reporting when the measure owner determines the measure no longer aligns with clinical practice or continued application of the measure may result in patient harm (see § 425.502(a)(5)).

(2) Proposals

As previously noted in the background section, we have a policy that future changes to the CMS Web Interface measures will be adopted through rulemaking for the Quality Payment Program and will be applicable to ACO quality reporting under the Shared Savings Program (81 FR 80501). We also note that, as discussed in the CY 2017 Quality Payment Program final rule with comment period (81 FR 77136), section 1848(q)(2)(D)(i)(II) of the Act requires the Secretary to update the final list of quality measures from the previous year (and publish an updated list in the **Federal Register**) annually. Updates may include the removal of quality measures, the addition of new quality measures, and changes to existing quality measures that the Secretary determines have gone through substantive changes. In the CY 2017 Quality Payment Program final rule with comment period, we indicated that in the future we would use rulemaking for the MIPS program to address substantive changes to measures (81 FR 77143). On June 20, 2017, we issued a proposed rule that included proposals to revise certain policies under the Quality Payment Program for CY 2018, including a proposal to make substantive changes to several measures reported through the CMS Web Interface. For example, we proposed substantive changes to the way performance on ACO–17 Tobacco Use: Screening and Cessation Intervention is calculated via the CMS Web Interface (see Table E, 82 FR 30469). The proposed changes would simply revise the measure specifications to measure the percent of tobacco users that received cessation counseling; instead of measuring a combined performance rate for beneficiaries who were screened for tobacco use and for the subset of beneficiaries who are tobacco users that received tobacco cessation counseling. In addition, a substantive change was proposed to the Influenza Immunization measure (ACO–14); however, the changes would apply only to the Registry and EHR data submission methods and not the CMS Web Interface reporting method (82 FR 30472). Finally, a substantive change was proposed for the Body Mass Index Screening and Follow-Up Plan (ACO–16); specifically, we proposed that the frequency of documenting BMI would change from 6 to 12 months (82 FR 30471).

Consistent with the way that we have addressed previous changes to measures, we reviewed the proposed substantive changes to the CMS Web Interface measures included in the CY 2018 Quality Payment Program proposed rule to assess whether the changes, if finalized, would warrant a change in how the measures are used to assess ACO performance under the Shared Savings Program. As part of this review, we considered whether the proposed substantive changes might raise sampling issues or require that we recalculate the measure benchmarks for purposes of the Shared Savings Program. Based on our review of the Quality Payment Program proposals and for the reasons discussed in the CY 2018 PFS proposed rule (82 FR 34112), we did not believe the proposed ''substantive'' changes to the CMS Web Interface measures would require that we revert these measures to pay-for-reporting for the 2018 performance year. Instead, we indicated that we believe it would be appropriate under the Shared Savings Program to: (1) Update the measure specifications through subregulatory guidance in order to continue to align the measures with the measure specifications used under the Quality Payment Program and the Million Hearts Initiative, and (2) retain the current phase-in schedule for the measures rather than redesignating any of the measures as pay-for-reporting.

However, the statutory directive under the Quality Payment Program to address substantive changes to measures in rulemaking and the proposals in the CY 2018 Quality Payment Program proposed rule to address substantive changes to certain Web Interface measures caused us to evaluate what recourse we might have in the future under the Shared Savings Program rules to revert a measure to pay-for-reporting in instances where a substantive change to the measure makes it inappropriate to hold ACOs accountable for performance on that measure. We anticipate that there could be future substantive changes to the CMS Web Interface measures made under the Quality Payment Program that would give us reason to redesignate a measure as pay-for-reporting under the Shared Savings Program. Currently, although the Shared Savings Program rules afford flexibility to redesignate a measure as pay-for-reporting when the measure owner determines the measure no longer aligns with clinical practice or causes patient harm, there is no discretion to modify how we assess CMS Web Interface measures in the event substantive changes are made to those measures under the Quality Payment Program that make it inappropriate to hold ACOs accountable for performance on the measure. Given the timing of the Quality Payment Program proposals in relationship to the timing for when the quality performance benchmarks must be established under the Shared Savings Program, it may in some cases be necessary to have flexibility to designate a pay-for-performance measure as pay-for-reporting outside the formal rulemaking process just before or following the start of a performance year, consistent with the way in which we have redesignated measures in the past when measure owners have made changes after the start of a performance year. Accordingly, we believe it would be appropriate to modify the Shared Savings Program regulations to provide additional flexibility to address substantive changes to CMS Web Interface measures that are made under the Quality Payment Program and to continue to facilitate alignment of measures with the Quality Payment Program and other CMS initiatives.

Therefore, we proposed to modify § 425.502(a)(5) to include the right for CMS to redesignate a measure as pay-for-reporting when a substantive change to a CMS Web Interface measure is made under the Quality Payment Program that we determine warrants a change in how the measure is used to assess ACO performance for purposes of the Shared Savings Program. This revision would supplement CMS's existing discretion to redesignate a measure as pay-for-reporting when the measure owner determines the measure no longer aligns with clinical practice or causes patient harm. Specifically, we proposed to revise the regulation at § 425.502(a)(5) to reserve CMS's right to redesignate CMS Web Interface measures that have undergone a substantive change as determined under the Quality Payment Program to pay-for-reporting status. Such measures would not necessarily be automatically redesignated as pay-for-reporting when a substantive change occurs (for example, as indicated previously, we do not believe the substantive changes proposed for 2018 present an impediment to holding ACOs accountable for performance on these measures in performance year 2018 and subsequent years); however, in the future, substantive changes made to CMS Web Interface measures under the Quality Payment Program (such as when the substantive change to a measure results in an issue with sampling, calculating performance, or calculating the quality benchmark) may make it inappropriate to hold an ACO accountable for performance on the measure for the time needed for CMS to obtain the information necessary to

calculate a quality benchmark for the substantively changed measure in advance of a performance year and/or until ACOs gain experience reporting the measure, as substantively changed. Although we expect to conduct at least a preliminary assessment of any substantive changes to the CMS Web Interface measures as part of the annual PFS rulemaking in order to determine whether any change to the phase in schedule for a measure is warranted, because we cannot always anticipate the types of substantive changes that may occur under the Quality Payment Program or the effect of those changes on our ability to calculate performance on the measure, we believed this proposal would provide us with additional flexibility to redesignate existing measures undergoing a substantive change as pay-for-reporting on a measure-by-measure basis. We invited comments on this proposal.

Comment: We received relatively few comments on this proposal. Those that commented were nearly all supportive. One commenter supported the proposal, but cautioned CMS that the discretion to revert a measure to pay for reporting should only be exercised in rare and necessary circumstances with utmost transparency to the public. One commenter questioned why CMS is using pay-for-reporting when results-based incentives help improve population health and requested a transparent and methodological process that would allow for industry review and sufficient time to make the related changes.

Response: We appreciate the support for the proposal. Our intent is to revert measures to pay-for-reporting only in those rare circumstances where it is necessary to do so to assess ACO quality performance appropriately. Any use of this discretion will be done with utmost transparency to ACOs. We believe this additional flexibility will enable us to more appropriately assess ACO quality performance, by ensuring that ACOs are not held accountable for performance on a measure when substantive changes to that measure affect our ability to assess performance on that measure appropriately. Otherwise, ACOs could be inappropriately held accountable for performance on such measures until such time as we could undertake rulemaking to modify the pay-for-performance status of the measure. During our evaluation of a measure change, we may determine methods to address that change so that ACOs can continue to be assessed on their performance on that measure. For instance, as described in the proposed rule, we evaluated the changes proposed to the Tobacco Use: Screening and Cessation Intervention in the CY 2018 QPP proposed rule, and concluded that we still would be able to use data reported on the measure to establish an appropriate benchmark that aligns with the updated specifications. As with redesignations that occur when the measure owner determines a measure no longer aligns with clinical practice or causes patient harm, redesignations that occur due to substantive changes to a measure will be communicated to ACOs as soon as possible through operational documents and other typical methods we use to communicate with ACOs.

We are finalizing this amendment to our regulations as proposed. Specifically, we are modifying § 425.502(a)(5) to include the right for us to redesignate a measure as pay-for-reporting when a substantive change to a CMS Web Interface measure that is used to assess quality performance for the Shared Savings Program is made under the Quality Payment Program.

b. Further Refining the Process Used To Validate ACO Quality Data Reporting

(1) Background

In the November 2011 final rule, we adopted a regulation at § 425.500(e) under which we retained the right to audit and validate the quality measure data ACOs submit through the CMS Web Interface (76 FR 67893 through 67894). Under this original validation process, we selected a subset of CMS Web Interface measures and a random sample of 30 confirmed and completely reported beneficiaries for each measure in the subset. The ACO was required to provide medical records to support the data reported in the CMS Web Interface for those beneficiaries. A measure-specific audit performance rate was then calculated using a multi-phased audit process. If, at the conclusion of the third phase of the audit, there was a discrepancy greater than 10 percent between the quality data reported and the medical records provided during the audit, the ACO was not given credit for meeting the quality target for any measure(s) for which the mismatch rate existed.

In the CY 2017 PFS final rule (81 FR 80489 through 80492), we revisited the Quality Measures Validation audit process and finalized four improvements to our audit process that addressed the number of records to be reviewed per measure, the number of audit phases, the calculation of an audit match rate, and the consequences if the audit match rate falls below 90 percent. Under the revised process, we will audit enough medical records to achieve a 90 percent confidence interval; conduct the audit in a single phase; and calculate an overall audit match rate. If at the conclusion of the audit process the overall match rate between the quality data reported and the medical records provided by the ACO is less than 90 percent, absent unusual circumstances, we will adjust the ACO's overall quality score proportional to the ACO's audit performance. The audit-adjusted quality score is calculated by multiplying the ACO's overall quality score by the ACO's overall audit match rate. For example, if an ACO's quality score is 75 percent and the ACO's audit match rate is 80 percent, the ACO's audit-adjusted quality score would be 60 percent. The audit-adjusted quality score is the quality score that will be used to determine the percentage of any earned savings that the ACO may share or the percentage of any losses for which the ACO is accountable. Under the revised audit methodology, our intent was to continue to audit a subset of ACOs, which we would identify by looking for data anomalies such as high skip rates, although we retained the flexibility to randomly select ACOs or specific measures for audit as we have done in the past. We also finalized a new requirement at § 425.500(e)(3) that an ACO that has an audit match rate of less than 90 percent may be required to submit a corrective action plan (CAP) under § 425.216 for our approval. In addition, we noted that we would maintain the right, as described in § 425.500(f), to terminate or impose other sanctions on any ACO that does not report quality data accurately, completely, or timely. These new policies applied to quality validation audits beginning in 2017 with the audits of quality reporting for the 2016 performance year.

(2) Proposals

Since publication of the CY 2017 PFS final rule, we have gained additional experience with the Quality Measures Validation audits, and have performed additional analyses related to these audits. Our analysis of the 2016 Quality Measures Validation audit results for Shared Savings Program ACOs indicates that the average match rate of ACOs audited in calendar year 2016 was 72 percent and the median performance was 80 percent. Typically, during the audit, we review medical record documentation and work with ACOs to better understand the mismatch between what was reported and what was documented and have determined through our analyses that ACOs continue to experience challenges in understanding certain aspects of the

measure specifications, coordinating collection of information across many different providers and practices, and satisfying the requirements for supporting documentation. Many of these errors are not indicative of poor quality of care but rather reflect minor errors in process or in understanding measure requirements. For instance, we have identified errors by individuals abstracting data from the medical record. In one case, a medical record abstractor incorrectly misinterpreted the less than symbol (<) in the quality measure specifications for the ACO–31 Heart Failure: Beta Blocker Therapy for Left Ventricular Systolic Dysfunction and ACO–33 Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy, and therefore, abstracted the data incorrectly for reporting.

Under our newly finalized single-phase approach to quality measure validation audits, minor errors are more likely to affect the final audit results and impact the calculation of shared savings or shared losses when the overall match rate is below 90 percent. Additionally, we note that the match rate threshold under the Hospital Inpatient Quality Reporting (HIQR) Program is 75 percent. The HIQR validates data submitted by hospitals, which are entities that generally have more experience with quality reporting, greater health record accessibility and integration, and a longer history of validation of quality data submitted to CMS.

As we stated in the proposed rule, in light of our analyses of the 2016 Quality Measures Validation audit results, we believe it is appropriate to consider making additional modifications to our Quality Measures Validation audit process. First, we are concerned that the 90 percent match rate adopted in CY 2017 PFS final rule may be too high and could inappropriately penalize ACOs that make quality data reporting errors that are unrelated to care quality. In the early years of phasing in this new audit methodology, we believe that the match rate should instead be based on actual ACO experience in order to focus on holding ACOs accountable for clinically related mismatches in reporting quality measures as they continue to gain experience with how to measure, report and improve quality under the program. We believe that basing the audit match rate threshold on actual Quality Measures Validation audit results would strike an appropriate balance between ensuring the accuracy of ACO quality reporting while not unduly penalizing ACOs for minor quality reporting errors that are not necessarily indicative of poor quality of care. Accordingly, we believe it would be appropriate to set the audit match rate threshold based on the median match rate (80 percent) for ACOs audited in calendar year 2016 rather than an alternative approach such as the mean match rate because the median match rate would be less affected by data outliers. Therefore, we proposed to revise § 425.500(e)(2) to indicate that if an ACO has a match rate below 80 percent, absent unusual circumstances, we would adjust the ACO's overall quality score proportional to the ACO's audit performance.

Second, we proposed to amend the method by which we adjust an ACO's overall quality score to reflect the ACO's audit performance. Specifically, we proposed to revise the methodology described in the 2017 PFS final rule (81 FR 80490) under which the audit-adjusted quality score is calculated by multiplying the ACO's overall quality score by the ACO's audit match rate. Instead, we proposed that for each percentage point difference between the ACO's match rate and the match rate considered passing the audit, the ACO's overall quality score would be adjusted downward by 1 percent. That is, if we finalize the proposal to establish an 80 percent match rate as the threshold for passing the Quality Measures Validation audit, and the ACO's match rate is 75 percent, then under this proposal we would adjust the ACO's overall quality score downward by 5 percent. To illustrate, assuming a match rate threshold of 80 percent, an ACO with an overall quality score of 90 percent would have an audit-adjusted quality score of 85.50 percent, that is, $(90 - [.05 \times 90]) = 85.50$.

Finally, we proposed a conforming change to § 425.500(e)(3) to reflect the 80 percent threshold such that if at the conclusion of the audit process CMS determines there is an audit match rate of less than 80 percent, the ACO may be required to submit a CAP.

We invited comment on the proposed refinements to the process used to validate ACO quality data reporting and to adjust an ACO's overall quality score to reflect the ACO's audit performance. We also sought comment on an alternative approach we considered to address the Quality Measures Validation audit match rate and the resulting impact on an ACO's overall quality score. Consistent with the approach used under the HIQR program, we considered revising § 425.500(e)(2) to provide that we would adjust the ACO's overall quality score if an ACO has a match rate below 75 percent. We did not propose this approach because the median match rate for the Quality Measures Validation audits conducted in calendar year 2016 was 80 percent, suggesting that a match rate of 75 percent may be too low for ACOs.

Comment: Nearly all commenters were supportive of our proposals to make additional modifications to our quality measure validation audit process. Commenters stated that the proposal to lower the threshold for passing the quality validation audit to an 80 percent match rate would be more in line with hospital quality reporting audit rates and would be more reasonable, given the current state of documentation in clinical records. A few commenters suggested that an audit match rate of no higher than 70 percent would be appropriate to ensure that only practices with true care quality issues would be targeted for an audit. One commenter stated that a match rate of 80 percent seems high for the first year given that the average match rate for the audit that occurred in CY 2016 was 72 percent. The commenter instead recommended a phased-in approach, for example, 75 percent in year 1, 77 percent in year 2 and 80 percent in year 3. One commenter disagreed with reducing the audit match rate, believing that reducing the match rate would reduce both the accuracy and integrity of ACO performance assessment.

Response: We do not believe it would be necessary or appropriate to establish a match rate of less than 80 percent because the results of the Quality Measures Validation audits conducted on Shared Savings Program ACOs in calendar year 2016 yielded a median match rate of 80 percent, suggesting that a lower match rate percent may be too low. The median match rate indicates that at least half of the audited ACOs achieved a match rate equal to or greater than 80 percent. We did not propose any changes to our methodology for identifying ACOs for audit, as stated earlier, we would identify ACOs for audit by looking for data anomalies such as high skip rates. Additionally we have retained the flexibility to randomly select ACOs or specific measures for audit. We also note that over time, we expect ACOs will become more experienced with the quality reporting requirements, improve their quality reporting processes and become better clinically integrated. In addition, because the audit process involves the exchange of information regarding medical record review and communication between ACOs and us, the audit process, itself, provides additional education on the quality measures and quality reporting. As a result, we expect that in the future, quality validation audit results that show a significant mismatch between

the information reported and the underlying medical records will more consistently reflect meaningful, clinically related quality reporting errors for which ACOs should be held accountable. Accordingly, we will periodically review the audit match threshold and seek to increase the match rate over time.

Comment: A commenter requested that CMS institute rigorous independent validation and verification procedures to ensure accuracy and completeness of self-reported data. The commenter recommended that such validation should be conducted by third-party organizations in a manner similar to current requirements for Medicare Advantage plans and other government healthcare programs.

Response: Since the inception of the Shared Savings Program, we have worked with an independent contractor to conduct the Quality Measures Validation audit. The organization currently contracted to conduct the audit is a CMS Quality Innovation Network-Quality Improvement Organization, and the individuals leading the audit from this organization have many years of experience doing medical record review and provide us with an independent assessment of the accuracy of the data entered into the CMS Web Interface by audited ACOs.

Comment: We also received a number of additional suggestions about policies that were established in prior rulemaking. For example, a few commenters expressed concerns about the CMS policy to adjust an ACO's overall quality score based on the ACO's audit performance. One of these commenters believes CMS over-weights the measures reported through the CMS Web Interface to the detriment of CG–CAHPS and claims-based measures. Another commenter believes that adjusting quality scores downward to reflect audit performance is unfair and provides no recourse for ACOs. A commenter suggested that further reductions in the earned quality score could be problematic given that a significant number of the existing measures require performance at or above 90 percent in order to earn the maximum points available for the measure.

Response: We thank the commenters for their thoughtful suggestions on possible ways we might further improve policies and/or operations related to the Quality Measures Validation audits and related adjustments to ACOs' overall quality scores. We will consider these issues further and may address these suggestions in future rulemaking and/or through guidance documents. We would emphasize, however, that we continue to believe it is appropriate to adjust an ACO's overall quality score based on the ACO's audit performance. The audit adjusted quality scores allow us to use more accurate information in the reconciliation of the ACO's performance for the prior year. The accuracy of an ACO's quality reporting is very important, as reflected in the requirement that ACOs completely and accurately report in order to be eligible to share in savings. We also continue to believe that the weights assigned to measures reported through the CMS Web Interface are appropriate relative to the weights assigned to CG–CAHPS and claims-based measures. The CMS Web Interface measures make up approximately one-half of the quality measure set and represent a number of clinically important concepts in the Preventive Health and At-Risk Population domains. The CAHPS for ACOs measures are used to calculate the Patient/Caregiver Experience domain and the claims-based measures are included in the Care Coordination/Patient Safety domain. Because the 4 measure domains that comprise the quality score are equally weighted, performance on the CMS Web Interface measures in the Preventive Health and At-Risk Population domains determines half of the ACO's overall quality score. Lastly, while many measures do require performance at or above 90 percent in order to earn the maximum points available for the measure, as one commenter pointed out, ACOs can earn points on measures as long as they perform at or above the minimum attainment level of 30 percent or the 30th percentile of the benchmark for the measure.

Comment: A commenter requested a general estimate of the increase in the number of charts that will be required to attain a 90 percent confidence interval.

Response: As described in the 2017 PFS final rule (81 FR 80489 through 80492), we do not expect that more than 50 records would be requested per audited measure to achieve a high level of confidence that the audited sample is representative of the ACO's quality reporting performance. We are not seeking to increase the number of records that would need to be audited at this time.

We are finalizing the policies for ACO Quality Measure Validation audits in this section as proposed. Specifically, we are finalizing our proposals to: (1) Revise § 425.500(e)(2) to indicate that if an ACO has a match rate below 80 percent, absent unusual circumstances, we will adjust the ACO's overall quality score proportional to the ACO's audit performance; (2) revise the methodology used to calculate an ACO's audit-adjusted quality score to provide for a one percent reduction to the ACO's overall quality score for each percentage point difference between the ACO's audit match rate and the 80 percent match rate; and (3) making a conforming change to § 425.500(e)(3) to reflect the 80 percent match rate.

3. Reducing Shared Savings Program Application Burden

a. SNF 3-Day Rule Waiver Application Requirement That ACOs Report Their Financial Relationships

(1) Background

The Medicare SNF benefit is for beneficiaries who require a short-term intensive stay in a SNF, requiring skilled nursing or skilled rehabilitation care, or both. Under section 1861(i) of the Act, beneficiaries must have a prior inpatient hospital stay of no fewer than 3 consecutive days in order to be eligible for Medicare coverage of inpatient SNF care. In the June 2015 final rule (80 FR 32804 through 32806, 32808), we provided ACOs participating in Track 3 with additional flexibility to attempt to increase quality and decrease costs by allowing these ACOs to apply for a waiver of the SNF 3-day rule to permit their prospectively assigned beneficiaries to receive coverage for inpatient SNF care without a prior 3-day inpatient hospital stay when they are admitted to a ''SNF affiliate,'' that is, a SNF with which the ACO has executed a SNF affiliate agreement, and certain additional eligibility criteria are met (see § 425.612(a)(1)). All other provisions of the statute and regulations regarding Medicare Part A post-hospital extended care services continue to apply. To qualify to use the SNF 3-day rule waiver, ACOs must submit a SNF 3-Day Rule Waiver application that includes supplemental information sufficient to demonstrate that the ACO has the capacity to identify and manage beneficiaries who would be either directly admitted to a SNF or admitted to a SNF after an inpatient hospitalization of fewer than 3 days. Required application materials and other program rules are discussed in detail in the 2018 PFS proposed rule (82 FR 34114 through 34115). We began accepting SNF 3-Day Rule Waiver applications in the summer of 2016 and approved 26 Track 3 ACOs to begin using the SNF 3-day rule waiver under the Shared Savings Program effective January 1, 2017.

(2) Proposal

As discussed in the proposed rule, the SNF 3-day rule waiver requirements are primarily based on criteria previously developed under the Pioneer ACO Model. As explained in the proposed rule, as a result of our recent experience implementing the waiver in the Next Generation ACO Model and the Shared Savings Program, we believe that the rules governing use of the SNF 3-day rule waiver are generally reasonable. However, based on our initial experiences in reviewing SNF 3-Day Rule Waiver applications, we believe there are two requirements, in particular, that impose an unnecessary burden on applicants, without a sufficient benefit to the administration of the Shared Savings Program.

First, the requirement under § 425.612(a)(1)(i)(A)(*4*) that an ACO submit, as part of its application for the SNF 3-day rule waiver, a narrative describing any financial relationships that exist between the ACO, SNF affiliates, and acute care hospitals is burdensome for ACOs and CMS. As explained in the June 2015 final rule (81 FR 32806), the SNF 3-day rule waiver only provides for coverage of SNF services that meet all applicable requirements except the requirement for a prior 3-day inpatient stay. The waiver does not protect financial or other arrangements between or among ACOs, ACO participants, ACOs providers/suppliers, or other individuals or entities providing services to Medicare beneficiaries from liability under the fraud and abuse laws or any other applicable laws (§ 425.612(e)(1)). The Shared Savings Program regulations do not prohibit ACOs or SNFs from having financial arrangements with acute care hospitals, nor do they require such arrangements. Therefore, we have found that the narratives are not useful to us for purposes of determining whether to approve a waiver request. Based on our experience with the implementation of SNF 3-day rule waivers, we proposed to remove the requirement at § 425.612(a)(1)(i)(A)(*4*) under which an ACO applying for the SNF 3-day rule waiver must submit a narrative describing any financial relationships between the ACO, SNF affiliate, and acute care hospitals. Removing this requirement would not only reduce burden for ACOs applying for the waiver but would also enable us to devote our application review resources to a rigorous review of other, more relevant application elements. Focusing our resources on the review of the information that is most directly relevant to determining an ACO's capacity to manage beneficiaries who are admitted to a SNF without a prior 3-day inpatient hospital stay, along with ongoing oversight and program compliance monitoring of the use of the waiver by approved ACOs (as described in section III.G.3.a.(1) of the proposed rule) would also allow us to more efficiently use our resources to ensure that the SNF 3-day rule waiver is being used appropriately and to address any potential concerns about use of the waiver. Although we do not believe it is necessary for ACOs to submit separate narratives describing their financial relationships for purposes of the SNF 3-day rule waiver, in the proposed rule we noted that under the Shared Savings Program regulations, ACOs, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities, including SNF affiliates, must maintain and give us access to certain documents and information related to items including financial arrangements related to ACO activities (§ 425.314(b)(1)). We also retain broad discretion under § 425.316 to audit ACOs, ACO participants, and ACO providers/suppliers for compliance with program rules, and the program rules also make clear that waivers under § 425.612 do not protect financial or other arrangements between or among ACOs, ACO participants, ACO providers/suppliers, or other individuals or entities providing services to Medicare beneficiaries or otherwise limit liability under the fraud and abuse laws or any other applicable laws (§ 425.612(e)).

Second, as explained in the proposed rule, we believe that the requirement under § 425.612(a)(1)(i)(C) that an ACO submit documentation demonstrating that each SNF included on its list of SNF affiliates has an overall rating of 3 or higher under the CMS 5-star Quality Rating System is unnecessarily burdensome. In order to meet this requirement, ACOs typically submit a screen shot from the CMS Nursing Home Compare Web site or other Nursing Home Compare information that reflects the star rating for each listed SNF. The submission of this documentation by the ACO does not add value to our review and approval of SNFs included on the ACO's SNF affiliate list. Instead, we obtain the information directly from our CMS Nursing Home Compare Web site during the application review process. In this way, we ensure that the most current information is used during the application review process. We also periodically monitor this information after an ACO has been approved to use the waiver because SNF affiliates are required to maintain an overall rating of 3 stars or higher, under § 425.612(a)(1)(iii)(A). Because we can obtain the required information directly from the CMS Nursing Home Compare Web site, the additional documentation submitted by the ACO as part of its application does not add value to our ability to review and approve SNF affiliates. Accordingly, we proposed to eliminate this documentation submission requirement by removing § 425.612(a)(1)(i)(C).

We sought comments on our proposed changes to the application requirements for the SNF 3-day rule waiver. We also welcomed other suggestions on how we might further decrease the burden for ACOs requesting approval to use the SNF 3-day rule waiver, without compromising our ability to ensure that ACOs and their SNF affiliates have the capacity to identify and manage beneficiaries receiving covered SNF services pursuant to the waiver.

Comment: Commenters uniformly supported these proposals. One commenter suggested eliminating the waiver application to reduce burden, and making the waiver available to all ACOs. A few commenters were supportive of the proposed changes to the waiver application but recommended that CMS ensure it has the resources to assess and monitor compliance with the requirement that SNF affiliates have and maintain at least a 3-star rating. One commenter encouraged CMS to reinforce in the final rule that the requirement for ACO SNF affiliates to have at least a 3-star rating is unchanged. In contrast, a few commenters recommended elimination of the requirement that SNF affiliates have and maintain at least a 3-star rating. For example, one commenter indicated that the requirement that SNF affiliates have and maintain at least a 3-star rating may impede beneficiary access or require beneficiaries to receive care at a SNF facility that is a greater distance from their family than a closer SNF facility that does not have at least a 3-star rating. A few commenters had recommendations related to CMS' methodology for determining star ratings. For example, one commenter suggested that CMS examine the star rating system, generally, to ensure appropriate risk adjustment is incorporated into the scoring methodology.

Response: We appreciate the comments in support of these proposals. As we stated in the June 2015 final rule (80 FR 32805), we believe incorporating the requirement that a SNF affiliate have

an overall rating of 3 or higher under the CMS 5-star Quality Rating System into the SNF 3-day rule waiver under the Shared Savings Program provides beneficiaries with evidence that the SNF affiliate provides quality care. As part of the application process, we intend to continue to verify that the ACO and its SNF affiliates meet all requirements related to the SNF 3-day rule waiver, but we believe that the burdensome and duplicative submission of CMS 5-star Quality Rating System documentation is not necessary to ensure compliance with the requirement that the ACO's SNF affiliates have a star rating of 3 or more. We emphasize that we are not removing or modifying the requirement in § 425.612(a)(1)(iii)(A) that SNF affiliates must have and maintain an overall rating of 3 or higher under the CMS 5-star Quality Rating System to remain eligible to partner with an ACO for purposes of the SNF 3-day rule waiver; we retain the requirement for SNF affiliates to have and maintain a 3-star or higher rating. Suggested changes to the methodology that we use for scoring facilities on Nursing Home Compare are outside the scope of this final rule though we intend to share these comments with the appropriate component within CMS.

Comment: We received several comments that did not directly address the proposals in this section but were more generally related to the SNF 3-day rule waiver. For example, one commenter expressed concerns that beneficiaries do not always know whether and when the ''standard'' SNF 3-day rule applies to them or if it has been waived because of their assignment to an eligible ACO.

Response: We thank the commenters for their thoughtful suggestions on possible ways we might further improve policies and/or operations related to informing beneficiaries regarding the requirements for coverage of SNF services and any applicable waiver of the SNF 3-day rule. We will consider these issues further and may address these suggestions in future rulemaking and/or through guidance documents.

We are finalizing the changes to the SNF 3-Day Rule waiver application procedures in this section as proposed. We are removing § 425.612(a)(1)(i)(A)(*4*), which requires SNF 3-Day Rule Waiver applicants to submit a narrative describing any financial relationships that exist between the ACO, SNF affiliate, and acute care hospitals. We are also finalizing our proposal to remove § 425.612(a)(1)(i)(C), which requires an ACO applying for the waiver to submit documentation demonstrating that each SNF affiliate on its SNF affiliate list has an overall rating of 3 or higher under the CMS 5-star Quality Rating System.

b. Modifications to the Shared Savings Program Initial Application

(1) Background

In order to participate in the Shared Savings Program, organizations must meet certain eligibility requirements, including the statutory requirement to define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care. Additionally, the ACO must demonstrate it meets patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments or the use of individualized care plans. We discussed and finalized details for ACO eligibility criteria, including the four required processes and patient-centeredness criteria, in the November 2011 final rule (76 FR 67826 and 67827) and made updates to them in the June 2015 final rule (80 FR 32722 through 32725). Section 425.204(c)(1) articulates the supporting documents and materials an ACO must submit to demonstrate that the ACO satisfies the eligibility requirements to participate in the Shared Savings Program.

To obtain a determination regarding whether an ACO meets the requirements to participate in the Shared Savings Program, a prospective ACO must submit a complete application in the form and manner required by us by the deadline established by us (§ 425.202(a)(1)). The content of the application is outlined at § 425.204. Section 425.204(c) states that as part of the application, and upon request thereafter, an ACO must submit to us certain supporting documentation to demonstrate that the ACO satisfies the requirements of the Shared Savings Program. The supporting documentation required to be included in the application is discussed in detail in the proposed rule (82 FR 34116 through 34117).

Once an applicant has submitted the information required under § 425.204, we evaluate it to determine whether the applicant satisfies the Shared Savings Program requirements. We notify ACO applicants during the application review process when information is missing or when supplemental documentation or other information is necessary to make a determination on the ACO's application and provide opportunities for the ACO to submit the requested additional information for review. At the end of the application review process, we approve or deny the application and notify the ACO of our determination.

(2) Proposals

In conducting Shared Savings Program application reviews, we have found that many of the document submission requirements in § 425.204(c)(1) substantially increase application and review burden without lending significant value to our review of an organization's application to confirm that the ACO meets the eligibility requirements for participation in the Shared Savings Program. We believe it would meet program needs and reduce applicant burden if we were to revise § 425.204(c)(1) to remove the requirement to submit supporting documents or narratives and instead provide that we may request these materials if additional information is needed in order to fully assess the ACO's application before making a decision to approve or deny the application.

To illustrate, as discussed in the proposed rule, we require under § 425.204(c)(1)(ii), as part of the application process, that the ACO submit documentation addressing the required processes and patient centeredness criteria under § 425.112. This requirement is addressed in the Medicare Shared Savings Program Initial Application through the requirement that an applicant ACO submit narratives describing how it will define, establish, implement, evaluate, and periodically update each process (see application on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/for-acos/application-types-and-timeline.html*). In these narratives, the ACO must also describe certain additional details regarding the required processes:

- Process to promote evidence-based medicine. The ACO must describe how it will:

++ Encourage the use of protocols grounded in evidence-based medicine in the case of diagnoses with significant potential for the ACO to achieve quality improvements, while taking into account the circumstances of individual beneficiaries; and

++ Use the internal assessments of this process to continuously improve the ACO's care practices.

- Process to promote beneficiary engagement. The ACO must describe how it will:

++ Evaluate the health needs of its assigned beneficiary population (including consideration of diversity in its patient population) and develop a

plan to address the needs of its population;

++ Communicate clinical knowledge/evidence-based medicine to beneficiaries in a way they can understand;

++ Engage beneficiaries in shared decision-making in ways that consider beneficiaries' unique needs, preferences, values and priorities;

++ Establish written standards for beneficiary access and communication as well as a process for beneficiaries to access their medical records; and

++ Use the internal assessments of this process to continuously improve the ACO's care practices.

• Process to internally report quality and cost metrics. The ACO must describe:

++ How the ACO will use these results to improve care and service over time; and

++ How the ACO will use the internal assessments of this process to continuously improve the ACO's care practices.

• Process to promote coordination of care. The ACO must describe:

++ The ACO's methods and processes to coordinate care throughout an episode of care and during care transitions, such as discharge from a hospital or transfer of care from a primary care physician to a specialist (both inside and outside the ACO).

++ The ACO's individualized care program, along with a sample individual care plan, and explain how the ACO uses this program to promote improved outcomes for, at a minimum, high-risk and multiple chronic-condition patients.

++ How individual care plans take into account the community resources available to beneficiaries.

++ Additional target populations that would benefit from individualized care plans.

++ How the ACO will use the internal assessments of this process to continuously improve the ACO's care practices.

++ How the ACO will encourage and promote use of enabling technologies for improving care coordination for beneficiaries.

++ How the ACO intends to partner with long-term and post-acute care providers, both inside and outside the ACO, to improve care coordination for its assigned beneficiaries.

As we explained in the proposed rule, as a result of our experience in reviewing these narratives, we have determined that while they can be helpful to verify that the ACO has established the required processes and defined patient-centeredness criteria prior to its entry into the Shared Savings Program, the specific details of the processes the ACO has established are not particularly important or relevant for purposes of assessing whether the ACO is eligible to participate in the program. In fact, ACOs have indicated that their initial plans for the processes required under § 425.112 as articulated in their program application often change as a result of obtaining additional information about their ACO participants' and ACO providers/suppliers' processes and gaining additional experience during implementation of the processes. We believe such improvements to ACO processes based on program experience are reasonable to expect and should be encouraged. First, under § 425.112(b), ACOs are required to evaluate and periodically update each process and as they do so, initially implemented processes will necessarily change to accommodate lessons learned. Moreover, once the ACO begins to request claims information and other CMS data and to incorporate this information into its operations, the ACO may discover that certain assumptions it made at the time of application should be adjusted to maximally improve the quality of care or cost efficiencies for the ACO's assigned population. In rare instances, particularly in the early days of the program before stakeholders fully understood the implications of program participation, we found review of such narratives useful to understand the level of an ACO's readiness for participation in the Shared Savings Program. However, such narratives have not been particularly useful in determining if the ACO meets the requirements for participation in the Shared Savings Program. In a vast majority of cases, we now believe it is sufficient that the ACO 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. Therefore, we believe it would reduce burden for ACOs, without compromising our ability to determine whether an ACO meets the criteria for participation in the Shared Savings Program, to require that the ACO certify that it meets the requirements in § 425.112, and only submit a narrative or other documentation describing how the ACO will implement the required processes and patient-centeredness criteria upon our request. Further, we do not anticipate that this change would have a significant effect on beneficiaries receiving services from ACO providers/suppliers because as noted earlier, we anticipate that ACOs would update each process as they gain experience and, as they do so, initially implemented processes that might have been reflected in the narrative or other supporting documentation submitted with their application would necessarily change to accommodate lessons learned.

Similarly, as part of the application process, the Shared Savings Program regulations require the ACO to submit materials documenting the ACO's organization and management structure, including an organizational chart, a list of committees (including names of committee members) and their structures, and job descriptions for senior administrative and clinical leaders (§ 425.204(c)(1)(iii)). As we indicated in the proposed rule, we have found the organizational chart useful for purposes of evaluating if an ACO meets eligibility requirements, and anticipate continuing to request this chart from applicants; however, we have found that further detail including lists of committees and job descriptions for senior administrative and clinical leaders have not added particular value to our review and approval of applications. Moreover, the receipt of such materials as part of the ACO's application has not significantly impacted our ability to determine whether the ACO meets the requirements regarding leadership and management in § 425.108. We believe, on balance, that our need for such detailed information from all applicants is outweighed by our desire to reduce application burden. In particular circumstances where additional information would aid our review, we believe our need for such detailed information can be reasonably met by requiring applicants to submit such materials upon our request. As a result, we believe it would be less burdensome for us to require ACO applicants to certify that, for example, they meet the leadership and management requirements found at § 425.108 rather than requiring all ACO applicants to submit detailed materials (such as job descriptions) or narratives about the ACO's committees and leadership.

While we do not anticipate having to routinely request such materials to supplement our review and approval of ACO applications to participate in the Shared Savings Program, we explained in the proposed rule that we believe it is important to retain the discretion to do so in limited cases where such detail could be useful. Therefore, we proposed to make revisions to our application requirements as discussed in the proposed rule (82 FR 34117 through 34120). We also noted that in cases

where an ACO is requested to submit additional material for review in conjunction with its application, and we find that the material is inconsistent with program requirements, then we may deny the ACO's application. Similarly, if we discover an inconsistency after the ACO has already been approved to participate in the program, the ACO may be subject to the pre-termination actions set forth in § 425.216, termination under § 425.218, or both.

In the proposed rule, we also explained that we do not believe it is necessary for ACO applicants to submit narratives describing how they would distribute shared savings payments or how the proposed plan would achieve the specific goals of the Shared Savings Program and the general aims of better care for individuals, better health for populations, and lower growth in expenditures, as required by § 425.204(d). Based on our experience, such narratives have not been useful in determining if the ACO meets requirements for participation in the program or whether an ACO's application should be approved. We believe it would be more useful to us and less burdensome for ACOs if we were instead to require that, an ACO, as part of its application to participate in the Shared Savings Program, certify that it has a method and plan to receive shared savings payments and to distribute those payments to its ACO participants and ACO providers/suppliers, as required by the statute. We note, however, that we continue to believe it is useful to stakeholders to know how various ACOs have chosen to use or distribute the shared savings they earn. Therefore, we indicated that in the interest of transparency, we will continue to require ACOs to publicly report information on their dedicated Web pages about their shared savings and shared losses, including information about the total proportion of shared savings invested in infrastructure, redesigned care processes, and other resources to support the three-part aim goals of better health for populations, better care for individuals, and lower growth in expenditures, including the proportion distributed among ACO participants, as required under § 425.308(b)(4).

In light of our experience with the review of the documentation submitted as part of the ACO's initial application, we proposed several modifications to our requirements for document submission. We proposed to retain all requirements related to ACO eligibility criteria and public reporting, as currently specified under the Shared Savings Program regulations. However, to reduce application burden without compromising our ability to evaluate applications effectively for compliance with Shared Savings Program requirements, we proposed to modify certain sections of our regulations that require ACOs to submit supporting materials and documentation at the time of application. Instead of requiring submission of certain materials, narratives, or supporting documentation, we proposed to require ACOs to certify that they meet the applicable eligibility and documentation requirements as specified under our program rules. At the same time, we recognized that there have been instances when the review of supporting documentation and/or narratives has been helpful in making a determination about an ACO's eligibility for participation in the program. Therefore, although we proposed to eliminate the general requirement that ACOs submit certain documentation as part of their initial application to participate in the Shared Savings Program, we proposed to retain the right to request the submission of supporting materials and documentation in cases when such additional information would be useful in making a determination regarding the ACO's application. We indicated that we believe that this proposed modification to the regulations governing ACO applications would introduce additional flexibility that would reduce the level of burden inherent in the Shared Savings Program application process while also ensuring we are still able to appropriately evaluate an ACO's eligibility for program participation.

Accordingly, in order to reduce application burden while retaining flexibility to obtain additional documentation when necessary to determine ACO eligibility and compliance with program rules, we proposed to remove the requirements in §§ 425.204(c)(1) and (d), 425.112(a)(3)(i) and (ii), and 425.112(b)(4)(ii) for the submission of certain specified documents and narratives as part of an ACO's application to participate in the Shared Savings Program. Specifically, we proposed to revise § 425.204(c)(1) to require an ACO, as part of its application, to certify that it satisfies the Shared Savings Program requirements and to submit, upon CMS request, supporting materials (including narratives) and documentation demonstrating that the ACO satisfies program requirements indicated in proposed revised § 425.204(c). Additionally, we proposed to revise § 425.204(d) to indicate that the ACO must certify, as part of its application to participate in the Shared Savings Program, that it has a mechanism and plan to receive and use payments for shared savings, including criteria for distributing shared savings among its ACO participants and ACO providers/suppliers. We also proposed to make a conforming change to remove paragraphs (d)(1) through (3) of § 425.204, which relate to the submission of narratives related to the ACO's use of shared savings payments. This proposal did not include a requirement that the ACO submit information regarding its mechanism and plan for receiving and using shared savings upon request. As explained in the proposed rule, we do not intend to request this information as part of the application process because in our experience, how an ACO intends to use or distribute shared savings has not been a relevant consideration during any application cycle to determine whether the ACO has met the eligibility requirements to participate in the Shared Savings Program. However, we noted that we continue to believe that information on how an ACO uses and distributes its shared savings is useful for the public, and therefore ACOs will continue to be required to publicly report this information under § 425.308(b)(4)(ii).

We also proposed similar changes to the requirements in § 425.112(a)(3)(i), (a)(3)(ii), and (b)(4)(ii) to remove references to the submission of narratives to explain or describe how the ACO will implement the required elements of the ACO's care processes and patient-centeredness criteria. ACOs must still implement these care processes and adopt a focus on patient-centeredness; however, we proposed that they would no longer need to submit descriptions of how they will satisfy these requirements as part of their initial application. We noted, however, that ACOs may still be required to submit upon request a description or documentation sufficient to describe how the ACO will implement the required processes and patient-centeredness criteria found at § 425.112 because under the proposed revisions to § 425.204(c)(1)(ii), CMS would retain the discretion to request such documentation from the ACO at any time.

In summary, we stated that we believe these modifications to the application requirements will significantly reduce the burden of applying to participate in the Shared Savings Program without reducing our ability to ensure that applicants meet the established

eligibility requirements. Rather than requiring every applicant to submit detailed supporting documents or narratives for all of these requirements, we would instead request supporting documents or narratives only if additional information is needed in order to fully assess an ACO's application before making a decision to approve or deny the application. Further, we did not anticipate that the proposed modifications to our application requirements would have any effect on beneficiaries receiving care from providers and suppliers participating in the Shared Saving Program, nor did we believe that the proposed changes would affect our program integrity efforts, because we would retain discretion to request such information (and more targeted and appropriate information) as needed. We sought comment on these proposals and on additional ways to reduce burden in the application process.

Comment: Commenters generally expressed widespread support for the proposals related to reducing application burden. However, a few commenters, including some beneficiary advocates, expressed significant concerns about the proposal to remove the requirement that ACOs submit documentation related to patient-centeredness as part of their applications, stating, for example: ''We believe that it is imperative that ACOs be held to the highest possible standard for patient-centeredness.'' These commenters encouraged CMS to explore alternatives to reduce application burden. One of these commenters suggested that CMS require an ACO applicant to submit any existing care processes, along with a description of its capacity and strategy for evaluating and updating these processes. This commenter agreed that it is important for CMS to retain the right to request additional documentation at any time. Another commenter stated a belief that removing the application narratives ''violates the spirit of the MSSP ACO model'' and stated that the inclusion of such narratives in the application supports care improvement activities by emphasizing the importance of the applicant's planning and introspection about its care processes.

Another commenter expressed concern that in the absence of the submission of narratives describing required processes and a rigorous evaluation by CMS, all health systems would be assessed solely based on cost savings and administration. The commenter was concerned that absent a requirement for ACOs to detail how they intend to implement the required processes, a world-class, integrated health care system would, on paper, look the same as a system that had not undertaken improvement activities. Similarly, another commenter noted, ''we are concerned that replacing the narrative with a certification may result in some program applicants simply checking the box to say that they have these processes which contain critical patient protections without actually considering whether the ACO is prepared to implement them in the context of the Shared Savings Program.''

Response: We agree that ACOs should be held to the highest possible standard for patient-centeredness, however, we respectfully disagree that the requirement, as part of the application, to submit a narrative detailing the ACO's plans for developing patient-centered processes accomplishes this goal. We believe that other program elements, like the patient experience of care survey measures used to assess ACO quality performance and our internal monitoring of utilization, are better indicators of how well ACOs are meeting patient-centeredness criteria. We intend to continue assessing and monitoring ACO performance regarding patient-centeredness and the other required care processes. In addition, we note that under the proposed changes to the application requirements, which we are finalizing in this rule, we retain the flexibility to request submission of various narratives and documentation when this additional information is needed to fully assess the ACO's application. We will continue to consider whether review of certain narratives would help support Shared Savings Program goals, and will consider whether it would add value to our ACO application review process to request a more refined or targeted narrative related to patient-centeredness and the other required care processes.

Comment: A commenter representing physician specialists raised concerns about the proposal to no longer require Shared Savings Program applicants to submit narratives describing how they would distribute shared savings payments. The commenter suggested that CMS should require ACOs to distribute shared savings to ACO providers/suppliers. Another commenter questioned how CMS would know if the ACO followed the plan it set forth if CMS no longer required the ACOs to provide details about how any shared savings would be distributed at the outset via their application.

Response: We respectfully disagree with the commenters who believe it is necessary for Shared Savings Program applicants to continue to submit narratives describing how they would distribute shared savings payments in order to permit us to review and approve an ACO's eligibility to participate in the program. We believe it is appropriate for ACOs to continue to have the freedom to choose how to distribute or otherwise use any shared savings they earn, within the confines of the agreements they make with ACO participants and ACO providers/suppliers. Furthermore, we believe it is the responsibility of the parties signing those agreements to understand and enforce the terms of the agreement. We note, however, that we are maintaining the requirement for ACOs to publicly report on how they use and distribute their shared savings and we intend to continue to monitor ACO adherence to that requirement.

We are finalizing the policies in this section as proposed. Specifically, we are finalizing our proposals to: (1) Remove the requirements in §§ 425.204(c)(1) and (d), 425.112(a)(3)(i) and (ii), and 425.112(b)(4)(ii) for the submission of certain specified documents and narratives as part of an ACO's application to participate in the Shared Savings Program; (2) revise § 425.204(d) to indicate that the ACO must certify, as part of its application to participate in the Shared Savings Program, that it has a mechanism and plan to receive and use payments for shared savings; (3) make a conforming change to remove paragraphs (d)(1) through (3) of § 425.204, which relate to the submission of narratives related to the ACO's use of shared savings payments; and (4) make similar changes to the requirements in § 425.112(a)(3)(i), (a)(3)(ii), and (b)(4)(ii) to remove references to the submission of narratives.

4. Addressing Compliance With ACO Participant TIN Exclusivity Requirement

a. Background

Under the Shared Savings Program, ACO participant TINs are not required to be exclusive to one Shared Savings Program ACO unless the TIN submits claims for primary care services used to determine the ACO's assigned population (§ 425.306(b)). The purpose behind this requirement is to ensure that we are able to assign a unique set of beneficiaries to each ACO participating in the Shared Savings Program. Therefore, as part of the Shared Savings Program application process and upon an ACO's request to add an ACO participant TIN, we check the TIN against all other Shared Savings Program ACO participant lists. If the

TIN appears on the ACO participant list of one or more other ACOs, the TIN is considered to be ''overlapping.'' We then determine whether the overlap is permissible under our program rules. If the overlap is not permissible (because the TIN has a history of billing for primary care services used in our assignment methodology) then we require the ACO that is seeking to add the TIN to its ACO participant list to rectify the overlap by the deadline we have established for making changes to the next performance year's ACO participant list. If the overlap is permissible (because the TIN does not have a history of billing for primary care services used in our assignment methodology) then the ACO participant TIN can be approved to be an ACO participant in more than one ACO for the performance year. Each time we run the assignment algorithm during the course of the performance year, we monitor overlaps to ensure that the overlaps continue to be in compliance with § 425.306(b).

In a few instances, we have discovered that ACO participant TINs that have been approved to participate in multiple ACOs subsequently began billing for primary care services used in assignment during a benchmark or performance year. Although our program rules permit us to take compliance action against ACOs for violations of Shared Savings Program requirements, they do not specifically address what compliance actions we would impose on ACOs in instances where an ACO participant falls out of compliance with the requirement in § 425.306(b)(2) that an ACO participant TIN that submits claims for primary care services used in assignment be exclusive to a single ACO during a benchmark or performance year, or when non-compliance with this requirement is discovered during the 3-month claims runout for a benchmark or performance year. Moreover, the program rules do not address what modifications to our assignment methodology could be made to account for this overlap.

We believe it is important for ACOs, ACO participants, and ACO providers/suppliers to have updated and accurate information regarding their participation status in the Shared Savings Program. For example, participation in a Shared Savings Program ACO has implications for ACO providers/suppliers under the new Quality Payment Program (see 81 FR 80496 through 80501). The Quality Payment Program replaces a patchwork system of Medicare programs with a flexible system that allows eligible clinicians to choose from two paths that link payments to quality: MIPS and participation in Advanced APMs. The Quality Payment Program, through MIPS and the APM incentive, will impact eligible clinicians' payments beginning in payment year 2019 based on 2017 reporting.

Under the CY 2017 Quality Payment Program final rule with comment period, eligible clinicians participating in Advanced APMs (including Tracks 2 and 3 under the Shared Savings Program) may become Qualifying APM Participants and receive a 5 percent APM Incentive Payment if they have a sufficient percentage of payments for Part B covered professional services, or a sufficient percentage of Medicare patients that are attributable to services furnished through an Advanced APM for a given performance year. In addition to earning a 5 percent APM Incentive Payment, Qualifying APM Participants are not subject to the MIPS reporting requirements and payment adjustment for a given performance year. As a result, revisions to ACO participant lists that occur mid-year or following the end of a benchmark or performance year could have widespread implications not only for the ACO, but also for its ACO providers/suppliers under the Quality Payment Program.

b. Proposals

As participation in the Shared Savings Program grows and more ACOs and ACO participants join the program, we believe overlapping TINs are likely to become more common. We also believe that changes to our program rules regarding the claims that will be considered in assigning FFS beneficiaries to an ACO (specifically, the policy finalized in the June 2015 final rule to exclude services furnished by several physician specialty types from the assignment methodology) may result in a greater number of permissible ACO participant TIN overlaps (see 80 FR 32753 and 32754). As a result, we anticipate there could also be an increased number of cases where ACO participant TINs with initially permissible overlaps could become out of compliance with the requirement at § 425.306(b)(2) that an ACO participant TIN be exclusive to a single Shared Savings Program ACO if the TIN bills for primary care services that are used to assign beneficiaries to the ACO. This could occur, for example, if a group practice that initially includes only physician specialty types whose services are excluded from the assignment methodology were to subsequently employ a non-physician practitioner who bills for primary care services. We believe these types of practice arrangements are becoming increasingly common.

Therefore, as we stated in the proposed rule, we believe it is necessary to streamline our approach to handling such situations in order to reduce the burden and uncertainty for ACOs when changes in ACO participant billing practices result in an ACO participant falling out of compliance with the exclusivity requirement at § 425.306(b)(2). Rather than the current policy under which an ACO may be required to remove an overlapping ACO participant and recertify its ACO participant list for the performance year (thus necessitating redetermination of beneficiary assignment and delays in or revisions to benchmark or performance year calculations), we believe it would be less disruptive for ACOs if we were to permit overlapping TINs that begin billing for services used in assignment during a benchmark or performance year (including claims for services furnished during the benchmark of performance year, but submitted during the 3-month claims runout) to remain on the ACO participant lists for all affected ACOs for the remainder of the performance year in which we determine that an overlap exists. For example, assume that, based on an analysis of claims for services furnished in performance year 2018, we were to identify an impermissible overlapping TIN in January 2019 after the ACO participant lists for performance year 2019 had already been certified. Under this proposal, the TIN would be able to remain on the ACO participant lists of all affected ACOs for the 2018 performance year as well as the remainder of performance year 2019. To ensure that an overlapping TIN is not inadvertently used in the assignment algorithm for multiple ACOs when determining where a beneficiary received the plurality of primary care services, which could result in assignment of the same beneficiary to multiple ACOs, we proposed to simply exclude any claims for services furnished by the overlapping TIN from the assignment methodology when conducting final beneficiary assignment for any benchmark or performance year in which the TIN bills Medicare for services used in our assignment methodology. The affected ACOs would be required to resolve the overlap prior to recertification of their ACO participant lists for the subsequent performance year. If the overlap remains unresolved when the ACOs certify their ACO participant lists for the next

performance year, we would remove the TIN from the ACO participant lists of all ACOs seeking to include the TIN, in accordance with our current policy for resolving overlaps. For example, in the hypothetical case above, if the overlap were to remain unresolved when the ACOs certify their ACO participant lists for performance year 2020, we would remove the TIN from the ACO participant lists for all ACOs seeking to include the TIN as an ACO participant for performance year 2020.

Therefore, we proposed to modify our program rules in § 425.306 and subpart E of part 425 to address this issue. We proposed to modify § 425.306(b) to indicate that if, during a benchmark or performance year (including the 3-month claims run out period for such benchmark or performance year), an ACO participant that participates in more than one ACO begins billing for services that would be used in assignment, we would not consider any services billed through that TIN when performing beneficiary assignment for the applicable benchmark or performance year. We also proposed to eliminate the reference to ''primary care'' in § 425.306(b)(2) when describing the services used to determine the ACO's assigned beneficiary population to conform with our proposal to implement section 17007 of the 21st Century Cures Act under which we would consider all services furnished in RHCs and FQHCs in the assignment methodology starting in the 2019 performance year. In addition, the ACOs in which the overlapping TIN is an ACO participant may be subject to compliance action (as provided under § 425.216) or termination under § 425.218. Compliance actions may include requiring each ACO that includes the TIN as an ACO participant to submit a corrective action plan explaining how the ACO plans to work with the overlapping ACO participant to resolve the overlap for the next performance year. If the overlap remains unresolved by the date specified by us in our request for a corrective action plan, we would remove the overlapping ACO participant TIN from the ACO participant list of each ACO for the subsequent performance year.

We also proposed to revise our general assignment methodology at § 425.400(a)(1) to add new paragraph (a)(1)(iii) to indicate that when we determine final assignment after the end of each benchmark or performance year, we will exclude claims for services furnished during the benchmark or performance year by an ACO participant that participates in more than one ACO. We stated that we believe that this policy will ensure a uniquely assigned beneficiary population for each ACO and prevent the same beneficiaries from being included in determining benchmark or performance year expenditures for more than one ACO.

Comment: Commenters were nearly all supportive of our proposed changes to our policies for addressing situations in which an overlapping ACO participant TIN begins billing for services that are used in beneficiary assignment during a benchmark or performance year. However, some commenters stated that our proposal to exclude all claims for services furnished by an overlapping ACO participant from the assignment methodology was overbroad and that such exclusions should be limited to instances in which there is a significant overlap. For example, one commenter recommended that CMS only exclude a TIN if the primary care services are billed over an extended period, for example, for more than one-half of the performance year.

Response: We appreciate receiving the comments in support of this proposal and the other thoughtful comments. We do not believe it would be appropriate to exclude a TIN only if the services used in assignment are billed during more than one-half of the performance year or if the overlap is otherwise significant. Such approaches would not ensure a uniquely assigned beneficiary population for each ACO and, therefore, the same beneficiaries could inappropriately be included in determining benchmark or performance year expenditures for more than one ACO.

Based on a review of the comments, we believe that finalization of the proposed policies will ensure that we are able to continue to assign a unique set of beneficiaries to each ACO participating in the Shared Savings Program and avoid making duplicate shared savings payments for ACOs with TINs that participate in more than one ACO, while preserving the flexibility that is currently extended to ACO participants that do not bill for services used in assignment, and recognizing the possibility for mid-year changes in care and billing practices by these ACO participants. We believe that implementing the proposed changes to our process for addressing ACO participant overlaps will improve ACO and ACO participant understanding of our policies and requirements regarding ACO participant exclusivity, while also reducing burden for ACOs that currently must recertify their ACO participant lists and may be subject to retrospective modifications or delays in assignment and other related benchmark or performance year calculations. Additionally, for purposes of the Quality Payment Program, ACO participant TINs and the eligible clinicians that bill through those TINs will have greater certainty regarding whether they qualify as participating in an APM or Advanced APM for a performance year. Under the proposed policy, which we are finalizing, an ACO participant will know for the entire performance year with certainty that it is participating in a particular APM (or Advanced APM) entity.

Comment: A commenter suggested that CMS alert ACOs when there is a provider or supplier identified as participating in more than one ACO so that both ACOs and the affected provider/supplier have an opportunity to correct the issue.

Response: Each time we run the assignment algorithm during the performance year, we monitor overlaps to ensure that the overlaps continue to be in compliance with § 425.306(b). We notify stakeholders when overlaps occur and require them to make appropriate corrections. Additionally, ACO participant list information is made publicly available at *https://data.cms.gov*. ACOs can use the Medicare Shared Savings Program ACO Participants data sets to identify allowable overlaps annually. The data sets also allow an ACO to verify whether TINs joining their ACO have the same legal business name as a TIN already participating in an ACO.

Comment: A few commenters expressed general concerns regarding the assignment process as it relates to services furnished by specialists.

Response: While these comments were beyond the scope of the proposed rule, we expect to continue to consider and refine the claims-based assignment process over time, and will take into consideration the important role played by specialty practices when assessing any potential changes to our assignment methodology.

We are finalizing the proposed changes to our policies for addressing compliance with the ACO participant TIN exclusivity requirement as proposed. Specifically, we are finalizing our proposals to: (1) Modify § 425.306(b) to indicate that if, during a benchmark or performance year (including the 3-month claims run out period for such benchmark or performance year), an ACO participant that participates in more than one ACO begins billing for services that would be used in assignment, we would not consider any services billed through that TIN when performing beneficiary assignment for the applicable benchmark or

performance year; (2) eliminate the reference to ''primary care'' in § 425.306(b)(2) when describing the services used to determine the ACO's assigned beneficiary population; and (3) revise our general assignment methodology at § 425.400(a)(1) to add new paragraph (a)(1)(iii) to indicate that when we determine final assignment after the end of each benchmark or performance year, we will exclude claims for services furnished during the benchmark or performance year by an ACO participant that participates in more than one ACO.

5. Treatment of Individually Beneficiary Identifiable Payments Made Under a Demonstration, Pilot, or Time Limited Program

a. Background

Under section 1899(d) of Act, ACOs participating in the Shared Savings Program are accountable for the total Parts A and B costs for the Medicare FFS beneficiaries assigned to the ACO. Therefore, in addition to Medicare Parts A and B claims, we include non-claims based individually beneficiary identifiable payments made from the Medicare Trust Funds when performing financial calculations for the Shared Savings Program, including establishing, adjusting, and updating financial benchmarks and calculating performance year expenditures. We internally track these non-claims based beneficiary identifiable payments through a separate CMS system that receives and stores these non-claims based payments made from the Medicare Trust Funds under a demonstration, pilot or time limited program.

To date, when we perform ACO benchmarking and financial calculations under the Shared Savings Program, we have included (in addition to all Medicare Parts A and B claims) all non-claims based individually beneficiary identifiable payments for the applicable benchmark or performance year that are included in the separate CMS system, including any payments made during the 3-month claims run-out period for the benchmark or performance year. This means that to date we have included in the calculation of historical benchmarks and performance year expenditures some interim payments made under a demonstration, pilot, or time limited program that will be subject to subsequent reconciliation to determine the final payment amount. However, because the various demonstrations, pilots, or time limited programs may have different operational schedules from the Shared Savings Program, it is not possible for us to include all interim and final beneficiary identifiable payments made under these initiatives in benchmarking and financial reconciliation calculations for the Shared Savings Program; and, as a result, these calculations have excluded some interim and final non-claims based beneficiary identifiable payments made under certain demonstrations, pilots, or time limited programs. For example, because of the timing and availability of BPCI non-claims based payment amounts, to date we have included only up to two quarters of interim payment data for BPCI in ACO benchmarking and financial reconciliation calculations for the Shared Savings Program and no final payment amounts.

To date, non-claims based individually beneficiary identifiable payments represent a relatively minor proportion of an ACO's total Part A and B beneficiary expenditure amounts as determined under the Shared Savings Program (mean of 0.09 percent overall impact of ACO non-claims based payments on total per capita expenditures and a mean of 137 person-years in an ACO's assigned beneficiary population with a non-claims based payment during the year; minimum −0.72 percent, 0 person-years; maximum 1.24 percent, 1,865 person-years). For the demonstrations, pilots, or time limited programs that include interim and final reconciliations, the impact of including the non-claims based payments could be positive or negative for an ACO for a given performance year. Additionally, a preliminary analysis suggests that interim payments made under select demonstrations, pilots, or time limited programs fluctuate on a quarterly basis. We refer the reader to the proposed rule (82 FR 34122 through 34123) for further details about the results of this analysis.

Fluctuations in the non-claims based payments for certain initiatives, such as BPCI, have generated stakeholder concern. Further, stakeholders note that the impact of including interim payments in financial calculations may become greater in the future, given the increasingly widespread interest in participation in alternative payment models and the growing number of such models being tested through the CMS Innovation Center. Stakeholders have therefore suggested that we should revise our policies to clarify that only final non-claims based payments made within the 3 months claims run out period under a demonstration, pilot, or time limited program will be included in the calculation of an ACO's benchmark and performance year expenditures.

b. Proposals

Our preliminary analysis, as discussed in the background section, suggests that interim non-claims based payments (that is, payments that are subject to reconciliation at a later date) made under a demonstration, pilot, or time limited program can fluctuate significantly from quarter to quarter and may not reflect the actual final reconciled payment amount. Thus, as we stated in the proposed rule, we agree with the stakeholders who have suggested that only final non-claims based payments made under a demonstration, pilot, or time limited program should be included in financial calculations related to benchmarks and performance year expenditures under the Shared Savings Program. We believe this would be a reasonable approach to determining Parts A and B expenditures for assigned beneficiaries for both benchmark and performance years given the uncertain impact of including interim payments that are subject to further reconciliation on financial calculations for the Shared Savings Program. We also agree that use of interim payments made under a demonstration, pilot, or time limited program could have an increasingly large effect on ACO benchmarks and performance year expenditure calculations in the future given widespread stakeholder interest in participating in alternative payment models and CMS interest in testing and expanding additional payment models that may lead to higher quality and more coordinated care at a lower cost to Medicare.

Therefore, we proposed to modify our regulations at §§ 425.602(a)(1)(ii), 425.603(c)(1)(ii), and 425.603(e)(2)(ii) to add new provisions to indicate that, (1) when establishing benchmarks for agreement periods beginning before 2018, we will include all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot, or time limited program, (2) for agreement periods beginning in 2018 and subsequent years, we would only include individually beneficiary identifiable payments made under a demonstration, pilot, or time limited program that are final and not subject to further reconciliation, and (3) for the 2018 performance year and subsequent performance years in agreement periods beginning in 2015, 2016, and 2017, the benchmark would be adjusted to reflect only individually beneficiary identifiable final payments made under

a demonstration, pilot, or time limited program. Additionally, we proposed to add new §§ 425.604(a)(6)(ii)(A), 425.606(a)(6)(ii)(A) and 425.610(a)(6)(ii)(A) indicating that when calculating expenditures for performance years before 2018, we will include all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot, or time limited program. We also proposed to add new §§ 425.604(a)(6)(ii)(B), 425.606(a)(6)(ii)(B) and 425.610(a)(6)(ii)(B) indicating that when calculating expenditures for performance year 2018 and subsequent performance years, we would only include individually beneficiary identifiable payments made under a demonstration, pilot, or time limited program that are final and not subject to further reconciliation. To be consistent with our treatment of claims-based payments, such final payments would have to be available in the separate CMS system by the end of the 3-month claims run out period.

We invited comments on this proposal.

Comment: We received few comments on this proposal. Those that commented were supportive, agreeing that the proposed approach would appropriately help reduce fluctuations in payment amounts from quarter to quarter. A few commenters suggested that interim payments provide a ''signal to final payments.'' In lieu of removing interim payments from our financial calculations, these commenters requested that CMS indicate the amounts of interim and final beneficiary identifiable payments made under demonstrations, pilots or other time-limited programs in the ACO financial reports.

Response: We appreciate the comments in support of this proposal. We continue to believe that our proposal to include only final payments made under a demonstration, pilot or time limited program is a reasonable approach to determining Parts A and B expenditures for assigned beneficiaries for both benchmark and performance years given the uncertain impact on ACOs' financial calculations of including interim payments that will be subsequently revised to reflect the final reconciled payment amounts. We are exploring improvements to feedback reports and data files provided to ACOs to increase program transparency. We appreciate the suggestions regarding including payments under a demonstration, pilot, or time limited program in the financial reports, and we will take them under advisement as we work to further refine the reports.

We are finalizing the policies in this section as proposed, with the exception of a minor revision to § 425.603(e)(2)(ii)(C) to address a technical error that was made in the proposed rule. In the proposed rule, we inadvertently included a reference to the benchmark in the proposed regulatory text for this provision. However, § 425.603(e) establishes the policies for determining risk adjusted county fee-for-service expenditures, which are used in calculating an ACO's regional fee-for-service expenditures. In this final rule, we are revising the language at § 425.603(e)(2)(ii)(C) to correct this reference.

I. Value-Based Payment Modifier and Physician Feedback Program

1. Overview

Section 1848(p) of the Act requires the establishment of a value-based payment modifier (VM) that applies to specific physicians and groups of physicians the Secretary determines appropriate starting January 1, 2015, and to all physicians and groups of physicians by January 1, 2017. On or after January 1, 2017, section 1848(p)(7) of the Act provides the Secretary discretion to apply the VM to eligible professionals (EPs) as defined in section 1848(k)(3)(B) of the Act. Section 1848(p)(4)(C) of the Act requires the VM to be budget neutral. The VM and Physician Feedback programs continue our initiative to recognize and reward clinicians based on the quality and cost of care provided to their patients, increase the transparency of health care quality information and to assist clinicians and beneficiaries in improving medical decision-making and health care delivery. As stated in the CY 2016 PFS final rule with comment period (80 FR 71277), the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) was enacted on April 16, 2015. Under section 1848(p)(4)(B)(iii) of the Act, as amended by section 101(b)(3) of MACRA, the VM shall not be applied to payments for items and services furnished on or after January 1, 2019. Section 1848(q) of the Act, as added by section 101(c) of MACRA, establishes the Merit-based Incentive Payment System (MIPS) that shall apply to payments for items and services furnished on or after January 1, 2019.

2. Overview of Existing Policies for the VM

In the CY 2013 PFS final rule with comment period, we discussed the goals of the VM and also established that specific principles should govern the implementation of the VM (77 FR 69307). We refer readers to that rule for a detailed discussion. In the CY 2013 PFS final rule with comment period (77 FR 69310), we also finalized policies to phase-in the VM by applying it beginning January 1, 2015, to Medicare PFS payments to physicians in groups of 100 or more EPs. A summary of the existing policies that we finalized for the CY 2015 VM can be found in the CY 2014 PFS proposed rule (78 FR 43486 through 43488). Subsequently, in the CY 2014 PFS final rule with comment period (78 FR 74765 through 74787), we finalized policies to continue the phase-in of the VM by applying it starting January 1, 2016, to payments under the Medicare PFS for physicians in groups of 10 or more EPs. Then, in the CY 2015 PFS final rule with comment period (79 FR 67931 through 67966), we finalized policies to complete the phase-in of the VM by applying it starting January 1, 2017, to payments under the Medicare PFS for physicians in groups of 2 or more EPs and to physician solo practitioners. In the CY 2016 PFS final rule with comment period (80 FR 71277 through 71279), we finalized that in the CY 2018 payment adjustment period, the VM will apply to non-physician EPs who are physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified registered nurse anesthetists (CRNAs) in groups with 2 or more EPs and to PAs, NPs, CNSs, and CRNAs who are solo practitioners.

In the CY 2016 PFS final rule with comment period (80 FR 71280), we adopted a two-category approach for the CY 2018 VM based on participation in the PQRS by groups and solo practitioners. For the purposes of the CY 2018 VM, Category 1 includes the following groups and solo practitioners:

(1) Groups that meet the criteria to avoid the CY 2018 PQRS payment adjustment as a group practice participating in the PQRS GPRO;

(2) Groups that have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals;

(3) Solo practitioners that meet the criteria to avoid the CY 2018 PQRS payment adjustment as individuals; and

(4) Groups and solo practitioners that meet the criteria to avoid the CY 2018 PQRS payment adjustment through participation in a Shared Savings Program ACO, if the ACO in which they participate successfully reports quality data as required by the Shared Savings Program.

Category 2 includes those groups and solo practitioners that are subject to the CY 2018 VM payment adjustment and do not fall within Category 1. Groups in Category 1 have been eligible to receive upward, neutral, or downward adjustments under our quality-tiering methodology, and groups and solo practitioners in Category 2 receive an automatic downward adjustment under the VM.

In the CY 2016 PFS final rule with comment period (80 FR 71288 to 71291), we finalized that we will apply the following adjustments to payments, for items and services furnished under the Medicare PFS in CY 2018, to physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs and at least one physician:

- Negative 4 percent (−4.0 percent) for those that fall into Category 2.
- Negative 4 percent (−4.0 percent) under the quality-tiering methodology for those in Category 1 that are classified as low quality/high cost and negative 2 percent (−2.0 percent) for those classified as either low quality/average cost or average quality/high cost.
- An upward adjustment of four times an adjustment factor (+4.0x) under the quality-tiering methodology for those in Category 1 that are classified as high quality/low cost and two times an adjustment factor (+2.0x) for those classified as either average quality/low cost or high quality/average cost.

We finalized that we would apply the following adjustments to payments, for items and services furnished under the Medicare PFS in CY 2018, to physician solo practitioners and physicians, PAs, NPs, CNSs, and CRNAs in groups with 2 to 9 EPs and at least one physician:

- Negative 2 percent (−2.0 percent) to those that fall into Category 2.
- Negative 2 percent (−2.0 percent) under the quality tiering methodology for those in Category 1 that are classified as low quality/high cost and negative 1 percent (−1.0 percent) for those classified as either low quality/average cost or average quality/high cost.
- An upward adjustment of two times an adjustment factor (+2.0x) under the quality-tiering methodology for those in Category 1 that are classified as high quality/low cost and one times an adjustment factor (+1.0x) for those classified as either average quality/low cost or high quality/average cost.

We finalized that we would apply the following adjustments to payments, for items and services furnished under the Medicare PFS in CY 2018, to non-physician solo practitioners who are PAs, NPs, CNSs, and CRNAs and to PAs, NPs, CNSs, and CRNAs in groups comprised solely of non-physician EPs:

- Negative 2 percent (−2.0 percent) for those who fall in Category 2.
- No downward adjustments under the quality-tiering methodology for those in Category 1 in CY 2018.
- An upward adjustment of two times an adjustment factor (+2x) under the quality-tiering methodology for those in Category 1 that are classified as high quality/low cost and one times an adjustment factor (+1.0x) for those classified as either average quality/low cost or high quality/average cost.

In the CY 2017 PFS final rule with comment period (81 FR 80520–80524), we finalized the following, with regard to Medicare Shared Savings Program ACO participant TINs whose ACO did not successfully report quality data on behalf of its EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504 for the CY 2017 and CY 2018 PQRS payment adjustments:

- For the CY 2017 VM payment adjustment period, we will use the data reported to the PQRS by the EPs under the ACO participant TIN (as a group or as individuals) outside of the ACO during the secondary PQRS reporting period in 2016 to determine whether the TIN would fall in Category 1 or Category 2 under the VM.
- We will apply the two-category approach finalized for the CY 2017 VM based on participation in the PQRS by groups and solo practitioners to determine whether groups and solo practitioners that participate in a Shared Savings Program ACO, but report to the PQRS outside of the ACO, would fall in Category 1 or Category 2 under the VM.
- We will assess the individual EP or group's 2016 data submitted outside the ACO and during the secondary PQRS reporting period against the reporting requirements for the CY 2018 PQRS payment adjustment.

3. Provisions of This Final Rule

As a general summary, we proposed the following modifications to the VM policies for the CY 2018 payment adjustment period:

- Reduce the automatic downward adjustment for groups and solo practitioners in Category 2 (those who do not meet the criteria to avoid the 2018 PQRS payment adjustment as individual solo practitioners, as a group practice, or groups that have at least 50 percent of the group's EPs meet the criteria as individuals) to negative 2 percent (−2.0 percent) for groups with 10 or more EPs and at least one physician, and negative 1 percent (−1.0 percent) for groups with between 2 to 9 EPs, physician solo practitioners, and for groups and solo practitioners that consist only of non-physician EPs.
- Hold all groups and solo practitioners who are in Category 1 (those who meet the criteria to avoid the 2018 PQRS payment adjustment as individual solo practitioners, as a group practice, or groups that have at least 50 percent of the group's EPs meet the criteria as individuals) harmless from downward payment adjustments under quality tiering for the last year of the program.
- To provide a smoother transition to the MIPS and to align incentives across all groups and solo practitioners, reduce the maximum upward adjustment under the quality-tiering methodology to two times an adjustment factor (+2.0x) for groups with 10 or more EPs. This is the same maximum upward adjustment under the quality-tiering methodology that we finalized and will maintain for groups with between 2 to 9 EPs, physician solo practitioners, and for groups and solo practitioners that consist only of non-physician EPs.

a. Approach to Setting the VM Adjustment Based on PQRS Participation

As noted in this final rule, under section 1848(p)(4)(B)(iii) of the Act, as amended by section 101(b)(3) of MACRA, the VM shall not be applied to payments for items and services furnished on or after January 1, 2019. Section 1848(q) of the Act, as added by section 101(c) of MACRA, establishes the MIPS that shall apply to payments for items and services furnished on or after January 1, 2019. In the interest of program alignment and providing a smooth transition between the VM and MIPS, as well as aligning with the changes to the policies for satisfactory reporting under the final year of PQRS, modifications to the CY 2018 VM payment adjustments are described in section III.F. of this final rule.

We did not propose any changes to the policies finalized in the CY 2016 PFS final rule with comment period (80 FR 71280) for determining whether a group or solo practitioner is considered to be Category 1 or Category 2 for purposes of the CY 2018 VM. Specifically, we did not propose any change to our existing policy that TINs that avoid the downward payment adjustment under PQRS (either as a group practice participating in the PQRS GPRO or through the individual participation of at least 50 percent of the group's EPs, or as a solo practitioner) will be considered Category 1 under the VM. These TINs therefore will avoid an automatic downward adjustment under the VM.

b. Payment Adjustment Amount

We proposed modifications to the VM policies for the CY 2018 payment adjustment period. As discussed in greater detail below, we proposed these modifications based on our general policy goals of better alignment and ensuring a smooth transition from the final year of the VM (2018) to the first year of MIPS (2019) as well as continuing to align the VM with the policies established for the PQRS.

As stated in the proposed rule (82 FR 34126), to maintain stability in the payment adjustment amounts applicable under the VM as we transition to the MIPS in 2019, we previously established that we will maintain generally the same VM payment adjustment amounts from the CY 2017 payment adjustment period to the CY 2018 payment adjustment period (80 FR 71288 through 71291). Under our existing policy (80 FR 71290), the estimated funds derived from the application of the downward adjustments to groups and solo practitioners in Category 1 and Category 2 are available to all groups and solo practitioners eligible for upward adjustments under the VM. The upward payment adjustment factor (the ''x'' factor) is determined after the performance period has ended based on the aggregate amount of downward payment adjustments. As noted in the proposed rule (82 FR 34126), despite our efforts to ensure a smooth transition from the VM to the MIPS, the 2017 VM adjustment factor has resulted in payment adjustments for some groups and solo practitioners that are significantly higher than the maximum upward adjustment under the MIPS, which will apply to payments starting in 2019, after the sunset of the VM in 2018. The magnitude of the 2017 VM adjustment factor is due in large part to the number of physician practices failing to satisfy the criteria to avoid the PQRS payment adjustment (Category 2). Furthermore, we believe it is likely that many physician practices that fail to meet these criteria and as a result are in Category 2 and are subject to automatic downward adjustments under the 2018 VM will be excluded from MIPS in 2019, due to the low-volume threshold. In a MIPS final rule with comment period, we estimated that 53 to 57 percent of Medicare clinicians are expected to be excluded from MIPS because they are: (1) A qualifying Alternative Payment Model participant; (2) an ineligible clinician type; (3) meeting the low-volume threshold; or (4) a newly enrolled clinician (81 FR 77517).

The 2017 VM adjustment factor is 15.48 percent, which is similar to the 2016 VM adjustment factor of 15.92 percent. We would expect, absent any policy change, that the 2018 VM adjustment factor would be similar or higher. The 2018 VM adjustment factor could potentially be higher than the 2017 VM adjustment factor, because non-physician EPs who will be subject to the 2018 VM may be less familiar with quality reporting and may fail to meet the criteria to avoid the CY 2018 PQRS payment adjustment, which would result in a greater number of groups and solo practitioners in Category 2. In addition, groups with 2–9 EPs and solo practitioner physicians will no longer be held harmless from downward adjustments under the quality-tiering methodology in the CY 2018 payment adjustment period.

In section III.F. of this final rule, we are finalizing changes to certain policies for the 2018 PQRS payment adjustment. We discuss the implications of these changes for PQRS with regard to the VM in greater detail below.

• *Quality-Tiering for groups and solo practitioners in Category 1:* As noted in section III.F. of this final rule, we proposed and are finalizing a change to the reporting criteria for the 2018 PQRS payment adjustment. Specifically, we are finalizing our proposal to lower the number of measures required and to eliminate the requirement for reporting across a number of domains. In the proposed rule, we acknowledged that some groups and solo practitioners may have reported differently under PQRS, had the proposed PQRS reporting criteria been established prior to the reporting period. For example, it is possible that groups and solo practitioners may have selected fewer or different PQRS measures to report or may have chosen to report through a different PQRS reporting mechanism, which could have resulted in a higher quality composite score under the VM. Based on these potential implications for the VM, we proposed to hold all groups and solo practitioners in Category 1 harmless from downward adjustments under the quality-tiering methodology in the CY 2018 payment adjustment period. This proposal would apply to groups and solo practitioners who would have otherwise received downward adjustments based on their quality composite score, their cost composite score, or both. The reason we proposed to include groups and solo practitioners that would otherwise have been subject to a downward adjustment based on their cost composite score was that a group or solo practitioner that is classified as ''high cost'' based on their cost composite score potentially could have reported differently under the PQRS and received a quality composite score that would be classified as ''high quality,'' if the PQRS reporting criteria proposed in section III.F. of the proposed rule had been established prior to the reporting period. A high quality/high cost classification would have resulted in a neutral adjustment under the VM in 2018.

In contrast to the existing policy for 2018 where only non-physician solo practitioners and groups comprised solely of non-physician EPs would be held harmless from downward adjustments under quality-tiering, our proposed policy would mean that all groups and solo practitioners that meet the criteria to avoid the 2018 PQRS payment adjustment would receive either a neutral or upward adjustment based on performance.

The following is a summary of the public comments received on our proposal and our responses:

Comment: The majority of the commenters supported our proposal. A few of the commenters who did not support the proposal stated that they believe it would make a retroactive change to existing policy. They stated that changes to the program's previously-finalized policies would penalize clinicians who fully participated in the program and reward those who did not. Other commenters that did not support the proposal stated that we should hold all practices that reported at least one measure harmless from downward adjustments under the VM or that the VM payment adjustment should be zero for all practices.

Response: We appreciate the commenters' support of our proposal. As noted in section III.F. of this final rule, we are finalizing a change to the reporting criteria for the 2018 PQRS payment adjustment. We believe that our proposed policy would minimize the impact on groups and solo practitioners who may have reported differently under PQRS if the PQRS reporting criteria had been established prior to the reporting period. For the commenters' who did not support the proposal, we note that because the statute requires the VM to be implemented in a budget neutral manner, the total amount of upward adjustments is based on the total amount of downward adjustments. We do not believe it would be appropriate to further reduce the available funds for upward adjustments by further reducing downward adjustments. We require groups and solo practitioners to report quality data to accurately assess their performance, and we believe that we

have set the automatic downward payment adjustment under the VM, as discussed later in this section, at a level that reflects the importance of participating in the quality reporting process. In general, the automatic downward VM payment adjustment is applied in addition to the PQRS payment adjustment for groups and solo practitioners that do not meet quality reporting criteria to avoid the PQRS payment adjustment. Historically the majority of available funds for upward adjustments has come from automatic downward adjustments to those groups and solo practitioners that fall into Category 2 (those who did not meet the quality reporting criteria to avoid the PQRS payment adjustment), not from downward adjustments under the quality-tiering methodology for groups in Category 1 (those who met the quality reporting criteria to avoid the PQRS payment adjustment). Based on this historical data, we do not have reason to believe this proposal would significantly disadvantage groups and solo practitioners who met the previously-established PQRS reporting requirements. Additionally, in the proposed rule (82 FR 34184), we stated that the preliminary estimates indicate that the implementation of all of the proposed policies for the CY 2018 VM would reduce the adjustment factor to below 10 percent. At this level, we believe that the potential upward VM payment adjustments we are finalizing for Category 1 groups and solo practitioners and the automatic downward payment adjustments we are finalizing for Category 2 groups and solo practitioners would still provide sufficient recognition and significant payment impact for these practices' 2016 quality reporting and performance; therefore, we would not want to further reduce the potential upward VM payment adjustments by further reducing the amount of the automatic downward payment adjustments.

Furthermore, if we eliminated the downward adjustments for Category 2 groups and solo practitioners, in addition to finalizing the policy to hold all groups and solo practitioners in Category 1 harmless from downward adjustments under the quality-tiering methodology in the CY 2018 payment adjustment period, then there would be no funds available for upward adjustments for the high-performing groups and solo practitioners.

Accordingly, we are finalizing as proposed the policy to hold all groups and solo practitioners in Category 1 harmless from downward adjustments under the quality-tiering methodology in the CY 2018 payment adjustment period.

We also proposed to reduce the maximum upward adjustment under the quality-tiering methodology in CY 2018 from four times an adjustment factor (+4.0x) to two times an adjustment factor (+2.0x) for those classified as high quality/low cost and from two times an adjustment factor (+2.0x) to one times an adjustment factor (+1.0x), for those classified as either average quality/low cost or high quality/average cost. This policy would align the upward adjustments for groups with ten or more eligible professionals with the existing policy for smaller groups and solo practitioners, as well as groups comprised solely of non-physician EPs (80 FR 71290). We proposed this change based on our concern that the 2018 VM adjustment factor (the ''x'' factor used to determine upward adjustments) could potentially be higher than the 2017 VM adjustment factor, as discussed previously. Lowering the maximum upward adjustment in 2018 would mitigate the effect of a high adjustment factor and ensure a smoother transition from the VM adjustment in 2018 to the MIPS adjustment in 2019. We welcomed public comment on this proposal.

The following is a summary of the public comments received on our proposal and our responses:

Comment: Most commenters supported our proposal. The few commenters who did not support the proposal stated that high-performing group practices should not have a reduction in their potential upward payment adjustment. Some of these commenters further stated that the proposal unfairly penalizes high-performing group practices who complied with the regulatory requirements and helps those who chose not to comply, and one recommended that CMS find an alternative method to ensure that high-performing group practices are fairly rewarded.

Response: We thank the commenters for their support of our proposal. We also acknowledge the fairness concerns raised by those commenters who did not support the proposal. Our intention in proposing this policy was not to penalize groups that had high performance based on the previously finalized policy, but as discussed in the proposed rule, we were concerned that the 2018 VM adjustment factor could potentially be higher than the 2017 VM adjustment factor. This could result in a high upward payment adjustment under the VM in 2018 followed by a significantly lower payment adjustment under MIPS in 2019. We believe that finalizing this proposal would have the intended consequence of lowering the maximum upward adjustment in 2018 as a result of a lower adjustment factor and thus ensuring a smoother transition from the VM adjustment in 2018 to the positive MIPS adjustments in 2019. Therefore, we are finalizing as proposed the policy to reduce the maximum upward adjustment under the quality-tiering methodology in CY 2018 for groups of physicians with 10 or more EPs from four times an adjustment factor (+4.0x) to two times an adjustment factor (+2.0x) for those classified as high quality/low cost and from two times an adjustment factor (+2.0x) to one times an adjustment factor (+1.0x), for those classified as either average quality/low cost or high quality/average cost. As stated in the proposed rule (82 FR 34184), preliminary estimates indicate that the implementation of all of the proposed policies for the CY 2018 VM would reduce the adjustment factor to below 10 percent. At this level, we believe that the final upward adjustments under quality-tiering for high-performing groups of physicians with 10 or more EPs would continue to reward them appropriately and align their adjustments at the same level as groups of physicians with 2 to 9 EPs, physician solo practitioners, and groups and solo practitioners consisting of non-physician EPs only, in addition to ensuring a smoother transition from the VM adjustment in 2018 to the MIPS adjustment in 2019.

Table 23 displays the final 2018 VM adjustments under the quality-tiering methodology, for groups and solo practitioners in Category 1. Under the final policies, groups of any size and composition would be subject to the same upward adjustments under quality tiering and would be held harmless from any downward adjustments based on performance.

TABLE 23—FINAL CY 2018 VM AMOUNTS UNDER THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PAS, NPS, CNSS, AND CRNAS WHO ARE SOLO PRACTITIONERS AND THOSE IN GROUPS OF ANY SIZE

Cost/quality	Low quality (%)	Average quality	High quality
Low cost	+0.0	+1.0x *	+2.0x *
Average cost	+0.0	+0.0%	+1.0x *
High cost	+0.0	+0.0%	+0.0%

* Under existing policy, these groups and solo practitioners are eligible for an additional +1.0x if their average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

Tables 24 through 26 illustrate how the final policies differ from the previously-finalized policies for each group size and composition.

TABLE 24—PREVIOUS AND FINAL CY 2018 VM AMOUNTS UNDER THE QUALITY-TIERING APPROACH FOR PHYSICIANS, NPS, PAS, CNSS, & CRNAS IN GROUPS OF PHYSICIANS WITH 10+ EPS

Cost/quality	Low quality		Average quality		High quality	
VM payment adjustment	Previous (%)	Final (%)	Previous	Final	Previous	Final
Low Cost	+0.0	+0.0	+2.0x *	+1.0x *	+4.0x *	+2.0x *
Average Cost	−2.0	+0.0	+0.0%	+0.0%	+2.0x *	+1.0x *
High Cost	−4.0	+0.0	−2.0%	+0.0%	+0.0%	+0.0%

* Under existing policy, these groups are eligible for an additional +1.0x if their average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

TABLE 25—PREVIOUS AND FINAL CY 2018 VM AMOUNTS UNDER THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PAS, NPS, CNSS, & CRNAS IN GROUPS OF PHYSICIANS WITH 2–9 EPS AND PHYSICIAN SOLO PRACTITIONERS

Cost/quality	Low quality		Average quality		High quality	
VM payment adjustment	Previous (%)	Final (%)	Previous	Final	Previous	Final
Low Cost	+0.0	+0.0	+1.0x *	+1.0x *	+2.0x *	+2.0x *
Average Cost	−1.0	+0.0	+0.0%	+0.0%	+1.0x *	+1.0x *
High Cost	−2.0	+0.0	−1.0%	+0.0%	+0.0%	+0.0%

* Under existing policy, these groups and solo practitioners are eligible for an additional +1.0x if their average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

TABLE 26—PREVIOUS AND FINAL CY 2018 VM AMOUNTS UNDER THE QUALITY-TIERING APPROACH FOR PAS, NPS, CNSS, & CRNAS WHO ARE SOLO PRACTITIONERS OR IN GROUPS CONSISTING OF NON-PHYSICIAN EPS ONLY

Cost/quality	Low quality		Average quality		High quality	
VM payment adjustment	Previous (%)	Final (%)	Previous	Final	Previous	Final
Low Cost	+0.0	+0.0	+1.0x *	+1.0x *	+2.0x *	+2.0x *
Average Cost	+0.0	+0.0	+0.0%	+0.0%	+1.0x *	+1.0x *
High Cost	+0.0	+0.0	+0.0%	+0.0%	+0.0%	+0.0%

* Under existing policy, these groups and solo practitioners are eligible for an additional +1.0x if their average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

• *Automatic Downward Adjustments for groups and solo practitioners in Category 2.* Under the previously finalized policies, the total maximum downward adjustment in 2018 under the PQRS and VM programs combined would have been negative 6 percent (−6.0 percent), while the maximum downward adjustment under MIPS in 2019 is negative 4 percent (−4.0 percent). In order to ensure a smoother transition to the downward payment adjustments under MIPS, we proposed to reduce the amount of the automatic downward adjustments applied to payments for TINs categorized as Category 2 (those that do not avoid the PQRS payment adjustment as individual solo practitioners, as a group practice, or as a group that has at least 50 percent of the group's EPs meet the criteria to avoid the payment adjustment as individuals).

For physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs and at least one physician, we proposed to reduce the automatic downward VM adjustment from negative 4 percent (−4.0 percent) to negative 2 percent (−2.0 percent) for those that fall in Category 2, meaning they did not meet the criteria to avoid the 2018 PQRS payment adjustment.

For physician, PA, NP, CNS, and CRNA solo practitioners; physicians,

PAs, NPs, CNSs, and CRNAs in groups with 2 to 9 EPs; and for PAs, NPs, CNSs, and CRNAs who are in groups comprised solely of non-physician EPs, we proposed to reduce the automatic downward VM adjustment from negative 2 percent (−2.0 percent) to negative 1 percent (−1.0 percent) for those that fall in Category 2.

We welcomed public comment on these proposals.

The following is a summary of the public comments received on our proposals and our responses:

Comment: Most of the commenters supported our proposals. Some of the suggestions provided by commenters who did not support the proposals included further reducing the automatic downward payment adjustment to −1.0 percent or zero percent for all practices, or holding harmless the practices that submitted any quality data (even if they did not meet the proposed PQRS reporting requirements). Other reasons given for not supporting the proposals were that decreasing the automatic downward payment adjustment would disadvantage groups who invested resources to succeed under the Value Modifier program by rewarding those that did not, and that the previously finalized automatic −4.0 percent downward adjustment better aligned with MIPS and that the intention of MACRA was not to reduce the downward adjustments under the existing programs.

Response: We thank the commenters who supported the proposal. For commenters who suggested that the automatic downward adjustment be further reduced or eliminated, we note that because the statute requires the VM to be implemented in a budget neutral manner, the total amount of upward adjustments is based on the total amount of downward adjustments. We discuss above in detail why we do not believe it would be appropriate to further reduce the available funds for upward adjustments by further reducing or eliminating downward adjustments.

For the commenter who expressed concern about the impact on groups who invested resources in successful participation in the Value Modifier program, we acknowledge and appreciate the efforts made by those groups and solo practitioners who successfully met the previously-finalized PQRS reporting criteria. We believe that the proposed policy strikes the appropriate balance between incentivizing both quality reporting and the provision of high-quality, efficient care and making a smooth transition to MIPS. In response to the comment that the previously-finalized negative four percent (−4.0 percent) automatic downward adjustment better aligned with MIPS, we note that the MIPS replaces three legacy programs, the PQRS, Value Modifier, and the Medicare EHR Incentive Program for eligible professionals. Under previously-finalized policies for the PQRS and Value Modifier programs, the combined total downward adjustment for not meeting the minimum quality reporting requirements would have been negative six percent (−6.0 percent), which would have exceeded the maximum downward adjustment of negative four percent (−4.0 percent) in the first year of MIPS. Therefore, we are finalizing as proposed that for the CY 2018 payment adjustment period: (1) For physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs and at least one physician, to reduce the automatic downward VM adjustment from negative 4 percent (−4.0 percent) to negative 2 percent (−2.0 percent) for those that fall in Category 2, meaning they did not meet the criteria to avoid the 2018 PQRS payment adjustment; and (2) for physician, PA, NP, CNS, and CRNA solo practitioners; physicians, PAs, NPs, CNSs, and CRNAs in groups with 2 to 9 EPs; and for PAs, NPs, CNSs, and CRNAs who are in groups comprised solely of non-physician EPs, to reduce the automatic downward VM adjustment from negative 2 percent (−2.0 percent) to negative 1 percent (−1.0 percent) for those that fall in Category 2.

Section 1848(p) of the Act does not specify the amount of payment that should be subject to the adjustment for the VM; however, section 1848(p)(4)(C) of the Act requires the VM be implemented in a budget neutral manner. In the past, under the VM, we have achieved budget neutrality by increasing payments for some groups and solo practitioners based on high performance and decreasing them for others based on low performance or failing to meet the criteria to avoid the PQRS payment adjustment as a group or as individuals. Under the VM proposals included in the proposed rule for the CY 2018 payment adjustment period, we would not decrease payments to groups and solo practitioners based on performance under the quality-tiering methodology, provided that they are classified as Category 1 under the VM (meaning that they meet the criteria to avoid the CY 2018 PQRS payment adjustment as individual solo practitioners, as a group practice, or as a group that has at least 50 percent of the group's EPs meet the criteria). We would continue to decrease payments to groups and solo practitioners in Category 2 (meaning that they did not meet the criteria to avoid the CY 2018 PQRS payment adjustment as individual solo practitioners, as a group practice, or as a group that has at least 50 percent of the group's EPs meet the criteria). Regardless of the VM proposals for the CY 2018 payment adjustment period, the aggregate expected amount of Medicare spending in any given year for physician and non-physician EP services paid under the Medicare PFS will not change as a result of the application of the VM. As discussed previously, because the VM must be implemented in a budget neutral manner, the amount available for upward adjustments for high performers would decrease under our proposals. In other words, groups and solo practitioners that performed well on cost and quality would receive a smaller increase in payment. For this reason, we sought comment on whether we have appropriately balanced the interests of high and low-performing groups and solo practitioners through this proposed change to the policy.

The following is a summary of the public comments received and our responses:

Comment: As discussed above, we received a few comments stating that the proposed policies would penalize practices that complied with existing requirements and reward those that did not. We also received a large number of commenters that supported all of our proposals and agreed with our intention to provide a smoother transition to the MIPS and to align incentives across all groups and solo practitioners.

Response: We thank the commenters for their feedback, but we do not agree with those who stated that the proposals would penalize practices that complied with the previously-established policies and reward those who did not. The Value Modifier program will continue to reward high-performing groups with significant upward payment adjustments in 2018, but under the policies we are finalizing in this rule, we will not apply downward adjustments to low-performing groups or solo practitioners who may have reported differently under the PQRS reporting criteria that we are adopting in section III.F. of this final rule. Also, we will not apply downward adjustments to groups and solo practitioners who are able to satisfy these PQRS reporting criteria by reporting six measures, but not nine. Moreover, the VM policies we are adopting will provide a smoother transition to MIPS where many of these practices may be excluded from MIPS based on the low-volume exclusion. As

stated above, we believe that the potential upward VM payment adjustments we are finalizing for Category 1 groups and solo practitioners and the automatic downward payment adjustments we are finalizing for Category 2 groups and solo practitioners would still provide sufficient recognition and significant payment impact for these practices' 2016 quality reporting and performance.

We proposed to make conforming revisions to §§ 414.1270, and 414.1275(c)(4) and (d)(3) to reflect the proposals described in this section. We sought public comment on these changes to the regulation text. We did not receive any comments on the proposed regulation text; therefore, we are finalizing the revisions as proposed.

J. MACRA Patient Relationship Categories and Codes

1. Development of Patient Relationship Categories and Codes To Improve Identification of Physician-Patient Relationship

a. Overview

The Quality Payment Program (QPP) aims to improve health outcomes, promote smarter spending, minimize burden of participation, and provide fairness and transparency in operations. These aims are centered on improving beneficiary outcomes and engaging patients through patient-centered policies, and enhancing clinician experience through flexible and transparent program design and interactions with easy-to-use program tools.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) was enacted on April 16, 2015. Section 101(f) of MACRA amended section 1848 of the Act to create a new subsection (r) entitled Collaborating with the Physician, Practitioner, and Other Stakeholder Communities to Improve Resource Use Measurement. Section 1848(r)(2) of the Act requires the development of care episode and patient condition groups, and classification codes for such groups. To facilitate the attribution of patients and episodes to one or more clinicians, section 1848(r)(3) of the Act requires the development of patient relationship categories and codes that define and distinguish the relationship and responsibility of a physician or applicable practitioner with a patient at the time of furnishing an item or service. The categories shall include different relationships of the clinician to the patient and reflect various types of responsibility for and frequency of furnishing care. Pursuant to section 1848(r)(3)(C) of the Act, we posted a draft list of patient relationship categories in April 2016 and solicited public comment on the categories and the policy principles that were used in developing them.[5] In December 2016, we solicited additional comment on potential modifications to these categories based on comments received previously, as well as a method to operationalize the coding of these categories on the Medicare claim.[6]

2. Operational List of Patient Relationship Categories

Based on the public comments received and consultation with stakeholders and experts regarding the draft list of patient relationship categories posted in April 2016 and the list of modified patient relationship categories posted in December 2016, we posted the operational list of patient relationship categories on May 17, 2017, pursuant to section 1848(r)(3)(E) of the Act, which is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/CMS-Patient-Relationship-Categories-and-Codes.pdf* The patient relationship categories on the operational list are the following:

- Continuous/Broad Services.
- Continuous/Focused Services.
- Episodic/Broad services.
- Episodic/Focused Services.
- Only as Ordered by Another Clinician.

3. Subsequent Revisions

Section 1848(r)(3)(F) of the Act requires that after the posting of the operational list of patient relationship categories and codes, not later than November 1st of each year (beginning with 2018), the Secretary shall, through rulemaking, make revisions to the operational list of patient relationship categories and codes as the Secretary determines appropriate. The revisions may be based on experience, new information and input from stakeholders. In preparation for potential subsequent revisions by November 1, 2018, we sought comment on the operational list of patient relationship categories available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/CMS-Patient-Relationship-Categories-and-Codes.pdf.*

4. Reporting of Patient Relationship Codes Using Modifiers

Section 1848(r)(4) of the Act requires that claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018, shall, as determined appropriate by the Secretary, include the applicable codes established for care episode groups, patient condition groups, and patient relationship categories under sections 1848(r)(2) and (3) of the Act, as well as the NPI of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner). Applicable practitioners are defined in section 1848(r)(9)(B) of the Act as a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5)), and a certified registered nurse anesthetist (as defined in section 1861(bb)(2)), and beginning January 1, 2019, such other eligible professionals (as defined in subsection (k)(3)(B)) as specified by the Secretary.

We have been planning for the use of procedure code modifiers for the reporting of patient relationships codes on Medicare claims. In December 2016, as described above, when we solicited comments on the potential modifications to the patient relationship categories, we also sought comment on the use of Level II Healthcare Common Procedure Coding System (HCPCS) Modifiers for the patient relationship codes. Public comments indicated that Current Procedural Terminology (CPT) Modifiers would be the best way to operationalize the reporting of patient relationship codes.[7]

We worked with the American Medical Association's (AMA) CPT Editorial Panel, which is responsible for maintaining the CPT code set. We submitted an application for the CPT modifiers for reporting of the patient relationship codes. The CPT Editorial Panel, at their June 2017 meeting determined that AMA would not include the modifiers in the CPT code set, pending future finalization of the modifiers by CMS, whereby CMS publishes the modifiers as Level II HCPCS Modifiers. Therefore, we proposed the Level II HCPCS Modifiers

[5] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Patient-;Relationship-Categories-and-Codes.pdf* (assessed 04/26/2017).

[6] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Patient-Relationship-Categories-and-Codes-Posting-FINAL.pdf.*

[7] The CMS Level II HCPCS Coding Workgroup meets regularly (generally monthly) to consider requests for new HCPCS codes and modifiers. Information on the code request and approval process is available at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html* (assessed 04/26/2017).

in Table 27 as the patient relationship codes, which we would add to the operational list if we adopt them in the final rule.

TABLE 27—PATIENT RELATIONSHIP HCPCS MODIFIERS AND CATEGORIES

No.	HCPCS modifier	Patient relationship categories
1x	X1	Continuous/broad services.
2x	X2	Continuous/focused services.
3x	X3	Episodic/broad services.
4x	X4	Episodic/focused services.
5x	X5	Only as ordered by another clinician.

We proposed that Medicare claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018, should include the applicable HCPCS modifiers in Table 27, as well as the NPI of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner). We anticipated there would be a learning curve with the use of the modifiers to report patient relationships, and believed that time would be needed to work with clinicians to ensure they gain experience in using these modifiers. Therefore, for at least an initial period while clinicians gain familiarity, we proposed that the HCPCS modifiers may be voluntarily reported on Medicare claims, and the use and selection of the modifiers would not be a condition of payment. Claims would be paid regardless of whether and how the modifiers are included. We would work with clinicians to educate them about the proper use of the modifiers.

We stated that the use of modifiers to report patient relationships would not change the meaning of the procedure codes used to report items and services and guidelines associated with use of such procedure codes. The modifiers would also not be tied or related to intensity of services (evaluation and management services). Finally, we noted that, although we may work with clinicians to explore incorporating these codes into the QPP in future years, the measures we have proposed and finalized to date, those we have proposed for 2018, and those we are currently developing for future rulemaking for the MIPS performance categories do not require patient relationship codes to properly measure clinicians' quality and resource use in the Medicare program.

We solicited comment on our proposal for voluntary reporting of the HCPCS modifiers on claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018 and on the proposed list of HCPCS modifiers in Table 27.

The following is a summary of the public comments received on our proposals and our responses:

Comment: Generally, commenters expressed support for our proposals and agreed this approach would provide significant potential for patient relationship codes to improve the attribution of patients to clinicians, and to improve the way clinicians are measured and assessed in pay-for-performance programs. Many commenters supported our proposal to allow clinicians to use the proposed HCPCS modifiers voluntarily at first before making it mandatory.

Response: We thank commenters for their support.

Comment: Some commenters supported the voluntary aspect of the proposal, but were concerned January 1, 2018 would be too early to implement even voluntary reporting due to educational, administrative, and IT system (structural) challenges. Commenters suggested CMS delay implementing mandatory reporting of patient relationship codes until adequate training, time for vendors testing the submission of claims, stakeholder feedback, burden reduction, and ample studies on the reliability and validity of how CMS will use the patient relationship categories to attribute patients and their costs to individual clinicians under episode-based measures.

Response: We appreciate the commenters' concerns with the timeline for implementation of the use of the proposed HCPCS modifiers. We agree that adequate training, including examples and outreach to clinicians, is important in the implementation of these modifiers. We believe opening up voluntary reporting on January 1, 2018 will allow flexibility for clinicians to participate when they are ready. Allowing for voluntary reporting, along with stakeholder feedback, will help inform further refinement of the modifiers, if necessary. As we stated in the proposed rule, the use and selection of the modifiers would not be a condition of payment for at least an initial period while clinicians become familiar with the modifiers.

Comment: A few commenters supported the initial voluntary reporting approach but suggested that CMS make clear that errors in submitting these codes during this voluntary reporting period will not impact payment. A commenter suggested that CMS work closely with professional associations to educate health professionals and that the training include extensive examples of real world clinical scenarios.

Response: We thank commenters for supporting our initial voluntary approach. We confirm that during the period when reporting is voluntary, errors related to the use of these patient relationship codes will not have payment consequences. We intend to educate stakeholders using a wide variety of clinical examples for training purposes.

Comment: Some commenters remained concerned that billing provisions such as ''incident to'' may thwart this goal, and requested that the name and NPI of the applicable practitioner appear on the claim and be able to be tracked throughout the claims process for services billed ''incident to.''

Response: We appreciate the concerns voiced with regard to accurately identifying the correct clinician that may take care of a patient during an episode of care. Our proposed approach would allow for multiple clinicians to code for their role in care during the episode, and information gathered during the voluntary period can help refine the patient relationship categories if necessary.

Comment: Many commenters expressed concern about the broadness and vagueness of the descriptors used in the five categories of the proposed HCPCS modifiers, which they believe are open to individual interpretation. Some specialty groups stated their belief that the patient relationship categories may not be applicable to their specialties and suggested that CMS provide further clarification of the modifiers or consider additional categories to properly document the clinician-patient relationship in all specialty settings. Many commenters believe it would be incredibly challenging for the proposed modifiers to adequately reflect co-management or team-based care, such as multispecialty facilities and academic medical centers, and also in situations where the physician's relationship with the patient changes over time. The commenters expressed concern regarding who would evaluate the self-assignment of patient relationships to ensure that the codes are being used correctly across clinicians when multiple physicians are in charge of a patient at different points in time, and also in most complex clinician-patient relationships. A commenter recommended that CMS consider framing the modifiers around the clinicians, instead of the care episode.

Response: We chose broad category descriptions to simplify the reporting

burden for clinicians, as well as allow for broad applicability of modifiers across all specialty settings. By allowing for voluntary reporting of the HCPCS modifiers for a period of time, we will be able to examine trends in their use and further refine the modifiers if necessary. The intent of the modifiers is to measure resource use, and by focusing on care episodes, multiple clinicians can identify their role in the patient's care.

Comment: Many commenters appreciated CMS for acknowledging that use of the proposed HCPCS modifiers may impose additional burden on physicians and their support staff. Some commenters expressed concern about the effectiveness, feasibility and utility of the patient relationship codes, in that including a patient relationship code on every single claim, coupled with the clinician confusion resulting from the vagueness and complexity of the patient relationship categories, would be a significant administrative burden for clinicians, which is contrary to the current administration's goals and objectives. Some commenters expressed concern that the introduction of these new modifiers at the time when the QPP is still in the initial implementation and learning period will significantly burden clinicians and their staff.

Response: We acknowledge stakeholders' concerns of administrative burden that may come with the introduction of these modifiers. By finalizing our proposal to allow voluntary reporting of the modifiers for at least an initial period, we hope the information we learn during this period will help us minimize burden for clinicians in reporting these modifiers. We believe providing the training resources and feedback needed to minimize clinician burden during this learning period will help clinicians as they learn how to use the modifiers. The voluntary period also will allow clinicians to participate at their own pace.

Comment: Several commenters recommended that CMS provide more detailed information regarding cost measures (resource use) and episode group measures so they can provide meaningful comments on the proposed HCPCS modifiers. The commenters stated, that without clear information on how the episode-based measures will be structured, they cannot assess whether the patient relationship categories are appropriate for the measures.

Response: We recognize that additional information on cost measures would help commenters in evaluating the patient relationship categories. While we are still developing episode-based measures, the patient relationship categories and codes can help as we define cost measures in the future. The current cost measures in MIPS and those in immediate development do not use these patient relationship codes. We believe additional experience and analysis will be needed before we incorporate the codes into cost measures. We plan to engage clinicians in the use of these codes as we gain experience with their use and submission.

Comment: Many commenters applauded CMS for acknowledging the process is a learning curve and ample education and training is needed. They recommended that CMS incorporate transparency and stakeholder feedback and engagement in their education and attribution methodology work. They believe that given the administrative complexity of implementing the modifiers and incorporating them into CMS' payment systems, studies and testing must be done on fully developed cost and resource use measures to be able to accurately attribute patient relationships to healthcare cost to individual physicians. A commenter believes refinements are needed to ensure the modifiers become a useful and reliable mechanism to attribute costs of care to clinicians without adding significant burden.

Response: We thank the commenters for their feedback. By implementing a voluntary approach to reporting the patient relationship categories, we intend to use the information collected, along with education and outreach to further refine the modifiers if necessary. We are committed to education and outreach during and after the voluntary period. The training and feedback, we believe, will enhance the understanding of the patient relationship categories and provide a mechanism for use of the modifiers without additional burden. We intend to integrate transparency in all operations that go into education and training on the use of the modifiers and the attribution methodology work.

After consideration of the public comments, we are finalizing our proposal to use the Level II HCPCS Modifiers in Table 27 as the patient relationship codes, which we will add to the operational list of patient relationship categories available at *www.cms.hhs.gov/medhcpcsgeninfo*. We are finalizing our proposal that Medicare claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018, should include the applicable HCPCS modifiers in Table 27, as well as the NPI of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner). We are finalizing our proposal that for at least an initial period while clinicians gain familiarity, the HCPCS modifiers may be voluntarily reported, and the use and selection of the modifiers will not be a condition of payment. By allowing for a voluntary approach to reporting, we will gain information about the patient relationship codes, allow for a long period of education and outreach to clinicians on the use of the codes, and inform our ability to refine the codes as necessary.

K. Changes to the Medicare Diabetes Prevention Program (MDPP) Expanded Model

1. Background

a. Authority for and Establishment of the MDPP Expanded Model

In the November 15, 2016 **Federal Register**, we issued a final rule to implement aspects of the Medicare Diabetes Prevention Program (MDPP) expanded model (81 FR 80459 through 80475 and 80552 through 80558) as part of the CY 2017 Physician Fee Schedule (PFS) final rule. Section 1115A(c) of the Act provides the Secretary with the authority to expand, through rulemaking (including implementation on a nationwide basis), the duration and scope of a model that is being tested under section 1115A(b) of the Act if certain determinations specified in the Act are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act. The MDPP expanded model is an expansion of CMS' Center for Medicare and Medicaid Innovation's (Innovation Center) Diabetes Prevention Program (DPP) model test under the authority of section 1115A of the Act. The Secretary expanded the DPP model test in duration and scope under the authority of section 1115A(c) of the Act. For further information on the DPP model test, and the associated National DPP administered by the Centers for Disease Control and Prevention (CDC), we refer readers to the CY 2017 PFS final rule and the following Web sites: *https://Innovation.cms.gov/initiatives/Health-Care-Innovation-Awards/* and *https://www.cdc.gov/diabetes/prevention/index.html*.

The aim of the MDPP expanded model is to continue to test a method of prevention of the onset of type 2 diabetes among Medicare beneficiaries with an indication of prediabetes as defined by the MDPP beneficiary eligibility criteria (finalized at § 410.79(c)(1)). Services available

through the MDPP expanded model are MDPP services furnished in community and health care settings by coaches, such as trained community health workers or health professionals. We have designated services under the MDPP expanded model to be covered as additional preventive services under Medicare, as defined in section 1861(ddd) of the Act.

For a detailed discussion of the DPP model test and the development of aspects of the MDPP expanded model, we refer readers to the CY 2017 PFS proposed rule (''Proposed Expansion of the Diabetes Prevention Program (DPP) Model'') (81 FR 46413 through 46418), and the CY 2017 PFS final rule (81 FR 80459 through 80475).

In the CY 2017 PFS final rule, we responded to and incorporated certain suggestions from the public comments we received that were within the scope of the MDPP proposals presented in the CY 2017 PFS proposed rule. We indicated in that final rule (81 FR 80459) that the MDPP expanded model would be implemented through at least two rounds of rulemaking. In the CY 2017 PFS final rule, we finalized MDPP policies that will enable CDC-recognized organizations to prepare for enrollment, including finalizing the framework for the MDPP expanded model, timeline and definitions for the MDPP expanded model (codified at § 410.79(a) and (b)), beneficiary eligibility criteria (codified at § 410.79(c) and (d)), supplier eligibility criteria and supplier enrollment requirements (codified at § 424.59, proposed to be redesignated as § 424.205). We also identified several issues, including some issues raised by commenters that we deferred to future rulemaking.

b. Summary of Provisions Finalized in the CY 2017 PFS Final Rule

In the CY 2017 PFS final rule (81 FR 80465 through 80468), we finalized the structure of MDPP services. We provided that the MDPP core benefit consists of at least 16 weekly core sessions over months 1 through 6 and at least 6 monthly core maintenance sessions over months 7 through 12, furnished regardless of weight loss (§ 410.79(b) and (c)(2)). We also finalized that Medicare will cover ongoing maintenance sessions after the 12-month core set of MDPP services if beneficiaries achieve and maintain the required minimum weight loss of 5 percent. In the CY 2018 PFS proposed rule, we proposed to further revise the structure of MDPP services as a 3-year service period, generally contingent upon a beneficiary's attainment of two performance goals: Achievement and maintenance of weight loss and attendance at a certain number of MDPP sessions (82 FR 34131 through 34132).

As used in this final rule, the term ''MDPP services period'' refers to the time period in which MDPP services are furnished under the MDPP expanded model over a minimum of 12 consecutive months and a maximum of 24 consecutive months from the date of the first core session the beneficiary attends. We use the term ''set of MDPP services'' to include the entirety of MDPP services available under the MDPP expanded model, including core sessions, core maintenance sessions, and, subject to § 410.79(c)(3), ongoing maintenance sessions offered over the course of the MDPP services period. For purposes of this final rule and the expanded model, MDPP services are covered under the ''additional preventive services'' benefit category under section 1861(ddd)(1) of the Act and paid from the Medicare Part B Trust Fund. As indicated in the CY 2017 PFS, we intended to begin supplier enrollment before MDPP services became available, and we finalized an expanded model start date of January 1, 2018.

In the CY 2018 PFS proposed rule, we proposed a new start date for the furnishing of MDPP services within the expanded model of April 1, 2018 (82 FR 34157 through 34158). That is, MDPP suppliers will not be able to furnish MDPP services, or to receive payment for these services, prior to April 1, 2018. We note that we proposed the supplier enrollment and compliance policies become effective on January 1, 2018. This stated that the change to delay the furnishing of MDPP services would allow time for organizations to enroll in Medicare before they begin furnishing and billing for MDPP services.

In the CY 2017 PFS final rule (81 FR 80459), we described a possible payment structure for MDPP services, but deferred full development of the payment structure to future rulemaking. In section III.K.2.d. of this final rule, we discuss our payment structure for MDPP services. This finalized payment structure took into consideration the significant number of public comments we received in response to the possible payment structure we described in the CY 2017 PFS proposed rule, as well as comments received on the CY 2018 PFS proposed rule. We also proposed payment policies for instances in which an MDPP beneficiary switches MDPP suppliers in the CY 2018 PFS proposed rule.

In the CY 2017 PFS final rule (81 FR 80471 through 80474), we required CDC-recognized organizations that will bill Medicare for MDPP services to enroll in Medicare as MDPP suppliers. We also finalized the requirements for coaches furnishing MDPP services. We finalized policies regarding CDC Diabetes Prevention Recognition Program (DPRP) full recognition for MDPP suppliers and we indicated an intention to propose policies in future rulemaking regarding whether a DPP organization without full CDC recognition could enroll as an MDPP supplier. We are finalizing an interim MDPP preliminary recognition standard in section III.K.2.e. of this final rule. Also, in this section of this final rule, we are finalizing revisions to the supplier eligibility and enrollment requirements, including establishment of standards and implementation of appropriate program integrity safeguards. In section III.K.2.f. of this final rule, we are finalizing policies related to MDPP beneficiary engagement incentives furnished by MDPP suppliers.

In the CY 2017 PFS final rule (81 FR 80459), we deferred establishing policies related to organizations delivering ''virtual'' DPP services, where services are not furnished in person. In section III.K.3. of this final rule, we explain that the MDPP expanded model covers in-person MDPP services (other than ad hoc virtual make-up sessions discussed in section III.K.2.c.iv.(3) of this final rule), and thus, explain why we are not currently finalizing any policies related to MDPP services furnished 100 percent virtually and state that we are considering a separate model under CMS's Innovation Center authority to test and evaluate virtual DPP services.

2. Policy Changes

a. Changes to Effective Date of MDPP Services

In the CY 2017 PFS final rule, we established at § 410.79(a) that MDPP services would be available on January 1, 2018. In the CY 2018 PFS proposed rule, we proposed to change § 410.79(a) to state that MDPP services would be available on April 1, 2018. We proposed this change because we want to ensure that MDPP suppliers have sufficient time to enroll in Medicare after the effective date of the CY 2018 PFS final rule.

Therefore, beneficiaries will not be able to receive MDPP services immediately on January 1, 2018 due to the time needed for supplier enrollment. For this reason, we proposed April 1, 2018 as the expanded model start date, which we believe allows a sufficient

amount of time (90 days) for eligible suppliers to enroll in Medicare before furnishing and billing for MDPP services. As a result of this proposed change, we stated that the following regulatory provisions, if finalized, would be effective April 1, 2018: § 414.84 related to payment for MDPP services; and § 424.210 related to beneficiary engagement incentives. We proposed that all other sections, if finalized, will be effective on January 1, 2018, including the policies proposed in section III.K.2.e. of the proposed rule related to supplier enrollment and compliance. We invited public comments on these proposals.

The following is a summary of the public comments received on this new proposed expanded model start date and whether 90 days is a sufficient amount of time for organizations to enroll in Medicare and prepare to furnish and bill for MDPP services and our responses:

Comment: Many commenters supported the proposed model start date of April 1, 2018. The commenters stated that a 90-day delay from January 1, 2018, was both reasonable and necessary to ensure MDPP suppliers would be ready to deliver services by April 1, 2018. Other commenters stated that enrollment of DPP organizations into the MDPP as of January 1, 2018, would allow sufficient time for organizations to apply, receive a supplier determination, comply with requirements, and ultimately, operate starting April 1, 2018. One commenter appreciated the alignment of the MDPP's implementation in Apri1 2018 with the CDC's recently-proposed DPRP standards that will allow DPP suppliers to prepare for enrollment as Medicare suppliers.

One commenter expressed concerns about delaying the availability of the services until April and recommended CMS keep the implementation date of January 1, 2018. The commenter stated that because the MDPP was first discussed in the 2017 rulemaking cycle and CMS had finalized a January 1, 2018 start date, CMS and suppliers alike had ample time to plan, enroll, and prepare to operationalize this program. The commenter suggested CMS work with speed and efficiency to make these services available on January 1, 2018, as the agency had previously finalized given the obesity and diabetes prevalence in the United States.

A few commenters suggested CMS delay the model start date beyond April 1, 2018, including several requests to delay until January 1, 2019. Most of the commenters stated the delay was necessary to allow Medicare Advantage (MA) organizations sufficient time to contract with MDPP suppliers thereby ensuring adequate coverage for their members. One commenter suggested delaying the start date to July 1st or October 1st 2018 to allow additional time for suppliers to be trained and in place when the service becomes available to Medicare beneficiaries.

Response: We appreciate all of the comments received on the proposed new effective date for MDPP services and thank the commenters for their recommendations. We note that we cannot make the MDPP service available to beneficiaries until there are MDPP suppliers enrolled in Medicare who can meet beneficiary demand for the service. Suppliers have been awaiting detailed requirements in order to enroll into Medicare as MDPP suppliers. Those requirements are finalized in this rule which becomes effective January 1, 2018. In response to commenters recommending a January 1, 2019 start date, CMS does not believe it is prudent to further delay the availability of this preventive service for the majority of Medicare beneficiaries, who are in Fee for Services (FFS). Additionally, DPP stakeholders have been preparing to offer this service to Medicare beneficiaries since the service was first proposed in the CY 2017 PFS proposed rule and finalized in CY 2017 PFS final rule (81 FR 80459). There are currently over 1500 organizations actively pursuing or maintaining DPP recognition through the CDC's DPRP which includes nearly a 90 percent increase between September 2015 and March 2017 alone. These organizations have made significant investments in pursuit of recognition and represent a growing supply of organizations that meet the qualifications specified in this rule to deliver the DPP to Medicare beneficiaries. At § 410.79(a), we are finalizing that MDPP services will be available under the MDPP expanded model as a Part B service for eligible Medicare beneficiaries beginning on April 1, 2018. Because MDPP services are a Part B service, all Medicare health plans (which include plans offered by Medicare Advantage Organizations, cost plans offered under sections 1833 and 1853 of the Act, and PACE organizations), are required to cover MDPP services for eligible beneficiaries. As a Part B service, Medicare health plans are required to provide beneficiaries with coverage of all MDPP services using medical necessity criteria that authorize coverage on *at least* the same terms as Original Medicare. In the CY 2017 final rule (81 CFR 80468 through 80470) and in section III.K.2.c of this final rule, we establish specific beneficiary eligibility requirements that regulate the coverage of MDPP services as a basic benefit. Therefore, notwithstanding other requirements under this final rule, MA plans must authorize coverage of MDPP on at least the same terms as those established in § 410.79(c) and (d) of this final rule. We note that Medicare health plans may generally also provide more generous coverage than Original Medicare as a supplemental benefit.

Comment: We received several comments related to our proposed delay of the start date for MDPP services from January 1, 2018 to April 1, 2018 that addressed whether such a delay would likewise delay the effective date for MA plans. The majority of commenters who provided comments on the delay with respect to MA plans recommended that CMS further delay the start date for MDPP services beyond the April 1 date, recommending new start dates ranging from June 1, 2018 to January 1, 2019. Concerns underlying the request for this additional delay were related to the number of MDPP suppliers available to contract with MA plans for MDPP services, the short timeline in which to negotiate and implement contracts with MDPP suppliers for an April 1 start date, and other operational challenges underlying the implementation of a new covered service between the November 2017 publication of the MDPP final rule and the April 1, 2018 start date. Other commenters supported the delayed start date in MDPP services from January 1, 2018 to April 1, 2018, citing the need for additional time to contract with MDPP suppliers and their desire to align with the proposed start date for Original Medicare.

Response: While we understand that Medicare Advantage Organizations have significant concerns regarding their ability to construct a network of adequate coverage for MDPP, we remind MAOs that, as a Part B service, § 422.112 permits MA plans to limit coverage to services from a network of providers so long as the MAO ensures that all covered services—which will include MDPP services—are available and accessible under the MA plan; an MAO must arrange for out-of-network access to specialty care when network providers are unavailable or inadequate to meet enrollees' medical needs. We further note that for section 1876 cost plans, § 417.416 requires that an Health Maintenance Organization or Comprehensive Medical Plan must furnish required services—which will include MDPP services—to its Medicare enrollees through providers and suppliers that meet applicable Medicare

statutory definitions and implementing regulations. The HMO or CMP must also ensure that the required services for which the Medicare enrollee has contracted are available and accessible and are furnished in a manner that ensures continuity. Therefore, we decline to accept commenters' recommendations to further delay the effective date for MA plans. As indicated in a November 23, 2016 Health Plan Management System (HPMS) memo, because MDPP is a Part B service, all Medicare health plans, including plans offered by Medicare Advantage plans, are required to cover the service for eligible beneficiaries. In this section, we are finalizing that MDPP services will be available under the MDPP expanded model as a Part B item/service for eligible Medicare beneficiaries, in both Original Medicare and Medicare health plans, beginning on April 1, 2018. Additional information on this topic will be released in future guidance, as appropriate.

Comment: In addition to a number of comments supporting a delay to the original start date for MDPP services of January 1, 2018, we received several comments requesting that CMS provide additional guidance and information on the implementation and operationalization of MDPP in the Medicare Advantage setting, with most comments focused on the impact of the proposed delay in the start date for MDPP services to April 1, 2018 on the implementation of MDPP services in Medicare Advantage.

Response: In response to requests from MAOs to provide additional guidance on the implementation of MDPP in MA, we have provided a number of responses to MAOs seeking clarification on the implementation of MDPP in the preamble of this final rule. As appropriate, we will provide additional information to MAOs on the implementation of MDPP in future guidance.

Comment: Several commenters expressed concern that Evidence of Coverage documents developed by MA plans, which were required to be delivered to MA enrollees by September 30th of 2017 prior to the finalization of this rule, may have been published without including MDPP services as an available covered service or may have indicated that MDPP services would be available per the January 1, 2018 date finalized in the CY 2017 final rule and not the April 1st, 2018 date in the CY 2018 proposed rule.

Response: At the time these EOCs were published, the MDPP Expanded Model was to become effective January 1, 2018 with a proposed rule to change the effective date to April 1, 2018; therefore, an EOC that indicates a January 1, 2018 start date for MDPP services was accurate at the time it was published. As we are finalizing our proposed effective date change to April 1, 2018 in this final rule, MA plans that have not included MDPP services in beneficiary documentation such as an EOC or have provided an effective date of January 1, 2018 should consult § 422.111(d) and follow existing guidance at Medicare Managed Care Manual 60.7 ''Other Mid-Year Changes Requiring Enrollee Notification.''

After considering the public comments, we are finalizing, at § 410.79(a), the policy as proposed with an effective date of April 1, 2018 for furnishing MDPP services. Based on the many comments received in support of the proposed date, we believe the 90-day period will allow eligible organizations adequate time to enroll in Medicare as MDPP suppliers and furnish the services to eligible beneficiaries beginning April 1, 2018.

b. Changes to the Set of MDPP Services

In the CY 2017 PFS final rule, we established the parameters of MDPP services. The policies and terms in this final rule seek to clarify, build on, and at times change these previously finalized policies. In particular, we proposed to refine and add terms related to the different aspects of ''MDPP services.'' In the CY 2018 PFS proposed rule, we proposed to refine the term ''MDPP services'' to refer to structured health behavior change sessions that are furnished under the MDPP expanded model with the goal of preventing diabetes among Medicare beneficiaries with prediabetes, and that follow a CDC-approved curriculum (§ 410.79(b)). The sessions provide practical training in long-term dietary change, increased physical activity, and problem-solving strategies for overcoming challenges to maintaining weight loss and a healthy lifestyle.

In the preamble to the CY 2017 PFS final rule, we referenced the set of MDPP services covered under the expanded model as the ''MDPP benefit.'' In the CY 2018 PFS proposed rule, we proposed to update this terminology. In cases where we would have previously referred to the term ''benefit'' to describe the entire set of MDPP sessions covered under the MDPP model, we proposed to use the phrase ''set of MDPP services.'' ''Set of MDPP services'' means the series of MDPP sessions, composed of core sessions, core maintenance sessions, and ongoing maintenance sessions, offered over the course of the MDPP services period (proposed § 410.79(b)).

In cases where we would have previously used the term ''benefit'' to describe a period of time, we proposed to refer to the ''MDPP services period.'' The 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 § 410.79(c)(2)(i) and, subject to § 410.79(c)(3), one or more ongoing maintenance session intervals during the ongoing services period described in § 410.79(c)(2)(ii) (§ 410.79(b)). The duration of the MDPP services period is discussed further in section III.K.2.c.iv. of this final rule. As noted throughout this section, the term ''benefit'' would no longer be used. We proposed to remove the term ''MDPP core benefit'' from the list of definitions.

In the CY 2017 PFS final rule, we included a definition for ''core sessions'' that referred to the set of core sessions covered under the MDPP expanded model. We proposed to revise the definition for ''core sessions,'' and instead define the singular ''core session'' as an MDPP service that is furnished by an MDPP supplier to an MDPP beneficiary during months 1 through 6 of the MDPP services period, is approximately 1 hour in length, and adheres to a CDC-approved DPP curriculum for core sessions (§ 410.79(b)). We believe that having a definition for the individual core session would be more uniform with other MDPP definitions, which are defined in the singular form. We proposed to revise the definition of ''core maintenance session'' as an MDPP service that is furnished by an MDPP supplier to an MDPP beneficiary during a core maintenance session interval, is approximately 1 hour in length, and adheres to a CDC-approved DPP curriculum for maintenance sessions (under § 410.79(b)).

We proposed to revise the definition of an ''ongoing maintenance session'' as an MDPP service that is furnished by an MDPP supplier to an MDPP beneficiary during an ongoing maintenance session interval; is approximately 1 hour in length and adheres to a CDC-approved DPP curriculum for maintenance sessions (§ 410.79(b)). The time period over which MDPP suppliers offer ongoing maintenance sessions, which differs from our previously finalized policy, is discussed in section III.K.2.b.i. of this final rule.

We proposed to add a definition for ''MDPP session,'' which means a core session, a core maintenance session, or

an ongoing maintenance session (§ 410.79(b)).

We invited public comments on these proposals.

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

Comment: A few commenters expressed support for the revised definitions and one commenter stated they were familiar with the terms ''core'' and ''maintenance'' in their current practice. Some commenters appreciated that the terms were aligned with the Centers for Disease Control and Prevention approved DPP curriculum with the addition of ongoing maintenance sessions. One commenter recommended CMS redefine the MDPP Services Period to include a core services period of 1 year and an ongoing maintenance services period of 1 year with the proposed 3-year MDPP payment model adjusted to reflect such changes. One commenter stated that CMS proposes that the core services period consist of two primary subsets: (a) Core sessions, which consist of 16 sessions offered at least one week apart during months one through 6, and (b) core maintenance sessions, which are provided during months 7 through 12. Because a Medicare beneficiary could, as a technical matter, complete the 16 sessions by the end of month 4, the commenter requested that CMS clarify the proposed regulatory language to take into account the fact that core maintenance sessions could be provided during months 5 through 12 (as opposed to only during months 7 through 12). In other words, the commenter was requesting that CMS clarify that months 5 through 6 could include either core sessions or core maintenance sessions, depending on the beneficiary and the pace at which that beneficiary participates in the MDPP. One commenter stated they were pleased that eligible beneficiaries will now be offered 16-weekly core sessions and 6 monthly core maintenance sessions regardless of their level of weight loss during the first 12 months.

Response: We appreciate the comments received on the proposed definitions for the MDPP Services Period. As we discuss more in section III.K.2.b.i of this final rule, we are finalizing that the ongoing maintenance services period will only be 1 year, and therefore, we agree with the comment to redefine the MDPP Services Period to include a core services period of 1 year and an ongoing maintenance services period of 1 year and will be modifying the definition to account for this change. Lastly, we clarify that monthly core maintenance sessions cannot begin prior to month 7 during the first 12 months because a core maintenance session interval is defined as occurring in months 7 through 12 of the MDPP services period. We understand that beneficiaries will complete the core sessions at different paces and some may complete 16 weekly sessions in the first 4 months; however, 16 weekly sessions is the minimum number of sessions to be furnished during months 1–6. Our definition of the MDPP Services Period being finalized at § 410.79(b) and (c)(2)(i), specifies that MDPP suppliers must furnish at least 16 core sessions during months 1–6 and that these core sessions must be offered at least 1 week apart. This definition allows flexibility to suppliers in terms of the frequency that core sessions may be offered. Suppliers can offer core sessions less frequently than weekly so they are spread more evenly across months 1–6 or they can offer them weekly. If a supplier chooses to offer them weekly and a beneficiary completes 16 sessions in months 1 through 4, the supplier will need to offer additional sessions during months 5 and 6 in order to avoid a 2-month break in service for the beneficiary. In this case, the number of additional core sessions offered is left to the discretion of the supplier. However given the evidence from the CDC's DPRP that it takes an average of 17 DPP sessions attended for an individual in the DPP to exceed the required minimum weight loss,[8] and the importance of the first 6 months in achieving weight loss as discussed in more depth in section K.III.2.d.iii.(3) of this final rule, we believe most beneficiaries who attend 16 sessions by month 4 would require high engagement during those 2 months in order to achieve or maintain weight loss by month 7.

Comment: Although unrelated to the current proposals regarding changes to the MDPP set of services, many commenters expressed support for Medicare's expansion of MDPP services as a Part B additional preventive service, and one commenter requested that CMS encourage Medicare Advantage Organizations to cover MDPP as they do other preventive and screening services. However, one commenter stated that the mandate of the MDPP beyond Medicare Part B to Medicare Advantage and PACE plans unduly restricts these plan providers and requested the ability to seek a waiver that would remove the requirement that an MA plan provide MDPP services if the MA plan is able to show that alternative prediabetes outreach is available to plan enrollees that may better fit the plan's service delivery model.

Response: We clarify in this final rule that under 42 CFR 422.100(a), MAOs offering MA plans must provide enrollees in that plan with coverage of all basic benefits, which are defined at § 422.100 (c)(1) as all Medicare-covered services, except hospice services. In the CY 2017 PFS final rule, we finalized our proposal to expand the duration and scope of the DPP model test through the MDPP expanded model under section 1115A(c) of the Act, as well as our proposal to designate MDPP services as ''additional preventive services'' as defined by section 1861(ddd) of the Act. Thereafter, in a November 23rd, 2016 HPMS memo, we stated that, as a Part B additional preventive service, MDPP services will be covered for eligible Medicare beneficiaries under Medicare health plans. We reiterate here that this includes Medicare Advantage plans. The commenter did not offer an explanation as to why the requirement that Medicare Advantage plans provide MDPP services to enrollees is more restrictive than coverage of any other new or existing Part B covered service that would be required under § 422.100(a), and we can see no reason that MDPP, in particular, would be more restrictive on plan providers than previous Part B services provided to enrollees as basic benefits under § 422.100(a). Furthermore, while we applaud MA plans that currently provide prediabetes outreach, we note that there is no current mechanism by which CMS may review existing prediabetes outreach or programs and then make a determination to waive particular MA plans from the requirements of § 422.100(a) as they relate to MDPP services. As such, we decline to do so here. We note that MA plans are free to provide existing prediabetes services and outreach that do not qualify as MDPP services as a supplemental benefit available to enrollees.

Comment: We received requests from commenters to provide flexibility to modify the curriculum that MA plans must provide to MA enrollees to meet the MDPP services coverage requirement. One commenter requested the removal of a specific curriculum element—the requirement that ongoing maintenance sessions be approximately one hour in length. Both commenters requested clarification as to whether MA plans may provide modified curriculums for MDPP services provided to MA enrollees so long as

[8] CDC's Diabetes Prevention Recognition Program dataset as of March 1, 2017.

they are similar to the CDC DPRP curriculum described at § 410.79(b).

Response: Although these commenters did not comment on any specific proposals on the changes to the MDPP set of services, we believe it is appropriate to respond to provide clarifications in this final rule with respect to MDPP services more generally. We decline to accept the commenter's recommendation to remove the requirement that MDPP suppliers must provide ongoing maintenance sessions that are approximately one hour in length. In the CY 2017 PFS final rule, we agreed with commenters that our former proposal of a one-hour requirement may be too rigid when compared against CDC-approved DPP curricula that vary in approach and mode of delivery. We noted that ''approximately one-hour in duration'' is an appropriate requirement for in-person sessions because completion of a curriculum topic may vary depending on factors such as number of attendees, how the program is delivered, beneficiaries' assessed need, the curriculum topic, and the approach to the curriculum. As stated in the CY 2017 PFS final rule, we do not believe the CDC DPRP Standard that ''each session must be of sufficient duration to convey the session content'' is an auditable requirement, and therefore, we declined to adopt it for MDPP because having auditable requirements is a critical component of our program integrity efforts (81 CFR 80468). We believe our previous amendment to the session duration (formerly § 410.79(c)(2)(i) and (c)(2)(ii), and redesignated at § 410.79(b) in this final rule) is satisfactory and that our rationale applies equally to MDPP suppliers providing MDPP services to MA enrollees. Therefore, we are not modifying the requirement that ongoing maintenance sessions must be ''approximately one-hour in duration.''

We also decline to adopt commenters' recommendation to permit MA plans flexibility in providing MDPP services so long as the curriculum is similar to the CDC DPRP curriculum described at § 410.79(b) as we believe adequate flexibility is already available to any MDPP supplier. As finalized in this final rule, MDPP services must meet the definition established at § 410.79(b) defining MDPP services as ''structured health behavior change sessions that are furnished under the MDPP expanded model with the goal of preventing diabetes among Medicare beneficiaries with prediabetes, and that follow a CDC-approved curriculum. The sessions provide practical training in long-term dietary change, increased physical activity, and problem solving strategies for overcoming challenges to maintaining weight loss and a healthy lifestyle.'' We also finalized in the CY 2017 PFS final rule that MDPP suppliers may, consistent with their CDC DPRP recognition, use either the CDC-preferred curriculum as designated by the CDC DPRP Standards or an alternative curriculum approved for use in DPP by the CDC (81 CFR 80467). The CDC preferred curriculum is available at *http://www.cdc.gov/diabetes/prevention/lifestyle-program/curriculum.html.* Therefore, MDPP suppliers, including those contracting with an MA plan or an MA plan itself when that MAO is enrolled in Medicare as an MDPP supplier, may choose to develop and use an alternative curriculum for MDPP services so long as the MDPP supplier has first had the curriculum approved by the CDC DPRP.

Comment: We received one comment that requested additional clarification on how MA plans will be required to report encounters for MDPP services to CMS.

Response: This question was asked in the context of a general request for CMS to provide additional guidance to MA plans regarding the implementation of MDPP in MA. Given this context, we believe that this could be a question about reporting this specific type of data to CMS under § 422.310, which requires MA plans to report data (for risk adjustment purposes) about services provided to MA enrollees. While unrelated to the changes to the set of MDPP services, we note that the application of § 422.310 in this context is not within the scope of the MDPP rule. We believe that there is no reason to treat MDPP services differently from other services furnished by an MA plan for which the data requirements of § 422.310 apply. We further note that additional guidance to MA organizations will be forthcoming.

After considering the public comments, we will finalize all definitions as proposed with the exception of the MDPP Services Period. In response to public comments, we are finalizing the definition of the MDPP Services Period as consisting of a core services period of 1 year and an ongoing maintenance services period of 1 year at (§ 410.79(c)(2)).

i. Ongoing Maintenance Session Time Limit

In the CY 2017 PFS final rule, we finalized that ''MDPP eligible beneficiaries'' (a term we proposed to remove and replace with ''MDPP beneficiary,'' as described further in section III.K.2.c. of this final rule) would have Medicare coverage for ongoing maintenance sessions for an unspecified length of time, provided that they maintained the required minimum weight loss, which is 5 percent weight loss from baseline. Based on public comments indicating the limited administrative and operational capability of many MDPP suppliers to provide ongoing maintenance sessions for an individual indefinitely (81 FR 80467), we stated our intent to propose a limit on the number or duration of ongoing maintenance sessions to be covered in the set of MDPP services in future rulemaking.

In the CY 2018 PFS proposed rule, we proposed a 2-year limit on Medicare coverage for ongoing maintenance sessions (§ 410.79(c)(2)(ii)). The CMS Chief Actuary noted in the certification of the expansion of the DPP model test that continued participation in a DPP after 3 years has generally been untested. In addition, a DPP clinical trial conducted by the National Institutes of Health from 1996 to 2001 followed participants in a DPP for 3 years and found that, at the end of the study, diabetes incidence was reduced by 58 percent in the group that received a DPP lifestyle intervention when compared to the placebo group.[9] Based on the lack of evidence about DPP services beyond 3 years and evidence of positive effects from DPP participation for 3 years, in the CY 2018 PFS proposed rule, we proposed a total MDPP services period of up to 3 years (consisting of 1 year of core sessions and core maintenance sessions, followed by up to 2 years of ongoing maintenance sessions, (§ 410.79(b)).

We considered alternatives to this proposal, such as limiting Medicare coverage for ongoing maintenance sessions to 1 year, which would limit the total MDPP services period to 2 years. Because the CDC DPRP does not require organizations to offer ongoing maintenance sessions, we also considered not covering ongoing maintenance sessions at all, which would limit the total MDPP services period to 1 year. However, we believe that beneficiaries can benefit from maintenance sessions beyond the 6 months of core maintenance sessions because weight loss is difficult to achieve and can be even more difficult to sustain. We believe that the behavior changes necessary to sustain weight loss will be more deeply ingrained through beneficiary participation in ongoing maintenance sessions. Existing evidence

[9] Available at *http://www.nejm.org/doi/full/10.1056/NEJMoa012512.*

also supports the effectiveness of participation in a DPP through 3 years.

We did not consider alternatives that would extend Medicare coverage for ongoing maintenance sessions beyond 2 years, and therefore, create an MDPP services period that would last longer than 3 years. Therefore, we proposed to continue to include ongoing maintenance sessions, but with a limit of up to 2 years. As stated earlier, we believe there is not enough evidence available to support the effectiveness of participation in a DPP beyond 3 years. We also believe, based on public comments received in response to the CY 2017 PFS proposed rule, that many suppliers have limited administrative and operational capacity to offer MDPP ongoing maintenance sessions indefinitely to all MDPP beneficiaries who maintain eligibility. As noted in section III.K.2.e.iv.4 of this final rule, an example of a capacity limit could include a situation where an MDPP supplier has met its class size maximum and therefore could not accept additional beneficiaries. We invited public comments on our proposal and the alternatives we considered.

The following is a summary of the public comments received on our proposal and the alternatives we considered and our responses:

Comment: We received several comments on the proposed time limit for ongoing maintenance sessions. Many commenters recommended limiting ongoing maintenance sessions to 1 year and defining the MDPP Set of Services as a 2-year service period. The majority of these commenters suggested that a 2-year service period better aligned with the evidence base, reduced supplier risk and administrative burden, and still allowed for adequate time for ongoing support to participants. One commenter stated that they support general limits to ongoing maintenance sessions, but expressed that by adding a third year to the overall MDPP services period, CMS is further expanding the DPP model test and the CDC National Diabetes Prevention Program curriculum without sufficient evidence to show that the benefit to beneficiaries would outweigh the burden on suppliers to continue to staff a third year of the program. Another commenter stated the scientific evidence to suggest an additional 24 months for ongoing maintenance sessions following the achievement of the 5 percent weight loss is unclear. In addition, some commenters expressed concern about MDPP suppliers delivering sessions to dwindling numbers of individuals over time and stated this was not a cost-effective approach, and could diminish the morale among those attending the ongoing maintenance sessions. One commenter suggested opportunities for MDPP beneficiaries to elect sessions beyond month 24 (possibly covered by the beneficiary's own funds). Another commenter stated they recognize the importance of ongoing maintenance classes, but find it unrealistic to have participants commit to a 3-year program. They stated that in their experience it is difficult to maintain retention in a 12-month program, and the effectiveness of the sessions furnished in a third year would diminish.

Response: Upon consideration of the comments received, we agree that limiting the ongoing maintenance sessions to 12 months following the 12-month core program will reduce administrative burden and financial risk for suppliers while still providing 1 year of ongoing support and maintenance to help solidify behavior change in MDPP participants. Although there is evidence to support the effectiveness of participation in a DPP through 3 years, we acknowledge that evidence does not specifically address whether our proposed 2 years of ongoing maintenance is superior to 1 year of ongoing maintenance in establishing long-term behavior change or reduced incidence of type 2 diabetes. However, we maintain our belief that evidence supports requiring ongoing maintenance sessions after the core services period as discussed in a subsequent response to comments in this section.

In addition, we appreciate the commenters who pointed out that the absence of new curriculum for ongoing maintenance sessions posed a significant threat to the continued engagement of beneficiaries for a full 24 months. We agree with the assertion made by commenters that the core maintenance curriculum could become too repetitive during a second year of ongoing maintenance resulting in increasingly lower levels of participation among beneficiaries during later intervals. Based on the comments received on our proposals, we also better understand how this could contribute to dwindling enrollment during the ongoing maintenance years and how dwindling enrollment could create significant financial hardships for suppliers. We agree that it would be difficult and possibly economically unsustainable to secure space, staff coaches, and produce materials for classes that were not well attended due to a steady decrease in participants over the course of the ongoing maintenance period. From these comments, we believe finalizing a 2-year requirement for the ongoing services period could have a negative impact on the number of DPP organizations that choose to enroll as MDPP suppliers due to the estimated financial hardships of this requirement.

Therefore, we believe that a modification to our policy to require 1 year of ongoing maintenance following the core services period is both supported by current evidence and responds to the practical considerations of implementing MDPP services by MDPP suppliers.

Comment: A few commenters recommended that ongoing maintenance sessions be available in perpetuity with some suggesting a restructuring of the ongoing maintenance sessions. One commenter suggested that CMS reconsider its proposed 2-year time limit on Medicare coverage for ongoing maintenance sessions. This commenter stated an appreciation for CMS' intent to control costs, but suggested that some Medicare beneficiaries may continue to benefit from MDPP for longer periods of time. Another commenter suggested that all beneficiaries who complete the program should be eligible for a lifetime of maintenance support independent of weight loss goal achievement. The commenter suggested the delivery of ongoing maintenance sessions could be restructured to include 2–3 sessions per year as needed.

Response: We disagree with the commenters that recommended we make ongoing maintenance sessions available in perpetuity. There is no evidence to suggest that ongoing maintenance sessions offered in perpetuity would provide any additional health benefit to Medicare beneficiaries. Similarly, and taking other public comments into account, there is no evidence to demonstrate a demand from beneficiaries for ongoing maintenance sessions in perpetuity. Lastly, there is no evidence to support that 2–3 sessions per year would be adequate for maintaining weight loss, and we do not believe this level of engagement is sufficient to warrant continued coverage of the MDPP services (please see more detailed discussion on session attendance during the ongoing services period in section III.K.2.c.iv.(b) of this final rule).

Comment: Some commenters supported the proposed 2-year time limit for ongoing maintenance sessions. One commenter supported CMS's proposal to provide 2 years of ongoing maintenance sessions for a total of 3 years of MDPP services. This commenter stated that patients require ongoing support to make long-lasting

behavioral changes, and since appropriate care plans and interventions may change over time, this item is most important for continued patient and program success. Another commenter stated that it is helpful, too, to cover the 2 years of maintenance after the core and core maintenance part of the DPP. The commenter stated that people do not change and maintain significant behavioral changes without this added opportunity for maintenance and support.

Response: We agree that maintaining significant behavioral change is challenging and requires ongoing maintenance and support. The evidence is less clear in terms of exactly how long ongoing maintenance is needed to sustain significant behavior change. Given this lack of clarity on the optimal length of maintenance coupled with the many comments we received from DPP organizations and other DPP stakeholders with keen insight into the delivery of DPP, we have chosen to finalize one of our alternatives and limit ongoing maintenance to 1 year.

Comment: Some commenters did not support the inclusion of ongoing maintenance sessions at all. Many of these commenters suggested that DPP organizations may not have the capacity to deliver ongoing maintenance sessions as proposed by CMS, and at this time, there is not a CDC curriculum for this program phase. Another commenter stated that ongoing maintenance beyond 12 months should not be required by MDPP suppliers as a condition for payment. A few commenters suggested that while individuals often need ongoing support to maintain behavior change, individuals start dropping out of programs at 12 months. Other commenters recommended that CMS more closely align the MDPP services period with the CDC Diabetes Recognition Program curriculum and requirements which do not include any ongoing maintenance sessions. One commenter stated that to date, the evidence-base regarding DPP has been based on a 1-year program, and therefore, recommend that the program should remain a 1-year program. Lastly, a few commenters appreciated the importance of ongoing maintenance sessions in supporting the sustainability of participant outcomes but stated that the proposed level of reimbursement under the MDPP would not support the cost of additional human and material resources that would be needed to follow Medicare participants for an additional 2 years.

Response: We disagree that the evidence-base regarding DPP has been based on a 1-year program. In developing our length of service proposals, we performed an extensive literature review of the evidence, consulted with current DPP providers, the CDC's National Diabetes Prevention Program (DPP) staff, physicians, and a large commercial insurer. This research provided us with the evidence to support anywhere from a 1-year DPP program to a 3-year DPP program. We acknowledge that the CDC's National DPP does not currently extend beyond a 12-month program; however, as a payer, we are interested in taking an approach, which has been supported by the existing evidence base and public commenters, that we believe is most likely to sustain the behavior change beyond 12 months.

After considering the public comments, we are finalizing the length of the MDPP Services Period as a 2-year MDPP services period, specifically finalizing that after year 1, suppliers of MDPP would have to offer 1 year of ongoing maintenance sessions to beneficiaries who continue to meet attendance/weight loss goals. Finalizing this alternate proposal reduces administrative burden and financial risk to suppliers while providing up to 1 year of additional support to beneficiaries. Based on our research and echoed by many of the public comments, we received in response to our CY2018 PFS proposed rule, we believe 12 months of ongoing maintenance should solidify the behavior change and help to ensure that weight loss outcomes are sustained.

ii. MDPP Services Period Clarifications

At § 410.79(b), we proposed to remove the existing definition of ''maintenance session bundle,'' and to establish new definitions for ''core maintenance session interval,'' and ''ongoing maintenance session interval,'' which we believe will more directly reflect the structure of the set of MDPP services, as well as support the policies in this final rule. Through these definition changes, we were seeking to clarify the differences between the two types of intervals. We proposed to define ''core maintenance session interval'' as 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 1 core maintenance session per month. We proposed to define ''ongoing maintenance session interval'' as one of the up to eight consecutive 3-month time periods during the ongoing services period described in § 410.79(c)(2)(ii), during which an MDPP supplier offers at least 1 ongoing maintenance session to an MDPP beneficiary per month.

We made the proposal to use the term ''interval'' instead of ''bundle'' because the performance payments are tied to attendance and weight loss performance goals and, in aggregate, constitute the payment to MDPP suppliers for furnishing MDPP services during the MDPP services period, but they do not provide specific payments for a particular subset of sessions. Therefore, we believe that the term ''bundle'' is not appropriate for describing performance payments for these time intervals. The new terms would allow us to more appropriately describe the relationship of the performance payments to the specific time periods where performance is measured. Furthermore, we proposed to define ''make-up session'' as a core session, a core maintenance session, or an ongoing maintenance session furnished to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session, core maintenance session, or ongoing maintenance session (§ 410.79(b)). We proposed to define ''virtual make-up session'' as a make-up session that is not furnished in person and that is furnished in a manner consistent with the DPRP standards for virtual sessions (§ 410.79(b)). Policies describing the parameters of make-up sessions and virtual make-up sessions are described further in section III.K.2.c.iv.(3) of this final rule.

We proposed an additional term that helps describe key aspects of the MDPP expanded model: ''performance goal.'' This term refers to an attendance or weight loss goal that an MDPP beneficiary must achieve during the MDPP services period for an MDPP supplier to be paid a performance payment (§ 414.84(a)). Because we proposed this term that more broadly speaks to the performance goals of this expanded model, we proposed to remove the definition of ''maintenance of weight loss.'' We also proposed to move the definition of ''coach'' from § 410.79(b) to § 424.205(a) (we proposed in section III.K.2.e to redesignate § 424.59, Requirements for Medicare Diabetes Prevention Program suppliers to § 424.205). We proposed to revise the definition of ''MDPP supplier'' to mean an entity that is enrolled in Medicare to furnish MDPP services as provided in § 424.59 (redesignated as § 424.205).

We did not receive comments on the proposed revisions to these definitions, and therefore, we are finalizing these revisions as proposed with the exception of the definition for ''ongoing maintenance session interval.'' In order to align with the finalization of the

MDPP Services Period as a 2-year period, we are finalizing the definition of the ongoing maintenance session interval as one of the up to four consecutive 3-month time periods during the ongoing services period described in § 410.79(c)(2)(ii), during which an MDPP supplier offers at least 1 ongoing maintenance session to an MDPP beneficiary per month.

c. Changes Related to Beneficiary Eligibility

In the CY 2017 PFS final rule, we established the eligibility criteria for Medicare beneficiaries to have coverage of the set of MDPP services, codified at § 410.79(c)(1) and (d), respectively. We previously finalized that an individual who met these criteria would be referred as an ''MDPP eligible beneficiary.'' However, in the CY 2018 PFS proposed rule, we proposed to remove this term, and instead, add the definition of ''MDPP beneficiary'' to mean a Medicare beneficiary who meets the criteria specified in § 410.79(c)(1)(i), who has initiated the MDPP services period by attending the first core session, and for whom the MDPP services period has not ended as specified in § 410.79(c)(3) (§ 410.79(b)). We believe that this revised definition will provide more clarity about when a beneficiary qualifies to receive MDPP services. We proposed to remove the definition of ''MDPP eligible beneficiary'' to avoid confusion between the two definitions, and we proposed conforming changes to § 410.79 to remove the term ''MDPP eligible beneficiary'' and use the term ''MDPP beneficiary'' in its place, where appropriate.

In the CY 2017 PFS final rule (81 FR 80470), we specified at § 410.79(c)(1) that Medicare beneficiaries are eligible for MDPP services if they meet all of the following criteria:

- Are enrolled in Medicare Part B.
- Have, as of the date of attendance at the first core session, a body mass index (BMI) of at least 25 if not self-identified as Asian or a BMI of at least 23 if self-identified as Asian (please see our discussion of BMI parameters in the CY 2017 PFS final rule at 81 FR 80468).
- Have, within the 12 months prior to attending the first core session, a hemoglobin A1c test with a value between 5.7 and 6.4 percent, a fasting plasma glucose of 110–125 mg/dL, or a 2-hour plasma glucose of 140–199 mg/dL (oral glucose tolerance test).
- Have no previous diagnosis of type 1 or type 2 diabetes (other than gestational diabetes).
- Do not have end-stage renal disease (ESRD).

In the CY 2018 PFS proposed rule, we proposed changes to these eligibility criteria at § 410.79(c)(1) to clarify the eligibility limitations related to previous type 1 or type 2 diabetes diagnosis (described further in section III.K.2.c.ii. of this final rule), move and edit the regulation text that specifies that each beneficiary can only receive the set of MDPP services once in their lifetime (described further in section III.K.2.c.iii. of this final rule), and make changes so that the provisions are specific to an individual beneficiary. We also clarify some of the eligibility criteria.

Comment: We received a variety of comments on referral pathways for MDPP services, though we did not specifically propose any new policies regarding referrals. Some commenters supported the policy that CMS allow multiple referral pathways for beneficiaries, including self-referral, referral by a physician, and referral from community-based organizations. One commenter who supported these multiple referral pathways also noted that beneficiaries who self-refer or are referred by community programs to MDPP may not fully benefit from care coordination by their primary care provider on their diabetes care. This commenter urged CMS to consider a mechanism to ensure that the beneficiary's primary care provider be notified of the beneficiary's participation in MDPP in cases where the primary care provider is not the referring person or entity.

MedPAC opposed the policy of multiple referral pathways, preferring instead that only a clinician referral be allowed, and required, for each MDPP beneficiary. MedPAC noted that clinician referrals would help ensure clinical appropriateness of MDPP services or integration with other medical services and health maintenance goals. They were also concerned that multiple referral pathways would assist in leading to broad expansion of MDPP services and up-take, far beyond the population for which it is appropriate. MedPAC offered the example of an MDPP supplier conducting an MDPP session for a large group of beneficiaries at a nursing home, without consideration of whether a general weight loss target is clinically appropriate for each beneficiary in that group. Other commenters noted that there was no mention in the proposed rule of a provider referral mechanism or reimbursement, and recommended creating patient referral codes.

Response: We note that in the CY 2017 PFS final rule we finalized that Medicare beneficiaries who meet the MDPP eligibility criteria may obtain MDPP services by self-referral, community-referral, or health care practitioner-referral. Since we did not propose any changes to the referral policy in this rule, we are not finalizing any changes to this policy, but reemphasize our position regarding beneficiary referrals to and from MDPP services. We note that MDPP is a preventive service. Given that preventive services are generally underutilized,[10] facilitating broad access to MDPP services is important. In addition, the MDPP expanded model has been certified by the CMS Office of the Actuary to be cost-saving, and therefore, we believe eliminating barriers, such as clinician referrals, will facilitate access to this cost-saving preventive service. We also note that Medicare beneficiaries can always consult with their health care provider about whether MDPP services are clinically appropriate for the beneficiary.

We acknowledge the concerns from MedPAC regarding uptake of MDPP services beyond the population for which it is appropriate. We believe the requirement for MDPP suppliers to maintain CDC preliminary or full recognition will provide some level quality assurance. Specifically, maintenance of CDC recognition will require MDPP suppliers to continue to achieve performance standards based on attendance and average weight loss among participants. If an MDPP supplier chose to enroll large numbers of individuals who were clinically inappropriate for MDPP (for example, who lack the cognitive capability to implement the behavior changes), these practices may drive down their average performance data, and negatively affect the supplier's ability to maintain CDC recognition. Nevertheless, we are establishing monitoring mechanisms such that if a supplier was offering MDPP services to large numbers beneficiaries for whom the services may not be appropriate, we could identify this supplier and take appropriate administrative action.

Comment: Two commenters asked whether MA plans can modify

[10] See, for example: Partnership for Prevention, ''Preventive Care: A National Profile on Use, Disparities, and Health Benefits,'' *Robert Wood Johnson Foundation* (2007), *https://www.rwjf.org/content/dam/farm/reports/reports/2007/rwjf13325;* Maciosek, et al., ''Greater Use of Preventive Services in U.S. Health Care Could Save Lives at Little or No Cost,'' *Health Affairs* 29, no. 9 (2010): 1656–1660, *http://content.healthaffairs.org/content/29/9/1656.full.pdf+html;* Farley, et al., ''Deaths Preventable in the U.S. by Improvements in Use of Clinical Preventive Services,'' American Journal of Preventive Medicine 38, no. 6 (2010): 600–609, *http://www.sciencedirect.com/science/article/pii/S0749379710002072.*

beneficiary eligibility requirements for MA enrollees. The first commenter asked for clarification on whether an MA plan may impose additional eligibility requirements for MA enrollees, such as the requirement that an enrollee have a primary care physician referral to access MDPP services or to require a blood test prior to authorizing MDPP services. The second requested that we provide MA plans with the flexibility to provide or arrange for MDPP services as deemed appropriate by the plans, which the commenter identified as the standard for other Parts A and B services.

Response: While we did not propose any additional policies regarding referrals or alternative MDPP beneficiary eligibility criteria, we respond to commenters here to clarify this issue. Under § 422.100(a), MA plans are required to provide enrollees in that plan with coverage of Medicare-covered services. As a Part B Medicare-covered service, § 422.100(f) requires CMS to ensure that an MA plan's coverage of MDPP services meets CMS fee-for-service rules described in this final rule and the CY 2017 PFS final rule. Additionally, § 422.101(b)(2) requires MAOs to comply with general coverage guidelines included in original Medicare manuals and instructions unless superseded by MA regulations or guidance in connection with coverage of basic benefits.

In response to commenter's request to require physician referrals for MDPP services, we note that previous MDPP guidance, the CY 2017 PFS final rule, intentionally does not include a requirement for a physician referral to be eligible for coverage. In that rule, we finalized that we would not require any specific type of referral for the MDPP expanded model test in order to ensure broad program access (81 CFR 80471). In finalizing this policy, we noted that we understood the value of coordinating results from the MDPP with a beneficiary's primary care provider, however, we declined to require this type of coordination because we believe it creates an additional burden for this new supplier type that will discourage DPP organizations from enrolling in Medicare as MDPP suppliers. Furthermore, regarding commenter's request to allow MA plans to arrange for MDPP services as deemed appropriately by the plan, we understand the commenter to be requesting that MA plans be permitted to arrange for MDPP services as deemed medically necessary by the plan, as is the current standard. While general coverage guidelines included in original Medicare manuals and instructions may permit MAOs to arrange for other Parts A and B services as deemed medically necessary by the plan, in the CY 2017 final rule (81 CFR 80468 through 80470) and in this section of this final rule we explicitly designate a set of criteria for determining eligibility for MDPP services. Therefore, to ensure access to MDPP services as a Medicare covered service is consistent with coverage available in Original Medicare, we decline to permit MA plans to modify the eligibility requirements established in this final rule when determining the eligibility of a plan enrollee for coverage of MDPP services.

Comment: Some commenters raised concerns that obtaining documentation for clinical blood values from beneficiaries to determine their eligibility prior to furnishing MDPP services will present challenges to MDPP suppliers. One commenter in particular raised concerns with requiring blood tests from every beneficiary, citing this as a structural barrier for beneficiary participation and a burden on MDPP suppliers who may not be able to afford to delay MDPP sessions for individuals who are missing the required documentation. This commenter recommended that CMS adopt CDC's National DPP requirement that at least 50 percent of participants qualify for the DPP based on blood values, and allow the remaining 50 percent to participate based on a risk assessment. This commenter also noted that the National DPP allows blood values to be collected and documented after an individual begins DPP sessions, and requested that CMS allow MDPP beneficiaries up to 30 days after the first core session to provide their blood test results given that the beneficiary meets all other MDPP eligibility criteria.

Response: We note that we finalized beneficiary eligibility criteria, including criteria for blood test results, in the CY 2017 PFS final rule. Since we did not propose any changes to the blood test requirements in this rule, we are not finalizing any changes but are clarifying our policy. We acknowledge that the CDC enforces the blood test eligibility criteria at the organizational level. However, since Medicare will be paying for individuals receiving a service, it is necessary that we enforce eligibility on an individual basis as well. We also acknowledge that CDC allows blood values to be collected and documented after an individual begins DPP sessions. We considered allowing this policy for MDPP beneficiaries. However, if a beneficiary began MDPP services and was later determined ineligible due to their blood values, we have no way to prevent an MDPP supplier from charging the beneficiary for the services already received. We do not want to allow situations where a beneficiary could potentially be held liable for a service he/she thought was covered by Medicare, so we are not pursuing a change to this policy.

As we did not propose any substantive changes to the beneficiary eligibility policies, including referral pathways and blood test documentation, we are not finalizing any changes to these policies.

i. Clarifying MDPP Eligibility Criteria Related to Gestational Diabetes and End-Stage Renal Disease (ESRD)

In the CY 2018 PFS proposed rule (82 FR 34133), we noted that we are not excluding beneficiaries with a prior history of gestational diabetes from eligibility for MDPP services, while beneficiaries with a prior history of a diagnosis of type 1 or type 2 diabetes are ineligible. The eligibility criteria are intended to identify a beneficiary at high risk for the development of type 2 diabetes in an individual that has not been diagnosed with type 1 or type 2 diabetes. Gestational diabetes is a condition that develops during pregnancy and typically resolves after delivery, although an individual with a history of gestational diabetes is at increased risk of subsequent type 2 diabetes development and may benefit from the set of MDPP services. Because of the clinical differences between gestational diabetes and type 1 or type 2 diabetes, we determined that it was appropriate not to exclude a beneficiary with a prior history of gestational diabetes from eligibility for MDPP services.

We also proposed (82 FR 34133) that a beneficiary who is diagnosed with ESRD after having begun receiving MDPP services would lose eligibility. We do not believe MDPP services are appropriate for beneficiaries with ESRD because beneficiaries with ESRD require dialysis, and the nutrition requirements for individuals on dialysis are very specific and therefore the MDPP curriculum will not apply.[11] We believe that a beneficiary receiving MDPP

[11] WE Mitch, ''Beneficial responses to modified diets in treating patients with chronic kidney disease,'' *Kidney International Supplements* April, 94 (2005): S133–5, *https://www.ncbi.nlm.nih.gov/pubmed/15752230.* J Rysz et al., ''The Effect of Diet on the Survival of Patients with Chronic Kidney Disease,'' *Nutrients* 9, no. 5 (2017): E495, *https://www.ncbi.nlm.nih.gov/pubmed/28505087.* ME Chen et al., ''Correlations of dietary energy and protein intakes with renal function impairment in chronic kidney disease patients with or without diabetes,'' *The Kaohsiung Journal of Medical Sciences* 33, no. 5 (2017):252–259, *https://www.ncbi.nlm.nih.gov/pubmed/28433072.*

services who develops ESRD will be best suited by ceasing to receive MDPP services and receiving attention by other health care professionals specifically suited to address his or her condition. Additionally, individuals with ESRD were not included in the DPP model test. We noted that suppliers can use the online HIPAA Eligibility Transaction System (HETS) to verify if a beneficiary has ESRD by checking his or her eligibility status as a Part B or ESRD Medicare beneficiary. Suppliers can find more information on this system at *https://www.cms.gov/hetshelp/.* We recognized that some Medicare beneficiaries may have other serious conditions, such as heart disease or cancer, and therefore may also have specific dietary requirements. We recommended that beneficiaries with complex dietary needs consult their health care provider as to whether they should participate in MDPP.

In summary, we noted that a beneficiary must maintain Medicare Part B coverage and not have ESRD throughout the duration of the MDPP services period to remain eligible to receive coverage for MDPP services. In conjunction with our proposal in the proposed rule related to diabetes diagnosis (explained further in section III.K.2.c.ii. of this final rule), we noted that a beneficiary must meet the eligibility requirements related to prediabetes and diabetes (including BMI, blood test results, and no diagnosis of diabetes other than gestational diabetes) as of the date of attendance at the first core session.

We invited public comments on these clarifications. The following is a summary of the public comments received on these clarifications and our responses:

Comment: Commenters noted their support for the clarifications related to gestational diabetes and End-Stage Renal Disease (ESRD) eligibility criteria. One commenter requested that CMS integrate checks on ESRD at the federal level. Another commenter requested that CDC and CMS align eligibility criteria related to gestational diabetes. The commenter noted that CDC does not allow individuals who previously had gestational diabetes to participate in DPP, whereas CMS does allow beneficiaries who previously had gestational diabetes to participate in MDPP. One commenter requested clarification on whether an individual with a history of gestational diabetes must still meet prediabetes and BMI eligibility requirements to participate in MDPP.

Response: We appreciate commenters' support for the clarifications about gestational diabetes and ESRD eligibility criteria. CMS currently has a system that suppliers can use to check whether an individual has Medicare coverage by way of ESRD, called the HIPAA Eligibility Transaction System (HETS). Suppliers can find more information on this system at *https://www.cms.gov/hetshelp/.* Medicare suppliers can also determine this information by contacting their Medicare Administrative Contractor (MAC). We note, however, that the HETS system may only identify beneficiaries entitled to Medicare by way of ESRD, as described in § 406.13 of this chapter. Beneficiaries who are entitled to Part B benefits by aging into Medicare, who then develop ESRD, are not captured as having ESRD in HETS. Therefore, we clarify that MDPP suppliers can rely on self-reported ESRD status for beneficiaries who age into Medicare. We view this process as similar to the other self-reported eligibility criteria we noted in the CY 2017 final rule (81 CFR 80469), including a history of type 1 or type 2 diabetes diagnosis. As noted in § 424.205(d)(11), before the initial core session is furnished, the MDPP supplier must disclose detailed information about the set of MDPP services to each MDPP beneficiary to whom it wishes to begin furnishing MDPP services. This information must include beneficiary eligibility requirements under § 410.79(c)(1), which include ESRD status and history of type 1 or type 2 diabetes diagnosis. We intend to include in guidance that this disclosure should inform beneficiaries to report this information to their MDPP supplier.

In response to the commenter who noted a discrepancy in eligibility criteria between CDC and CMS regarding individuals with a previous diagnosis of gestational diabetes, we believe that the commenter was mistaken. CDC has always allowed women with a previous diagnosis of gestational diabetes to participate in the National DPP. If a woman has a previous diagnosis of gestational diabetes and meets the BMI and age criteria, she is eligible for the National DPP and would not need a blood test or an elevated risk test score.[12] Similarly, if a Medicare beneficiary has had a previous diagnosis of gestational diabetes and meets all other MDPP eligibility criteria, the beneficiary is eligible to receive MDPP services, as described at § 410.79(c)(1)(i)(E).

We also note that the DPRP Standards allow women who become pregnant and develop gestational diabetes to continue participation in the national DPP. Similarly, we clarify if a Medicare beneficiary becomes pregnant and develops gestational diabetes while receiving MDPP services, that beneficiary may continue participation in MDPP (as long as the beneficiary continues to meet the applicable performance goals required for eligibility). We encourage commenters to look to the final 2018 DPRP Standards, when available, for any updated information on how gestational diabetes is treated for the purposes of CDC performance data reporting.

Because we did not propose any policies, we are not making any modifications to the beneficiary eligibility criteria related to gestational diabetes and ESRD, at § 410.79(c)(1)(i)(E) and (c)(1)(i)(F), respectively.

ii. Diabetes Diagnosis During the MDPP Services Period

In the CY 2017 PFS final rule, we finalized at § 410.79(c)(1) that to be eligible for coverage for the set of MDPP services, a Medicare beneficiary must have prediabetes, as shown through a qualifying BMI and blood test results, and must have no previous diagnosis of type 1 or type 2 diabetes (other than gestational diabetes). We received public comments in response to the CY 2017 PFS proposed rule that asked whether a beneficiary would remain eligible for the set of MDPP services if the beneficiary developed type 2 diabetes during the MDPP services period. In the CY 2017 PFS final rule, we deferred action in response to these public comments and are now addressing them in this final rule.

We proposed in the CY 2018 PFS proposed rule (82 FR 34133 through 34134) that the diabetes diagnosis exclusion applies only at the time of the first core session (that is, if a beneficiary develops diabetes during the MDPP services period, it would not affect the beneficiary's eligibility to continue receiving MDPP services). Specifically, we proposed to revise the eligibility requirements for MDPP services to state that a beneficiary has, as of the date of attendance at the first core session, no previous diagnosis of diabetes, other than gestational diabetes (§ 410.79(c)(1)(i)(E)). This policy proposed was based in part on the fact that the DPP model test, which demonstrated cost savings, did not exclude from the model individuals

[12] Centers for Disease Control and Prevention, ''Centers for Disease Control and Prevention Diabetes Prevention Recognition Program Standards and Operation Procedures,'' *CDC* (2015), *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf.*

who developed type 2 diabetes. Additionally, whereas suppliers can check HETS to verify if a beneficiary has Medicare coverage by way of ESRD, and can rely on self-report for beneficiaries who age into Medicare and then develop ESRD, we believe requiring a supplier to reassess other beneficiary eligibility criteria such as diabetes status and blood test results, and subsequently removing those who no longer meet the eligibility criteria is impractical and unduly burdensome.

Alternatively, we considered deeming any beneficiary who develops diabetes during the MDPP services period to be ineligible to continue to receive coverage for MDPP services because these services are intended to be preventive. If a beneficiary progresses to type 2 diabetes, other treatment options, such as Diabetes Self-Management Training (DSMT), may be more appropriate than services that seek to prevent a condition the beneficiary already has. However, it is important to note that the receipt of MDPP services does not preclude a beneficiary from accessing other treatments for diabetes during the time period that the beneficiary is covered for MDPP services. An MDPP beneficiary who ultimately also receives DSMT at some time during the MDPP services period because he or she develops diabetes after beginning the set of MDPP services will receive different types of information and training. For example, a beneficiary receiving DSMT furnished by certified diabetes educators acquires knowledge for self-care and life style changes including blood sugar monitoring, insulin usage, medication management, and crisis management. In contrast, MDPP services will be furnished by trained coaches who teach beneficiaries with prediabetes how to lower their risk of progressing to type 2 diabetes with methods that do not include medication or other interventions for beneficiaries diagnosed with diabetes. Despite some common elements, the interventions for the MDPP expanded model and the DSMT benefit target different populations and furnish different services.

We sought public comments on our proposal and whether individuals who develop type 2 diabetes during the MDPP services period should continue to be eligible for coverage of MDPP services for the full duration of the MDPP services period.

The following is a summary of the public comments received on the proposal that if a beneficiary develops type 2 diabetes during the MDPP services period, it would not affect the beneficiary's eligibility to continue receiving MDPP services and our responses:

Comment: The majority of commenters supported the proposal to allow beneficiaries who develop diabetes while receiving MDPP services to continue to be eligible for MDPP for the remainder of the MDPP Services Period. The commenters noted that MDPP services will continue to be beneficial to beneficiaries with diabetes, that the MDPP curriculum varies from other Medicare-covered diabetes curriculum, such as DSMT, and that it would be impractical and unduly burdensome for suppliers to continually verify a beneficiary's diabetes status and blood test results. Of those who supported the proposal, some commenters requested that MDPP suppliers also refer beneficiaries who develop diabetes to their health care provider while other commenters requested that MDPP suppliers inform the beneficiary of Medicare-covered diabetes services, such as DSMT. Some commenters remained neutral on the proposal, either requesting further clarification or recommending that CMS continue testing this policy to ensure beneficiary access, clinical goals, and program savings. One commenter disagreed with the proposal and recommended that individuals who develop diabetes only remain eligible for MDPP services until the end of the type of session the beneficiary is receiving (that is, core sessions, core maintenance sessions, or ongoing maintenance sessions). This commenter suggested that MDPP suppliers be required to refer beneficiaries who develop diabetes to medical nutrition therapy and DSMT services, noting concern that these beneficiaries may not receive the necessary referrals and underutilize these benefits.

Response: We agree with the commenters who noted that MDPP services will continue to be beneficial to beneficiaries with diabetes, that the MDPP curriculum varies from other Medicare-covered diabetes curriculum, such as DSMT, and that it would be impractical and unduly burdensome for suppliers to continually verify a beneficiary's diabetes status and blood test results. We also note that the DPP model test, which demonstrated cost savings, did not exclude from the model individuals who developed diabetes. We clarify, for those who recommended continued testing, that CMS will monitor this policy over time and make adjustments if necessary. We clarify that we believe it is most appropriate for MDPP suppliers to recommend that beneficiaries who develop diabetes during the MDPP services period see their primary health care provider who is best suited to develop a treatment plan for beneficiaries, which could include continuation or discontinuation of MDPP services, or other diabetes-related health care services such as DSMT. As finalized in last year's final rule, and discussed further at section III.K.2.c of this final rule, however, we are not requiring MDPP suppliers to refer beneficiaries to health care providers. Additionally, an MDPP supplier (and the MDPP beneficiary) may be unaware that the beneficiary has developed diabetes, and therefore, we do not believe that mandatory referrals are appropriate. We note that the receipt of MDPP services does not preclude a beneficiary from accessing other treatments for diabetes during the time period that the beneficiary is covered for MDPP services, but emphasize the importance of beneficiaries who develop diabetes to consult with their health care provider on the most appropriate treatment plan for their diabetes, which may or may not include MDPP services.

Comment: Some commenters noted data reporting discrepancies between CDC and CMS. They noted that the proposed 2018 DPRP standards suggest that DPP programs no longer submit data to CDC on participants that have received a type 2 diabetes diagnosis while receiving DPP services, whereas CMS will continue to collect data on, and pay for services for, these individuals. Commenters noted that this will cause a gap in MDPP suppliers' required crosswalk between a beneficiary's DPRP data and billing documentation for CMS. Commenters recommended that CDC and CMS align their data submission guidelines to best track and support these beneficiaries.

Response: We appreciate the comments on this difference in data submission requirements. As with other parts of the MDPP expanded model, we are coordinating closely to align with CDC to ensure there are not major discrepancies between our programs. We encourage commenters to look to the final 2018 DPRP standards, when available, for any updated information on data reporting regarding individuals who develop type 2 diabetes while receiving DPP services.

Comment: Some commenters noted incorrect information in the CY 2018 PFS proposed rule. In discussing the alternative considered to our proposed diabetes diagnosis policy, we stated, ''[f]or example, a beneficiary receiving DSMT furnished by certified diabetes educators acquires knowledge for self-care and life style changes including

blood sugar monitoring, insulin usage, medication management, and crisis management'' (emphasis added). Commenters brought to our attention that the National Standards for Diabetes Self-Management Education and Support do not require health professionals to hold a certification in diabetes education to offer DSMT services and recommended we replace ''certified diabetes educators'' with a more appropriate phrase, such as ''health professionals who have experience in diabetes education.''

Response: We appreciate commenters bringing this to our attention.

In response to the comments, we are finalizing our proposal, without modification, that the diabetes diagnosis exclusion applies only as of the date of attendance at the first core session, (that is, if a beneficiary develops diabetes during the MDPP services period, it would not affect the beneficiary's eligibility to continue receiving MDPP services) at § 410.79(c)(1)(i)(E).

iii. Once-Per-Lifetime Set of Services

In the CY 2017 PFS final rule, we specified that coverage for the set of core MDPP services is available only once per lifetime for each MDPP beneficiary (codified at § 410.79(d)(1)). In the CY 2018 PFS proposed rule, we proposed to delete § 410.79(d)(1) and move this provision to § 410.79(c)(1)(i)(B) to place it with other MDPP beneficiary eligibility criteria. We also proposed to edit this provision to specify that coverage for the full set of MDPP services, inclusive of ongoing maintenance sessions as opposed to only core MDPP services, is available only once per lifetime per MDPP beneficiary (82 FR 34134). Since we had proposed to limit the ongoing services period to 2 years (which we are finalizing as 1 year), we believed that this revision is necessary to clarify that coverage for the entire set of MDPP services is subject to this limitation—otherwise, the once-per-lifetime limitation has no practical effect because an MDPP beneficiary could continue to attend ongoing maintenance sessions long after the MDPP beneficiary has completed the core services period. In addition, for the reasons stated previously, we do not have evidence to support coverage of MDPP services for more than 3 years. We also are clarifying that the once-per-lifetime coverage limit applies to a beneficiary who receives a set of MDPP services under the MDPP model expansion. This limitation would not apply to beneficiaries who participated in a DPP as part of the DPP model test unless they receive the set of MDPP services under the MDPP expanded model. We invited public comments on our proposal.

The following is a summary of the public comments received on the proposed provision that coverage for the full set of MDPP services, inclusive of ongoing maintenance sessions as opposed to only core MDPP services, is available only once-per-lifetime per MDPP beneficiary and our responses:

Comment: The majority of commenters opposed the once-per-lifetime limit on MDPP services, generally, including the previously finalized once-per-lifetime limit on the core set of services finalized in the CY 2017 PFS final rule and the proposed limit on the ongoing services. Some commenters only supported the lifetime limit if maintenance sessions were to be available for all beneficiaries regardless of weight loss, or if all beneficiaries who complete the core services can receive 2–3 maintenance sessions per year. Other commenters recommended that beneficiaries be able to access MDPP services annually, similar to what is allowed in some private plans. Commenters who opposed the once-per-lifetime limit stated that the limit will decrease access to MDPP services, especially for those beneficiaries that need the most assistance. These commenters noted that behavior changes take time and often require multiple attempts or ongoing support. They additionally noted that major life events may prevent a beneficiary from participating.

Some commenters recommended that beneficiaries be allowed to re-enroll in MDPP services. Others recommended providing exceptions to the once-per lifetime limit in the case of a major life event, allowing a 6- to 12-month waiting period for a beneficiary to re-enroll in MDPP after stopping (similar to Medicare's obesity counseling benefit), or both approaches. One commenter recommended that CMS allow MDPP beneficiaries to participate in an introductory session where beneficiaries can learn the requirements of the program and coaches can assess a beneficiary's readiness for change before initiating core sessions. The commenter recommended that CMS allow a beneficiary the opportunity to withdraw within 30 days from the start of the core services period without triggering the once-per-lifetime limitation so that those MDPP beneficiaries who may not be ready to complete the program may withdraw from MDPP and participate at a later time. Another commenter suggested that CMS and CDC identify and encourage the use of a validated ''readiness to change'' assessment instrument and a ''life stress'' assessment instrument to engage beneficiaries in a shared decision-making process so that individuals commit to the MDPP at a time they are most likely to succeed in the program. Some commenters also encouraged CMS to study the effect of allowing beneficiaries to enroll in the program multiple times.

Response: We recognize that behavior changes take time and often require multiple attempts or ongoing support. We also understand concerns that major life events may prevent a beneficiary from participating during the MDPP services period. However, we finalized in the CY 2017 PFS final rule that the core set of MDPP services would only be available once-per-lifetime per MDPP beneficiary (previously at § 410.79(d)(1); now at § 410.79(c)(1)(i)(B)). The MDPP model expansion was designed to permit access to MDPP services to the greatest extent possible within the limits of how MDPP could be expanded. We also believe that having MDPP services available once-per-lifetime will better engage beneficiaries to make behavior changes than if they could re-start services again at any time. We believe that this same rationale applies to ongoing maintenance sessions and continue to believe the once-per-lifetime limit is the most appropriate policy at this time, particularly given the added flexibilities beneficiaries have to use make-up sessions.

In finalizing the once-per-lifetime limitation on MDPP services in the CY 2017 PFS final rule, we added in flexibility for beneficiaries by not including any attendance requirements for beneficiary eligibility in the first year of core services following the first core session. Therefore, beneficiaries can attend as many or as few sessions as the beneficiary wishes in the first year, and as long as they meet the 5 percent weight loss goal in months 10–12, they are eligible for ongoing maintenance sessions. If an unexpected or life-altering event does occur during the core services period, the beneficiary is not required to attend a certain number of sessions. The beneficiary can take a break and begin attending MDPP sessions again within the first year. The beneficiary could also still be eligible for ongoing maintenance sessions, as long as the beneficiary begins attending sessions again and meets the 5 percent weight loss goal in months 10–12. Additionally, in this rule, we are finalizing the ability for beneficiaries to attend in-person or virtual make-up sessions if they miss a regularly scheduled session. We believe that these policies provide flexibility for beneficiaries who experience difficulty

attending sessions during both the core services and ongoing services periods in light of the once-per-lifetime service limitation.

We appreciate the comments received recommending the allowance of an introductory session and 30-day window to withdraw, as well as the use of an assessment tool to assess if the beneficiary is ready to start MDPP services, so that the beneficiary can understand the eligibility requirements and determine if he or she is ready to begin. We note that suppliers may speak to beneficiaries about their readiness while assessing them for eligibility or before the beneficiary begins MDPP services. This could include the use of any tools that the supplier may have to help a beneficiary make their own determination about whether to commit to the MDPP services period or not. However, MDPP suppliers may not use these tools to screen beneficiaries for their perceived ability to successfully complete the MDPP performance goals. Selecting beneficiaries based on these purposes would not comply with the MDPP supplier standard proposed (and which we are finalizing) in § 424.205(d)(8), which prohibits an MDPP supplier from denying an MDPP beneficiary access to MDPP services during the MDPP services period, including on the basis of the beneficiary's weight, health status, or achievement of performance goals, with few exceptions. We also note that in § 424.205(d)(11), which we are finalizing in this final rule, the supplier standards require MDPP suppliers to provide an MDPP beneficiary information about the MDPP set of services prior to beginning furnishing such services. This information must include eligibility requirements throughout the MDPP services period, including the once-per-lifetime limitation. We believe that this information will supply the beneficiary with the necessary information to make an informed decision on whether to begin MDPP services.

We acknowledge commenters' concerns on life altering events precluding a beneficiary's participation and understand that there will be circumstances that preclude an individual from participating. As stated previously, we believe the ability for a beneficiary to attend in-person and virtual make up sessions could assist in some of these circumstances. Additionally, because only 2.4 percent of participants in the DPP model test re-enrolled in the model while the model test was still active, we believe that the number of beneficiaries requesting to re-enroll in MDPP will be quite small. However, we plan to monitor the once-per-lifetime limitation to consider whether an exceptions policy for beneficiaries who experience life-altering events is necessary, and if appropriate, we will address this issue in future rulemaking.

In the CY 2017 PFS final rule, we stated that beneficiaries could self-report to MDPP suppliers that they had not previously received MDPP services. We recognize that self-reported information may not be the most reliable source for MDPP suppliers to use before submitting claims for MDPP beneficiaries, and there is a risk that information that is inaccurately self-reported could result in the denial of payments for MDPP services. In the CY 2018 PFS proposed rule, we noted that we were considering ways MDPP suppliers would be able to reliably verify if a beneficiary has received MDPP services from another supplier, such as through a standardized tracker (82 FR 34134), and we sought public comments on any additional ways MDPP suppliers could access this information. We noted that we intend to provide administrative guidance on any resources to assist MDPP suppliers in identifying beneficiaries' previous receipt of covered MDPP sessions, as appropriate.

The following is a summary of the public comments received on ways that MDPP suppliers can reliably verify if a beneficiary has received coverage of MDPP services from another supplier and our responses:

Comment: Commenters generally raised concerns about the use of beneficiary self-reported data, noting that such data is often unreliable. Commenters also noted that verifying previous MDPP service use would require a sophisticated tracking system and urged CMS to work with MDPP suppliers to ensure accurate tracking of eligibility and progress through the MDPP services period. To this end, we received comments on a variety of ways for MDPP suppliers to verify if a beneficiary has previously received MDPP services from another supplier.

Some commenters requested that CMS document whether an individual has previously received MDPP services, and make this information available to MDPP suppliers to check a beneficiary's previous MDPP service use, at the federal level. One commenter suggested that CMS could build a beneficiary-level database that would contain information about MDPP status. The database could include the beneficiary's first name, last name, and birthdate so that MDPP suppliers could look up a beneficiary based on those three variables in order to identify his or her eligibility and program status based on time-to-date and MDPP sessions already furnished in the MDPP services period. The commenter recommended against the use of social security numbers in this context, due to data security concerns. For looking up beneficiaries where those three pieces of information identify multiple individuals, the commenter suggested that a hotline could be set up and MDPP suppliers could call in to verify eligibility of a specific beneficiary for MDPP services. Another commenter similarly recommended building a master database for MDPP suppliers to use to verify MDPP use, and that CMS permit self-reporting until such a database exists. One commenter noted that CMS could consider leveraging state and local health information exchanges, where they exist, to transfer beneficiary information on MDPP service use.

Commenters were divided on CMS designing a paper tracker, such as the one mentioned in the CY 2018 PFS proposed rule, that beneficiaries could take with them to a new supplier to share information. One commenter recommended that CMS develop such a tracker to assist in data sharing between MDPP suppliers. However, this commenter also noted that for potential, small, and new DPP suppliers that typically have limited staff, the administrative processes involved with such a tracker may be burdensome. Another commenter raised concerns about such a tracker, noting that beneficiaries could lose their trackers and possibly modify results.

Response: We appreciate the suggestions on ways that MDPP suppliers can determine a beneficiary's prior use of MDPP services for the purposes of verifying eligibility. We recognize that self-reported data is not always reliable; however, we did state in the CY 2017 PFS final rule that beneficiaries could self-report to MDPP suppliers about their previous MDPP service use.

We agree that a beneficiary-level data system could provide a useful way for MDPP suppliers to check whether an MDPP beneficiary had previously received MDPP services both before a beneficiary starts receiving MDPP services and when an MDPP beneficiary switches MDPP suppliers. When we considered creating such a data system, we recognized that it would need to contain data beyond what we will receive in claims data (such as baseline weight), and therefore, would require that MDPP suppliers continuously submit updated beneficiary information to us to populate the system. We believe

that creating such a system would post a significant burden that would outweigh the benefit for MDPP suppliers. Moreover, other commenters have urged us to pursue a more streamlined interaction between CDC and CMS DPP-related data systems.

Given these various stakeholder views and our considerations about what a data system would entail, we believe that creating an additional data system for MDPP suppliers to verify beneficiary eligibility would be inconsistent with commenters' general requests for fewer, rather than additional, data submission requirements (please see more information at III.K.2.d.v of this final rule). Thus, we do not intend on creating a beneficiary-level data system at this time. Instead, we are exploring an electronic mechanism using claims data and existing CMS systems that MDPP suppliers could access to verify beneficiaries' prior receipt of MDPP services and plan to provide additional information on this mechanism in future guidance, as appropriate. In addition, we are still considering developing a paper tracker that an MDPP beneficiary can take with them between suppliers to prevent disruption in MDPP services. However, as described in section III.K.2.d.v of this final rule, a supplier accepting a new beneficiary in the middle of his or her services period would need to obtain the beneficiary's previous MDPP records to verify data such as baseline weight or weight loss from baseline that is necessary before the new supplier could submit any performance payments. Obtaining this documentation would be necessary to satisfy the MDPP supplier requirement at § 424.205(g) that an MDPP supplier shall maintain documentation that includes services furnished and body weight measurements.

Comment: We received several comments regarding the MDPP's once-per-lifetime limit and its application and operationalization within Medicare Advantage. One commenter asked whether an MA plan could provide introductory classes or offer a waiting period after a beneficiary has received MDPP services before the once-per-lifetime limit is implicated, or if MA plans could provide accommodations for extenuating circumstances that may interfere with a beneficiary's ability to complete the program as an exception to the once-per lifetime requirement.

Response: As in Original Medicare, the once-per-lifetime limit is implicated for an MA enrollee upon the receipt of MDPP services. The rationale for this policy can be found in the CY 2017 PFS final rule (81 CFR 80470) and section III.K.2.c.iii of this final rule. Under § 422.100(a), MA plans are required to provide enrollees in that plan with coverage of Medicare-covered services. As a Part B Medicare-covered service, § 422.100(a) requires MA plans to provide coverage of MDPP services to plan enrollees. Additionally, § 422.100(f) goes on to require that CMS must ensure that an MA plan's coverage of MDPP services meets CMS fee-for-service rules, which are described here in this final rule and the CY 2017 PFS final rule. These rules explicitly require that, to be eligible for coverage for MDPP services, a beneficiary must not have previously received the set of MDPP services in his or her lifetime. Therefore, the once-per-lifetime per beneficiary limit applies equally to MA enrollees, and we decline to permit MA plans to implement a ''waiting period'' after an enrollee has received MDPP services without implicating the lifetime limit on MDPP services. We note, however, that nothing in this final rule or the CY 2017 PFS final rule (81 CFR 80170 through 80562) prevents an MA plan from making available to its enrollees additional or more extensive MDPP-like services as a supplemental benefit. For instance, where an MA plan believes that its prediabetic enrollees could benefit from introductory classes that, while not MDPP services, would allow the enrollee to decide whether to go on to receive MDPP services, an MA plan may elect to provide those classes as a supplemental benefit. Similarly, where an enrollee has begun MDPP services and is unable to complete the program due to extenuating circumstances, an MA plan may elect to make available to that enrollee other, MDPP-like services as a supplemental benefit.

Comment: Two commenters suggested that CMS facilitate data sharing among MDPP suppliers, such as by constructing a master database that MDPP suppliers and Medicare Advantage Organizations could consult to determine whether a given Medicare beneficiary or MA enrollee previously received MDPP services. Commenters indicated that such data sharing abilities would be useful when a beneficiary moves from Original Medicare to an MA plan or between MAOs. Without this database, one commenter recommended that CMS permit self-reporting from beneficiaries as a means for MA plans to determine whether the beneficiary has or has not utilized the once-per-lifetime set of services when determining a beneficiary's eligibility for MDPP services.

Response: As discussed in this section, we are exploring existing CMS systems that MDPP suppliers could access to verify if beneficiaries have previously received MDPP services and intend to release additional details through guidance. We intend that this would also allow any MDPP supplier that is furnishing MDPP services to an MA enrollee to determine whether a given beneficiary has previously received MDPP services under Original Medicare, regardless if the MDPP supplier seeking the verification is the plan itself or has contracted with an MA plan to provide MDPP services to enrollees. We emphasize that when determining whether an enrollee is eligible for MDPP services, MA plans should treat the once-per-lifetime limit for MDPP as they would similar services, such as mammograms, that are available on a time-limited basis. Additional information on this matter will be released in future guidance, as appropriate.

After consideration of the public comments, we are finalizing the once-per-lifetime limitation on MDPP services as proposed at § 410.79(c)(1)(i)(B). However, we plan to monitor this policy to consider whether an exceptions policy for beneficiaries who experience life-altering events is necessary, and if appropriate, we will address this issue in future rulemaking. We did not make any proposals regarding ways that MDPP suppliers can reliably verify if a beneficiary has received coverage of MDPP services from another supplier, and intend to release future guidance on this, as appropriate.

iv. Eligibility Throughout the MDPP Services Period

In the CY 2017 PFS final rule, we specified the minimum number and frequency of sessions that MPP suppliers must offer to MDPP beneficiaries (codified at § 410.79(c)(2)(i) and (c)(2)(ii)). We finalized that MDPP suppliers must furnish ongoing maintenance session intervals to MDPP eligible beneficiaries who have maintained 5 percent weight loss from their baseline weight as measured during the previous maintenance session interval. As defined at § 410.79(b), ''baseline weight'' is the MDPP beneficiary's body weight recorded during that beneficiary's first core session.

However, because in the CY 2018 PFS proposed rule, we proposed to tie payment for MDPP services to the beneficiary's achievement of performance goals, we proposed additional changes to tie the beneficiary's eligibility for continued coverage of ongoing maintenance

session intervals to his or her achievement of performance goals, namely requiring a minimum level of attendance (82 FR 34134 through 34135). Because our proposed policies for payment and coverage differ somewhat, we are addressing them separately below.

(1) MDPP Services Period

As discussed in section III.K.2.b. of this final rule, we are revising § 410.79(c)(2), which describes MDPP services periods, to specify that the 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 § 410.79(c)(2)(i) and, subject to § 410.79(c)(3), up to 4 ongoing maintenance session intervals during the ongoing services period described in § 410.79(c)(2)(ii).

We proposed to revise § 410.79(c)(2) to specify that there are 2 service periods in which Medicare will cover MDPP services for a beneficiary: The core services period; and the ongoing services period (82 FR 34134 through 34135). Together these would make up the MDPP services period. The core services period is the first 12 months of the MDPP services period, and consists of core sessions and core maintenance sessions. There are 16 core sessions that are offered at least a week apart in months 1 through 6, beginning on the date of attendance at the first core session. Core maintenance sessions are offered at least once per month in months 7 through 12 of the core services period. We proposed to move the requirements for MDPP suppliers to offer these services to § 424.205(d)(10) because they are more appropriately included among other requirements for MDPP suppliers. Consistent with our policies finalized in the CY 2017 PFS final rule, we do not condition coverage for the core services period upon weight loss or attendance. However, we note that an MDPP beneficiary must attend at least 1 core session to initiate the MDPP services period.

These proposals were consistent with CDC's 1-year curriculum, divided into two 6-month periods. We recognize that framing the MDPP services period in terms of months may cause some confusion because the CDC terminology uses weeks. However, we stated that we believe that framing the MDPP services period in months would better align with our payment structure. We did not make eligibility for the core maintenance sessions contingent upon an attendance-based performance goal; because the CDC DPP curriculum covers 12 months of sessions, we stated that we believe that coverage for the 12 months of the core services period should be available to all MDPP beneficiaries, regardless of attendance. The 12-month CDC DPP curriculum is based on evidence from the original DPP randomized clinical trial, and the curriculum used in that trial, which achieved a 58 percent reduction in type 2 diabetes risk (with 71 percent reduction in those over age 60).[13]

As discussed in section III.K.2.e.iv.4 of this final rule, MDPP suppliers must offer a minimum of 16 core sessions, no more frequently than once each week, in months 1 through 6, and at least 1 core maintenance session each month in months 7 through 12 of the core services period. However, some MDPP suppliers may choose to furnish more than the minimum number of sessions, and these coverage parameters would allow beneficiaries to receive more than the minimum number of sessions if the MDPP supplier elects to furnish them.

We did not receive comments on the proposed description revisions for the MDPP services periods, and therefore, are finalizing these proposals at § 410.79(c)(2). However, we note that we are finalizing changes at § 410.79(c)(2) to reflect that we are finalizing shortening the ongoing services period from 2 years to 1 year. We are also finalizing the movement of requirements for MDPP suppliers to offer these services to § 424.205(d)(10) because they are more appropriately included among other requirements for MDPP suppliers.

(2) Ongoing Services Period

As discussed in section III.K.2.b.i. of this final rule, we proposed at § 410.79(c)(2)(ii) that the ongoing services period consists of up to eight 3-month ongoing maintenance session intervals offered during months 13 through 36 of the MDPP services period; however, we are modifying this proposal to finalize that the ongoing services period consists of up to *four* 3-month ongoing maintenance session intervals offered during months *13 through 24* of the MDPP services period. Medicare's coverage of the ongoing services period is subject to limitations discussed subsequently in this section.

[13] WC Knowler et al., ''Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin,'' New England Journal of Medicine 346, 6 (2002): 393–403, *https://www.ncbi.nlm.nih.gov/pubmed/11832527*. The Diabetes Prevention Program (DPP) Research Group, ''The Diabetes Prevention Program,'' Diabetes Care 25, 12 (2002): 2165–2171, *http://care.diabetesjournals.org/content/25/12/2165.long*.

(a) Eligibility for the Ongoing Services Period

Our existing regulations at § 410.79(b) state that Medicare will cover MDPP services in the first 12 months of the MDPP services period, without regard to a beneficiary's achievement of performance goals, whereas § 410.79(d)(2) specifies that, for coverage of ongoing maintenance sessions, the beneficiary must have achieved weight loss of 5 percent from his or her baseline weight. In the CY 2018 PFS proposed rule, we proposed to delete § 410.79(d)(2) and move this provision to § 410.79(c)(1) with other MDPP beneficiary eligibility criteria. We also proposed to add paragraph (c)(1)(ii) to § 410.79 to specify that beneficiaries must also attend at least one in-person core maintenance session in months 10 through 12 of the MDPP services period and achieve or maintain required minimum weight loss at a minimum of one in-person session during the final core maintenance session interval to be eligible for coverage of the first ongoing maintenance session interval. We proposed to establish that a beneficiary must attend at least one in-person core maintenance session in months 10 through 12 of the MDPP services period because, as stated in the CY 2017 PFS final rule, an MDPP beneficiary must achieve at least 5 percent weight loss from baseline at least once during the previous maintenance session interval to have coverage of an ongoing maintenance session.

Because we proposed that weight measurements used for determining beneficiary eligibility for coverage or supplier payment must be taken in person by an MDPP supplier at an MDPP core maintenance or ongoing maintenance session (§ 410.79(c)(1)(iv)), a beneficiary must attend at least one in-person core maintenance session during months 10 through 12 to have his or her weight measured to determine whether he or she qualifies for coverage of the first ongoing maintenance session interval. We believe that in-person measurements are the most feasible method for weight ascertainment at this time for services where the beneficiary would have regular in-person sessions with the MDPP supplier. We believe that self-reported weight loss is not reliable for the purposes of determining continued coverage of MDPP services for a beneficiary. We invited public comments on these proposals.

The following is a summary of the public comments received on eligibility for the ongoing services period and our responses:

Comment: We received a variety of comments on our proposal that weight measurement must be taken in-person at an MDPP session, although they were in relation to the proposed policy regarding virtual make-up sections discussed in section III.K.2.c.iv.3.b of the proposed rule (82 FR 34136 through 34137). Some commenters supported the proposal, while others requested alternate forms of weight measurement, such as via Bluetooth-enabled scales or self-reported weight.

Response: As discussed further in section III.K.2.c.iv.3.b of this final rule, while we recognize the use of Bluetooth-enabled scales for virtual weight reporting in some DPP programs, we believe that virtual weight reporting is not appropriate or necessary for a predominantly in-person model (we are using the term ''Bluetooth-enabled'' as we understand it described in the CDC DPRP as a scale that uses a cellular, wireless, Bluetooth, or other electronic connection to automatically send weight data to the supplier). Except for the limited number of virtual-make up sessions, MDPP sessions are required to be offered and attended in person and corresponding weight are also required to be taken in-person. We also believe that self-attested weight measurement is generally unreliable, and therefore believe that in-person weight measurement is the most reliable and appropriate form of weight measurement for the MDPP expanded model.

After consideration of the comments received, we are finalizing the eligibility criteria for the ongoing services period as proposed at § 410.79(c)(1)(ii). We are also finalizing changes to the definition of ''ongoing maintenance session interval'' at § 410.79(b) to reflect shortening the ongoing services period from 2 years to 1 year.

(b) Eligibility for Ongoing Maintenance Session Intervals 2 Through 8

In addition to achieving weight loss performance goals, as previously finalized in the CY 2017 PFS final rule § 410.79(d)(2) (now finalized at § 410.79(c)(1)(ii) and (c)(1)(iii)), we proposed that beneficiaries must also meet an attendance-related performance goal in order for Medicare to cover ongoing maintenance session intervals. We proposed to add paragraph (c)(1)(iii) to § 410.79 to specify that for coverage of ongoing maintenance session intervals 2 through 8, an MDPP beneficiary must attend at least three ongoing maintenance sessions during the previous ongoing maintenance session interval, at least one of which must be an in-person ongoing maintenance session to record an in-person weight measurement, in addition to maintaining 5 percent weight loss from baseline at least once during the previous ongoing maintenance session interval.

We believe that adding an attendance-related performance goal during the ongoing services period is important because it will provide an incentive to keep MDPP beneficiaries engaged after the core services period. MDPP beneficiaries who meet the specified attendance and weight loss goals will have Medicare coverage of ongoing maintenance sessions, which are a part of the set of MDPP services, but not a part of the CDC DPP curriculum. We believe that the subsequent attendance goal requirements during ongoing maintenance session intervals will motivate beneficiaries to take on more individual responsibility for their behavior changes over time because coverage of these services is dependent upon their attendance and achievement and maintenance of weight loss.

In addition, this policy closely aligns with our policy for supplier payment for ongoing maintenance session intervals. As described further in section III.K.2.d.iii.5. of this final rule, we proposed that a supplier would be paid for furnishing an ongoing maintenance session interval only if the MDPP beneficiary both attended three sessions, as well as maintained a 5 percent weight loss from baseline measured at least once in that interval. However, in light of our proposal to pay MDPP suppliers upon the beneficiary's attendance of three ongoing maintenance sessions (in addition to maintaining at least a 5 percent weight loss), we believe that we similarly need to have attendance goals for beneficiaries to continue to have coverage of ongoing maintenance sessions and mitigate the supplier's risk of providing services without payment. Without requiring attendance, an MDPP beneficiary who maintained 5 percent weight loss but only attended two ongoing maintenance sessions in an ongoing maintenance session interval would be eligible for coverage of ongoing maintenance sessions, but the supplier would not receive payment for furnishing that ongoing maintenance session interval. In effect, the MDPP supplier could be required to furnish up to 12 months (finalized in this final rule at § 410.79(c)(2)(ii)) of MDPP services without payment. For this reason, we proposed to require beneficiaries to attend all three sessions within an ongoing maintenance session interval to have coverage of the subsequent interval.

We considered an alternative where a beneficiary would have continued coverage of ongoing maintenance session intervals if he or she attends at least one in-person ongoing maintenance session during an ongoing maintenance session interval, as long as that beneficiary maintained at least 5 percent weight loss from baseline at least once during that interval. However, we do not believe that this alternative would align with our proposed supplier payment requirements for ongoing maintenance sessions discussed in section III.K.2.d.iii.5 of this final rule, which would require suppliers to furnish, and the beneficiary to attend, all three sessions of the ongoing maintenance session interval for the supplier to receive payment for that interval. We invited public comments on our proposal and the alternative we considered.

The following is a summary of the public comments received on our proposal to add attendance requirements for beneficiary eligibility for ongoing maintenance session intervals 2–8 and our responses:

Comment: The majority of commenters noted that beneficiary eligibility requirements for ongoing maintenance session intervals are too strict and requested flexibility in eligibility requirements for the ongoing services period. Some commenters noted that the eligibility requirements would be especially difficult for certain populations, such as those that face socio-economic barriers or individuals in rural areas who may lack transportation options or other services required to attend MDPP sessions.

Many commenters noted that requiring perfect attendance at ongoing maintenance sessions (that is, 3 out of 3 ongoing maintenance sessions per interval) places too much burden on beneficiaries. These commenters noted that requiring perfect attendance at ongoing maintenance sessions is an unrealistic expectation, given that certain life events, often beyond the beneficiary's control, could prevent the beneficiary from attending a session. These commenters noted that this fact, combined with the limited number of allowed virtual make-up sessions and the once-per-lifetime limitation on MDPP services, could limit beneficiary access to MDPP services. These factors have the potential to permanently disqualify the beneficiary from receiving additional MDPP services, even if the beneficiary maintained weight loss. Additionally, commenters noted that MDPP suppliers may need to offer additional ongoing maintenance

sessions beyond the minimum to ensure that beneficiaries meet attendance goals; however, offering these extra sessions would be costly and may limit MDPP supplier participation, further limiting beneficiary access.

Commenters who provided this information on the challenge of having perfect attendance often recommended allowing beneficiaries to maintain eligibility if they attend 2 out of 3, rather than 3 out of 3, ongoing maintenance sessions per interval, in addition to maintaining 5 percent weight loss. Some commenters recommended that beneficiaries only be required to attend 1 out of 3 ongoing maintenance sessions per interval, in addition to maintaining 5 percent weight loss, to be eligible for the next interval.

Response: After consideration of the public comments received with respect to beneficiary eligibility for ongoing services, we acknowledge that requiring a beneficiary to have perfect attendance to be eligible for the next interval is strict, and that allowing some flexibility is reasonable. When considering comments on this policy, we considered how changing attendance requirements for eligibility would affect beneficiaries' engagement and our ability to determine whether the maintenance of weight loss is attributable to the sessions attended during the ongoing services period. As noted in our proposal, we considered an alternative of requiring at least 1 session attended per interval; however, we do not believe that requiring attendance at only 1 MDPP session per interval provides enough MDPP sessions to be attributable to the outcome of maintained weight loss. A beneficiary who can only attend 1 session over the course of 3 months may be engaged in other activities that are contributing more to his or her weight loss maintenance than MDPP, and we do not believe continued coverage of ongoing maintenance sessions is appropriate in this case. However, we believe that weight loss maintained by a beneficiary who attends at least 2 monthly sessions (with the option of attending all 3 sessions offered by an MDPP supplier within an interval) can be reasonably attributed to the receipt of ongoing maintenance services. Suppliers have the option (but are not required) to offer both in-person and virtual make-up sessions, which offer the beneficiary additional flexibility with attendance. If a beneficiary is not able to attend a regularly scheduled ongoing maintenance session, the beneficiary may have the ability to attend a make-up session at another time (as described in section III.K.1.c.iv.(3) of this final rule).

We also understand based on comments that there could be scenarios in which attendance at an in-person monthly session may be challenging and impractical for a beneficiary, due to transportation barriers or some other life event, and if the supplier did not offer make-up sessions (because they are not required), the beneficiary could lose coverage for the next interval even if they are engaged and maintain weight loss. We also understand that if MDPP suppliers believe additional ongoing maintenance sessions beyond the monthly sessions are needed to ensure that beneficiaries meet attendance goals, this would be costly and potentially limit supplier participation. Although make-up sessions are an option for MDPP suppliers, we share the concern commenters raised about the potential burden placed on suppliers to make accommodations for beneficiaries who miss a session in order to maintain their eligibility.

Since the performance goals of the MDPP expanded model are more heavily weighted towards outcomes (that is, weight loss) than process measures (that is, attendance), and the specific outcome during the ongoing services period is maintenance of weight loss, which is required both for the ongoing maintenance session interval performance payment and coverage of the next ongoing maintenance session interval, we believe reducing the attendance requirements by 1 session allows sufficient flexibility to beneficiaries and suppliers without misattributing a beneficiary's maintenance of weight loss to other activities occurring outside of MDPP, during the ongoing services period. While in section III.K.2.d.iii.(3) of this final rule we describe our final policy which increases the attendance-based performance payment amounts for core sessions, we believe that placing more emphasis on weight loss maintenance, rather than attendance, during the ongoing services period maintains the integrity of the program while providing beneficiaries and suppliers more flexibility. We believe this modification will still provide an incentive to keep MDPP beneficiaries engaged after the core services period.

We note that we are aligning these eligibility requirements with our finalized payment structure, described more in section III.K.2.d.3 of this final rule. As discussed in section III.K.2.c.iv.2.b of the CY 2018 PFS proposed rule, we find it important to align attendance goals for beneficiaries to maintain eligibility for ongoing maintenance sessions with performance goals required for payment during ongoing maintenance sessions. Without requiring the same number of attendance goals, an MDPP beneficiary who maintained 5 percent weight loss but only attended two ongoing maintenance sessions in an ongoing maintenance session interval would be eligible for coverage of ongoing maintenance sessions, but the supplier would not receive payment for furnishing that ongoing maintenance session interval. In effect, the MDPP supplier could be required to furnish up to 12 months (finalized in this final rule at § 410.79(c)(2)(ii)) of MDPP services without payment. To alleviate this concern, we are aligning our finalized payment policies, described more in section III.K.2.d.3 of this final rule, to align with our finalized eligibility policies.

After consideration of the public comments, we are finalizing that an MDPP beneficiary must attend at least 2 ongoing maintenance sessions per ongoing maintenance session interval (and achieve a 5 percent weight loss during at least one in-person session during the interval) to be eligible for subsequent ongoing maintenance session interval after the first. This policy will be finalized at § 410.79(c)(1)(iii).

Comment: A number of commenters requested modification to a previously finalized policy that stated that ongoing maintenance sessions are available only if the MDPP eligible beneficiary has achieved maintenance of weight loss (a policy finalized previously at § 410.79(d)(2); now at § 410.79(c)(1)). Many of these commenters noted that a 5 percent weight loss seemed too high and recommended alternatives to the 5 percent weight loss goal to determine continued eligibility for ongoing maintenance session intervals, such as attendance alone or HbA1c level. One commenter suggested allowing beneficiaries to reach the 5 percent weight loss goal once every 6 months, rather than 3 months, to maintain eligibility for the next ongoing maintenance session interval.

Response: We appreciate commenters' concerns that maintaining 5 percent weight loss during each ongoing maintenance session interval to be eligible for the next interval will be difficult for some beneficiaries. We also appreciate the comments received that suggest lowering the weight loss criteria or using different criteria. However, we note that we finalized our weight loss policy in the CY 2017 PFS final rule (previously at § 410.79(d)(2); now at § 410.79(c)(1)) as it relates to eligibility

for ongoing maintenance sessions, and did not propose any adjustments to the 5 percent weight loss goal in this year's proposed rule. In last year's final rule, we noted that the requirement that beneficiaries maintain 5 percent weight loss is consistent with the weight loss goal tested in the DPP model test, and was factored into the Secretary's determination to expand the model and the Chief Actuary's certification that MDPP expansion would not result in an increase of Medicare spending. Therefore, we are not changing the requirement that beneficiaries must maintain the 5 percent minimum weight loss in order to be eligible for ongoing maintenance sessions. To account for the fact that weight does fluctuate, and to allow beneficiaries more flexibility, we finalized last year that beneficiaries need only meet the 5 percent weight loss goal at 1 session during a 3-month interval. We believe that this allows beneficiaries the opportunity for weight fluctuation within an interval, while maintaining the MDPP goals of continued lifestyle change over time.

Comment: We received comments that CMS should grant flexibility to certain tribal health programs to determine their own diabetes prevention measures of success. These commenters noted that the 5 percent weight loss goal is too stringent and that weight loss alone does not adequately reflect the overall progress a participant is making toward lasting lifestyle changes and the prevention of diabetes. These commenters also recommended separate categories for weight loss goals for men and women, citing sedentary lifestyle and metabolism barriers of Native women, and that Native women struggle with weight loss more than Native men because of hormonal body changes and gradual lean muscle loss that come with age.

Response: We appreciate this request for flexibility from tribal communities. However, we note that the MDPP expanded model is an expansion of the DPP model test, which was based on the CDC National DPP. We are relying on measures that were shown to be successful in the DPP model test, which includes the same percentage achievement of weight loss for men and women, and the MDPP expanded model relies on these measures for eligibility during the ongoing services period. However, we will continue consultation with tribal communities and attempt to address their concerns as appropriate.

After consideration of the public comments, we are finalizing that an MDPP beneficiary must only attend 2 ongoing maintenance sessions per ongoing maintenance session interval (and maintain 5 percent weight loss during one in-person session) to be eligible for the next ongoing maintenance session interval. This policy will be finalized at § 410.79(c)(1)(iii).

(c) Limitations on the Set of MDPP Services

In the CY 2018 PFS proposed rule, we proposed to add § 410.79(c)(3) to specify that coverage of the MDPP services period would end upon completion of the core services period for a beneficiary that is not eligible for the first ongoing maintenance session interval as proposed under § 410.79(c)(1)(ii); that is, if the beneficiary does not attend at least 1 in-person core maintenance session during the second core maintenance session interval and/or does not achieve the required minimum weight loss during this interval (82 FR 34136). For any beneficiary who is eligible for at least 1 ongoing maintenance sessions interval, but who does not meet the requirements for coverage of a subsequent interval based on failure to meet attendance or weight loss goals proposed at § 410.79(c)(1)(iii), the beneficiary's coverage of the set of MDPP services would end upon completion of his or her current ongoing maintenance session interval. It is important to note that performance payments, discussed in section III.K.2.d.iii.5. of this final rule, will be tied to the achievement of the same performance goals a beneficiary must meet to have coverage for the ongoing maintenance session intervals. Therefore, if an MDPP beneficiary does not meet weight loss or attendance goals to have coverage of the subsequent ongoing maintenance session interval, the supplier will not receive payment for that ongoing maintenance session interval or any subsequent performance payments related to that beneficiary.

We did not receive comments on our proposal to add specifications on when coverage of the MDPP services period ends, and therefore, are finalizing our policies as proposed at § 410.79(c)(3). We note that we are finalizing changes at § 410.79(c)(3) to reflect shortening the ongoing services period from 2 years to 1 year (so now there are only four intervals).

(d) Beneficiaries Who Change MDPP Suppliers During the MDPP Services Period

In the CY 2017 PFS final rule (81 FR 80470), we confirmed that a beneficiary may change MDPP suppliers at any time. However, we deferred to future rulemaking specific policies to address coverage of and payment for MDPP services when beneficiaries change MDPP suppliers. In the CY 2018 PFS proposed rule, we clarified that a beneficiary may change MDPP suppliers at any time during his or her MDPP services period, subject to beneficiary eligibility requirements (82 FR 34136). Based on evidence from the CDC DPRP, we believe that the instances of beneficiaries changing MDPP suppliers will be relatively infrequent. However, we intend to monitor how often beneficiaries change MDPP suppliers, as well as MDPP suppliers' billing patterns to detect any aberrant billing patterns suggestive of fraudulent or discriminatory practices. Payment policies related to when a beneficiary changes MDPP suppliers are discussed in section III.K.2.d.v. of this final rule.

The following is a summary of the public comments received on our clarifications about beneficiaries changing suppliers and our responses:

Comment: We received some comments noting that beneficiaries may switch suppliers more often than we anticipate, given the mobility of the ''baby boom'' generation and the fact that many seniors are ''snowbirds,'' traveling south for the winter. Other commenters requested clarification about when MDPP beneficiaries may switch suppliers.

Response: We clarify that beneficiaries are generally not required to switch suppliers. However, if the beneficiary chooses to switch MDPP suppliers, the beneficiary may do so at any time and for any reason within the MDPP services period (which includes both the core services period and ongoing services period).

Since we did not propose any changes to the policy that beneficiaries may change suppliers at any time during the MDPP services period, we are not finalizing any changes to this policy.

(3) Make-Up Sessions

(a) General Requirements

In the CY 2018 PFS proposed rule, we proposed at § 410.79(d)(1) that suppliers may offer make-up sessions to an MDPP beneficiary who missed a regularly scheduled session (82 FR 34136 through 34137). We proposed to define, at § 410.79(b), ''make-up session'' to mean a core session, core maintenance session, or ongoing maintenance session furnished to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session, core maintenance session, or ongoing maintenance session. We proposed that make-up sessions may be delivered in person or virtually, although virtual make-up sessions are subject to

additional requirements in this rule (and the term ''virtual make-up session'' is separately defined). We proposed the availability of make-up sessions to be consistent with CDC's DPRP Standards and to ensure that MDPP beneficiaries have the opportunity to receive the full DPRP curriculum, even if they are unable to attend a particular regularly scheduled MDPP session.

We proposed that the curriculum delivered during a make-up session must address the same CDC-approved DPP curriculum topic as the session that the beneficiary missed (§ 410.79(d)(1)(i)). To be consistent with CDC's proposed 2018 DPRP Standards,[14] we proposed that the MDPP supplier may furnish to the beneficiary a maximum of one make-up session on the same day as a regularly scheduled session (proposed at § 410.79(d)(1)(ii)), and the MDPP supplier may furnish to the beneficiary a maximum of one make-up session per week at § 410.79(d)(1)(iii)).

(b) Virtual Make-Up Sessions

There is a growing area of research examining the effectiveness of DPP delivered virtually. CDC began recognizing Virtual DPP organizations in 2015 and emerging evidence suggests that virtual delivery of DPP services can show similarly successful participant weight loss and health benefits to DPP delivered in other settings, including among Medicare-age participants.[15] Since CDC's DPRP Standards permit virtual make-up sessions, and we recognize that MDPP beneficiaries may encounter situations where they are unable to attend in-person make-up sessions, we proposed to allow MDPP suppliers to offer a limited number of virtual make-up sessions (§ 410.79(d)(2)). We proposed to define ''virtual make-up session'' in § 410.79(b) as a make-up session that is not furnished in person and that is furnished in a manner consistent with the DPRP standards for virtual sessions. All requirements in § 410.79(d)(1) apply to virtual make-up sessions. In addition, we proposed that virtual make-up sessions are subject to additional requirements.

First, as indicated by the applicable definition, we proposed virtual make-up sessions must be furnished in a manner consistent with CDC's DPRP Standards for virtual sessions (§ 410.79(d)(2)(i)). To align with CDC's DPRP Standards, virtual make-up sessions refer to any modality, or method of furnishing MDPP services, that is not in person. This includes, but is not limited to:

(1) Furnishing services online where the behavior change program is furnished 100 percent online, with participants accessing course resources and a coach via a computer, laptop, tablet, smart phone, or other device with Internet access. This modality requires that the MDPP beneficiary have an Internet connection to participate in all aspects of the virtual make-up session;

(2) Furnishing services online with other means of support by a coach (for example, telecommunications, video conferencing). This modality requires that the MDPP beneficiary have an Internet connection for some aspects of the virtual make-up session, but not all; and

(3) Distance learning, where a coach is present in one location and participants are calling, video-conferencing, or otherwise using telecommunications technology to access the coach from another location. This modality does not require that the MDPP beneficiary have an Internet connection for any of the aspects of the virtual make-up session.

By defining MDPP virtual make-up sessions as being consistent with CDC's DPRP Standards for virtual sessions, we allowed our proposed definition to change over time as such standards are updated.

Second, we proposed that a supplier may only offer virtual make-up sessions based on an individual MDPP beneficiary's request (§ 410.79(d)(2)(ii)). A supplier may not cancel a regularly scheduled MDPP session and offer the session to all MDPP beneficiaries virtually. However, the supplier may cancel a regularly scheduled MDPP session and offer the session to all MDPP beneficiaries in person. We believe that this is necessary to ensure that the MDPP expanded model remains a model predominantly furnished in person. Individual beneficiary needs may be accommodated, but suppliers should not use virtual make-up sessions as a means to move toward virtually-delivered MDPP sessions more generally.

Third, to further ensure that MDPP services are largely furnished in-person, we proposed at § 410.79(d)(2)(iii) that a supplier may offer: (a) No more than 4 virtual make-up sessions within the core services period to an MDPP beneficiary, of which no more than 2 virtual make-up sessions may be core maintenance sessions; and (b) no more than 3 virtual make-up sessions that are ongoing maintenance sessions to an MDPP beneficiary during any rolling 12-month time period. At § 410.79(d)(3), we proposed that these same limitations on the number of virtual make-up sessions also apply for the purposes of determining whether a beneficiary has attended a sufficient number of MDPP sessions in order to be eligible for ongoing maintenance sessions (§ 410.79(c)(1)) and for assessing whether a beneficiary has met the attendance-related performance goals used to determine whether an MDPP supplier is eligible to receive a performance payment (§ 414.84(b)). The limitation on the number of virtual make-up sessions is not applicable to in-person make-up sessions.

We assume not all suppliers will have the ability to offer virtual make-up sessions, and we are not requiring suppliers to offer virtual make-up sessions. Conversely, an MDPP supplier could offer only virtual make-up sessions and no in-person make up sessions if the supplier chooses as long as the proposed limits for these sessions are not exceeded. We believe that allowing fewer than these proposed number of virtual make-up sessions will make it difficult for suppliers to meet DPRP Standards, and therefore remain enrolled as an eligible MDPP supplier. However, the DPP model test only offered in-person sessions (no virtual sessions) and therefore the MDPP expanded model is intended to predominantly offer services in person. Allowing more than the proposed number of virtual make-up sessions would not support an evaluation of an in-person MDPP model, as described further in this section. We sought comment on our proposals and specifically on the proposed limitations on virtual make-up sessions.

We considered the following alternatives to this proposal. We considered not allowing any make-up sessions to be furnished virtually. However, we believe that this would place undue restrictions on MDPP suppliers who are willing and offer virtual make-up sessions to MDPP

[14] Available at *https://www.federalregister.gov/documents/2017/07/14/2017-14792/proposed-data-collection-submitted-for-public-comment-and-recommendations*

[15] See, for example: F Chen et al., ''Clinical and Economic Impact of a Digital, Remotely-Delivered Intensive Behavioral Counseling Program on Medicare Beneficiaries at Risk for Diabetes and Cardiovascular Disease.'' PLoS ONE 11, 10 (2016), *https://doi.org/10.1371/journal.pone.0163627*. W Su et al., ''Return on Investment for Digital Behavioral Counseling in Patients With Prediabetes and Cardiovascular Disease.'' Preventing Chronic Disease 13 (2016), *http://dx.doi.org/10.5888/pcd13.150357*. J Ma et al., ''Translating the Diabetes Prevention Program lifestyle intervention for weight loss into primary care: a randomized trial.'' JAMA Intern Med. 173, 2 (2013): 113–21, *https://www.ncbi.nlm.nih.gov/pubmed/23229846*. CS Sepah et al., ''Translating the diabetes prevention program into an online social network: Validation against CDC standards.'' The Diabetes Educator 40, 4 (2014): 435–443, *https://www.ncbi.nlm.nih.gov/pubmed/24723130*.

beneficiaries, particularly if these are offered to other DPP participants who are not Medicare beneficiaries.

We also considered allowing an MDPP supplier to furnish between 1 and 3 sessions within the core services period and either 1 or 2 ongoing maintenance sessions each year as virtual make-up sessions per MDPP beneficiary. However, we believe that allowing fewer sessions to be furnished as virtual make-up sessions than proposed would not provide sufficient flexibility for MDPP suppliers to meet CDC's DPRP Standards, which require organizations to meet attendance requirements for their panel of participants. Organizations may struggle to meet DPRP attendance requirements without the flexibility to provide virtual make-up sessions.

We also considered permitting suppliers to offer any number of virtual make-up sessions, and for attendance at any number of virtual make-up sessions to count toward attendance goals. However, as stated previously, since the DPP model test only offered DPP services in person, the MDPP expanded model is intended to predominantly offer MDPP sessions in person as well. Therefore we believe that it is important to limit the number of virtual make-up sessions so that MDPP beneficiaries are predominantly receiving MDPP sessions in person.

We proposed that the payment policies detailed in section III.K.2.d. of this final rule apply to virtual make-up sessions. Specifically, as indicated in sections III.K.2.c.iv and III.K.2.d.iii.10.b. of this final rule, weight measurements used for the purposes of determining the achievement or maintenance of weight loss for weight loss performance payments, or for determining eligibility for coverage of ongoing maintenance sessions, would be required to be taken at an in-person session, not during a virtual make-up session. As noted at § 410.79(d)(3), make-up sessions are counted toward performance goals for both eligibility and payment, which specify that at least one ongoing maintenance session per ongoing maintenance session interval must be attended in person for the purposes of in-person weight measurement. We sought public comments on these proposals and the alternatives considered.

The following is a summary of the public comments received on our proposals regarding make-up sessions, and specifically on the limitations on virtual make-up sessions, and our responses:

Comment: We received some comments on make-up sessions generally, both virtual and in-person. One commenter supported CMS' proposal to allow for same day make-up sessions, finding them to be operationally feasible by allowing patients to come early or stay late to make up a session. Another commenter noted that furnishing to the beneficiary a maximum of one-make-up session on the same day as a regularly scheduled session may pose a barrier to beneficiaries if they cannot make the regular session on the same day and recommended an option to allow a window for make-up sessions of 1–2 business days for either virtual or in-person make-up sessions. A third commenter generally agreed with the proposed definitions and options for make-up sessions, noting that the proposal was feasible to provide and would encourage beneficiaries to receive the necessary educational component and coach support.

Response: We appreciate commenters' support of the proposals. In response to the commenter who noted that furnishing a maximum of one-make-up session on the same day as a regularly scheduled session may pose a barrier to beneficiaries if they cannot make the regular session on the same day, we believe that the commenter was misunderstanding the proposal. Make-up sessions are not required to be offered on the same day as a regularly scheduled session. However, to be consistent with CDC's proposed 2018 DPRP Standards,[16] if the MDPP supplier wishes to offer a make-up session on the same day as a regularly scheduled session, we clarify our intent is for suppliers may furnish a maximum of one make-up session on the same day as a regularly scheduled session. The intent of this policy is to allow most make-up sessions to be scheduled on different days than regularly scheduled session, since beneficiaries may not be able to attend a make-up session on the same day as a regularly scheduled session. The only limitations on when make-up sessions can be offered is that any core make-up session is considered a core session, and therefore must occur during months 1–6. Similarly, any core maintenance make-up session is considered a core maintenance session and must occur during months 7–12.

Comment: The majority of commenters who commented on these policies supported the use of virtual make-up sessions. The additional commenters requested clarification about weight measurement for, and monitoring of, virtual make-up sessions. Of those who supported the use of virtual make-up sessions, there were an equal number of comments supporting and opposing the proposed limitations on virtual make-up sessions (that is, that a supplier may offer no more than 4 virtual make-up sessions within the core services period, of which no more than 2 may be core maintenance sessions; and no more than 3 virtual make-up sessions that are ongoing maintenance sessions during any rolling 12-month time period). Those who supported the limitations noted that the limits would foster compliance and adherence to program goals. Those who opposed the limitations requested that CMS either raise the allowed number of virtual make-up sessions or allow exceptions to the proposed limitations on virtual make-up sessions if the beneficiary cannot come in person. These commenters stated that an increased number of allowed virtual make-up sessions would increase access to MDPP services and improve beneficiary choice of supplier, and noted that the use of virtual DPP has a strong evidence base.

Response: While we recognize that there is an emerging evidence base demonstrating effectiveness of virtual DPP, we do not believe that we should allow a greater number of virtual make-up sessions than proposed, or allow exceptions to the proposed limitations at this time. As noted in this rule, the DPP model test only offered in-person sessions (no virtual sessions) and therefore the MDPP expanded model is intended to predominantly offer services in person. Allowing more than the proposed number of virtual make-up sessions would not support an evaluation of an in-person MDPP curriculum. However, we believe it is appropriate to permit some virtual make-up sessions because, as discussed in this rule, we understand, based on research into current practices at CDC DPRP recognized DPP providers, that it is difficult for DPP suppliers to meet DPRP recognition without the allowance of at least some virtual make-up sessions, and organizations must meet DPRP Standards to become MDPP suppliers. Therefore, in order to have a sufficient number of MDPP suppliers to ensure access to MDPP services, and to also ensure fidelity with the original DPP model test, we believe that a supplier's ability to furnish a limited number of virtual make-up sessions is necessary.

Comment: One commenter requested clarification on monitoring the use of virtual make-up sessions. The commenter asked if there will be an

[16] Available at *https://www.federalregister.gov/documents/2017/07/14/2017-14792/proposed-data-collection-submitted-for-public-comment-and-recommendations.*

additional HCPCS code or modifier used to indicate virtual visits since there is a proposed limit to the number of visits the beneficiary can receive virtually.

Response: We do plan to monitor virtual make-up sessions through the claims system to indicate when a beneficiary has received the maximum number of virtual make-up sessions permitted. In order to collect information on virtual make-up sessions, we are creating a modifier that suppliers will include on claims to indicate the use of virtual make-up sessions. This modifier is discussed further in section III.K.2.d.iii.10.c of this final rule. We intend to provide information on how to use this modifier on claims submitted by MDPP suppliers in conjunction with other billing instructions in future guidance.

Comment: We received multiple comments on weight measurement for virtual make-up sessions. Some commenters supported the proposal that weight measurement must be taken in person. One commenter encouraged the allowance of beneficiary attestation for weight measurement associated with virtual make-up sessions, including reporting via Bluetooth-enabled scales, which allows the weight measurement taken on the scale to be transmitted to the supplier. This commenter also recommended that CMS allow weight measurements to be taken at any in-person visit with any member of a care delivery team (regardless of whether the weight measurement is with the MDPP supplier) as long as the weight measurement occurs within a month of the associated core maintenance session or ongoing maintenance session.

Response: While we recognize the use of Bluetooth-enabled scales for virtual weight reporting in some DPP programs, we believe that virtual weight reporting is not appropriate or necessary for a predominantly in-person model. Except for the limited number of virtual-make up sessions, MDPP sessions are required to be offered and attended in person and corresponding weight are also required to be taken in-person. We also believe that self-attested weight measurement is generally unreliable,[17] and therefore, believe that in-person weight measurement is the most reliable and appropriate form of weight measurement for the MDPP expanded model.

We appreciate the commenter's request for flexibility by allowing weight measurement to be taken in-person, but outside of an MDPP session, by any member of a care delivery team within a month of the MDPP session. However, we believe that requiring weight measurement to be taken by an MDPP supplier during an MDPP session is the most appropriate and reliable method for weight measurement to ensure accuracy. We have not proposed any program integrity safeguards about transferring weight measurement between providers, suppliers, or care delivery teams, nor do we expect MDPP suppliers to have systems in place to facilitate such information transfer. We also believe that weight must be measured on the same date and at the time of the MDPP session to ensure that weight measurement falls within the correct time frame or interval for the purposes of eligibility and payment. If a member of the beneficiary's care delivery team is also part of the MDPP supplier's organization, for example serving as the DPP coordinator or coach, then this type of arrangement is appropriate, as long as the conditions for weight measurement are met.

Comment: One commenter sought clarification on if a beneficiary who completed a virtual make-up session could come in to an MDPP supplier in person at another time to have their weight measured and counted for that session. The commenter noted that this may be particularly important if that weight measurement is needed for the MDPP supplier to submit a claim for payment.

Response: As noted in proposed § 410.79(c)(1)(iv), which we are finalizing as proposed, weight measurements used to determine the achievement or maintenance of the required minimum weight loss must be taken in person by an MDPP supplier during an MDPP session. Additionally, as discussed in section III.K.2.d.iii.10.b of this final rule, we also are finalizing at § 414.84(b) that all performance payments associated with weight loss require weight measurement to conducted in person at an MDPP session. We believe it is important that weight measurements occur on the date of an MDPP session so that they fall within the correct interval for the purposes of eligibility and payment. Thus, a beneficiary could not complete a virtual make-up session and come in to an MDPP supplier in person at another time to have his or her weight measured and counted for that session.

We re-emphasize that that virtual make-up sessions cannot be used to record weight for the purposes of beneficiary eligibility for or during ongoing services period or payment, due to the concerns we have laid in this section out regarding any measurement that is not taken in person. This is why we are finalizing in this final rule, discussed in section III.K.2.c.iv.a and III.K.2.c.iv.b, that a beneficiary must attend at least one in-person core maintenance session during the final core maintenance session interval and at least one in-person ongoing maintenance session during each ongoing maintenance session interval in order to have weight recorded in person for the purposes of eligibility and payment (§ 410.79(c)(1)(ii) and (c)(1)(iii)).

After consideration of the public comments received, we are finalizing our proposals on make-up sessions at § 410.79(d). We are finalizing changes to these policies to reflect shortening the ongoing services period from 2 years to 1 year.

d. Payment for MDPP Services

i. MDPP Payment Discussion in Prior Rulemaking

In the CY 2017 PFS proposed rule (81 FR 46415 through 46416), we discussed a potential MDPP payment structure and the associated payment amounts and sought information from the public to inform future MDPP proposals. We received a number of public comments on these topics and considered this information in the development of our proposals for the MDPP payment structure, payment amounts, and related issues.

ii. Conceptual Framework for Payment for MDPP Services

We proposed to pay for the set of MDPP services through a performance-based payment methodology that makes periodic performance payments to MDPP suppliers during the MDPP services period. The aggregate of all performance payments constitutes the total performance-based payment amount for the set of MDPP services. We proposed a maximum total performance payment amount per beneficiary for the set of MDPP services of $810. Performance payments would be made to MDPP suppliers periodically during the course of a beneficiary's MDPP services period based upon a number of factors, including the beneficiary's completion of a specified number of MDPP sessions and the achievement of

[17] See, for example: Gorber, et. al, ''A Comparison of Direct vs. Self-Report Measures for Assessing Height, Weight and Body Mass Index: A Systematic Review,'' *Obesity Reviews* 8, no. 4 (July 2007): 307–26, *https://www.ncbi.nlm.nih.gov/pubmed/17578381*; Engstrom, et. al, ''Accuracy of Self-Reported Height and Weight in Women: An Integrative Review of the Literature,'' *Journal of Midwifery and Women's Health* 48, no. 5 (Sept–Oct 2003): 338–45, *https://www.ncbi.nlm.nih.gov/pubmed/14526347*; Lin, et. al, ''Accuracy and Reliability of Self-Reported Weight and Height in the Sister Study,'' *Public Health Nutrition* 15, no. 6 (June 2012): 989–999, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3511620/*.

the required minimum weight loss that is associated with a reduced incidence of type 2 diabetes, rather than individual payments being made upon the furnishing of any service as is typical of FFS payment methodologies in the Medicare program.

The aggregate amount of the performance payments proposed would equal the total performance-based payment amount for the set of MDPP services during the MDPP services period, including core sessions, core maintenance sessions, and ongoing maintenance sessions. Even though these performance payments would be made periodically and in amounts that would not be evenly distributed across the course of sessions furnished during the MDPP services period, payment for each session would be included in the total performance-based payment amount. For example, the proposed performance payment of $25 that would be paid to MDPP suppliers upon furnishing the first MDPP core session is relatively large on a per-session basis compared to other attendance-based performance payments (as calculated on a per-session basis) ranging from approximately $3 to $20 made during the MDPP services period. However, the performance payment for the first core session would make payment for some of the MDPP supplier resources used in furnishing the first session, as well as make a partial prospective payment attributable to the MDPP supplier furnishing subsequent sessions.

Once the required minimum weight loss is achieved and the 12-month core services period, described at proposed § 410.79(c)(2)(i), concludes, we would make additional 3-month interval performance payments for ongoing maintenance sessions when the required minimum weight loss is maintained, whereas no additional interval performance payments would be made for ongoing maintenance sessions if the required minimum weight loss is not maintained. Finally, when a beneficiary achieves a significant percentage of weight loss, specifically a level of 5 percent (the required minimum weight loss) or 9 percent, we proposed to make additional performance payments to the MDPP supplier. This proposal would provide performance payments in addition to the performance payments we may have already made for the previous MDPP sessions furnished to the beneficiary because those sessions resulted in the beneficiary achieving the weight loss performance goal.

In total, based on our consultation with DPP organizations holding commercial contracts, review of information related to DPP organizations that currently hold or are in the process of obtaining CDC recognition, and comments received on the discussion of the payment structure and payment amounts for the set of MDPP services included in the CY 2017 PFS proposed rule (81 FR 46415 through 46416), we believed that the proposed performance-based payment methodology would pay MDPP suppliers appropriately for the resources used in furnishing MDPP services throughout the MDPP services period. We noted that we sought public comment on the payment structure and payment amounts for the set of MDPP services in the CY 2017 PFS proposed rule, and we used the information provided by commenters in developing the proposed performance-based payments included in the CY 2018 PFS proposed rule (82 FR 34138 through 34152).

In the proposed performance-based payment structure, it is important to note that a beneficiary's performance goals would not be considered in the same way for beneficiary coverage and supplier payment during each specific period within the MDPP services period. During the core services period, a beneficiary would not be required to achieve attendance and/or weight loss performance goals for coverage of MDPP services, although a beneficiary would be required to achieve specified performance goals for an MDPP supplier to receive performance payments during this period. In contrast, achieving performance goals would be required for both coverage of MDPP services and performance payments during the ongoing services period.

For example, a supplier would be required to offer a minimum of 16 core sessions during the core services period according to § 410.79(c)(2)(i), but a beneficiary would not need to achieve an attendance or weight loss performance goal to be eligible for coverage of core maintenance sessions. However, MDPP supplier performance payments during the core services period would be based on the beneficiary's achievement of attendance and/or weight loss performance goals. During the ongoing services period, achievement of performance goals would affect both coverage and supplier payment. We noted that a beneficiary would need to attend at least 1 core session to initiate the core services period, and attend at least 1 core maintenance session during the final core maintenance session interval to determine whether he or she has achieved the required minimum weight loss to have coverage of ongoing maintenance sessions. Because we proposed, as discussed in section III.K.2.d.iii.4 of the proposed rule (82 FR 34143 through 34145) to make a performance payment for core maintenance sessions only when the beneficiary attends at least 3 sessions within a 3-month interval, it is possible that an MDPP supplier would not be paid a separate performance payment for the second core maintenance session interval, but the beneficiary would still have coverage of the first ongoing maintenance session interval. This would occur if the beneficiary attended only 1 or 2 core maintenance sessions during the second core maintenance session interval and achieved or maintained the required minimum weight loss as measured at 1 of those 2 sessions.

iii. Performance Payments for MDPP Services

(1) Overview of Public Comments on Discussion of Payment for MDPP Services in Prior Rulemaking

Commenters on the discussion of payment for MDPP services in the CY 2017 PFS proposed rule (81 FR 46415 through 46416) expressed a variety of perspectives on the performance-based payment methodology presented in that proposed rule. We describe the comments on the prior discussion as background for our proposals for the performance-based payment methodology for MDPP services that was included in the CY 2018 PFS proposed rule (82 FR 34137 through 34155).

In summary, commenters on the CY 2017 PFS proposed rule recommended that a sustainable payment rate structure for MDPP services should mirror performance-based payment models in the existing employer marketplace. They requested that we not tie Medicare payment to weight loss or that we make separate weight loss and attendance payments; that we tie payment to aggregate, rather than individual, beneficiary weight loss; or that we tie payment to other factors besides or in addition to weight loss. Some commenters requested that we provide information on how the payment rates included in the CY 2017 PFS proposed rule discussion were determined due to their concerns that the amount of MDPP payments was not consistent with payments for other similar services. Multiple commenters urged that higher payments be made at the beginning of the MDPP services period to cover program start-up costs, that we decrease supplier financial risk by providing sufficient payment for beneficiaries who do not achieve weight loss performance

goals, and that we implement risk-stratification of payments to reduce the risk of MDPP suppliers preferentially seeking to furnish MDPP services to low-risk beneficiaries most likely to achieve weight loss and avoiding high-risk beneficiaries.

The proposed MDPP payment structure in the CY 2018 PFS proposed rule was generally similar to that which was discussed in the CY 2017 PFS proposed rule (81 FR 46415 through 46416). However, the proposed performance payment amounts for core sessions, core maintenance session 3-month intervals, and ongoing maintenance session 3-month intervals differed somewhat based on our consideration of the comments received in response to the CY 2017 PFS proposed rule in the context of our policy goal to prioritize the achievement and maintenance of the required minimum weight loss that is associated with a reduction in the incidence of type 2 diabetes. We proposed a payment structure for MDPP services that is performance-based in relation to two meaningful performance goals.

First, the proposed payment structure valued beneficiary weight loss most significantly. Weight loss is a key indicator of success among individuals enrolled in a DPP due to the strong association between weight loss and reduction in the risk of type 2 diabetes.[18] Second, the proposed payment structure valued beneficiary attendance because, in the DPP model test, session attendance was associated with greater weight loss. According to the second year independent evaluation of the DPP model test, those beneficiaries who attended at least 1 core session lost an average of 7.6 pounds, while beneficiaries who attended at least 4 core sessions lost an average of 9 pounds. Body mass index was reduced from 32.9 to 31.5 among Medicare beneficiaries who attended at least 4 core sessions.[19]

In addition to weight loss, we considered linking other criteria such as hemoglobin A1c level to MDPP performance payments, or using aggregate, instead of individual, weight loss for MDPP payments. However, the MDPP expanded model was determined to meet the statutory requirements for expansion, with certification of the DPP model test based on findings that demonstrated that weight loss was associated with reductions in Medicare expenditures. Although elevated hemoglobin A1c levels were included as part of the beneficiary eligibility criteria in the DPP model test, hemoglobin A1c levels were not evaluated post-intervention in that model. Therefore, we did not propose to use hemoglobin A1c blood values in the performance-based payment methodology for MDPP services under the MDPP expanded model, which is based on certification of the DPP model test. We further noted that the CDC does not require post-MDPP services hemoglobin A1c blood values to be determined as part of its 2015 DPRP Standards or its proposed 2018 DPRP Standards, and we aim to align with the CDC's DPRP Standards as much as possible. While 5 percent weight loss is considered a performance measure for CDC recognition, the CDC does not examine pre-post DPP differences in hemoglobin A1c as part of its DPRP Standards.

The proposed MDPP payment structure would incentivize MDPP suppliers to prioritize the achievement and maintenance of beneficiary weight loss by furnishing MDPP services, and provide a balance between performance-based payments related to weight loss and session attendance. We believed that it would be inappropriate for payment to be tied to attendance alone because weight loss is more directly associated with a reduction in the incidence of type 2 diabetes than attendance at MDPP sessions. We further believed that the proposed performance-based payment structure based on individual beneficiary success, rather than average weight loss across all MDPP beneficiaries who receive MDPP services from an MDPP supplier, would maximize the focus of MDPP suppliers on the achievement of the performance goals for all beneficiaries, including those beneficiaries who experience challenges with achieving attendance and/or weight loss performance goals. Therefore, we did not believe it would be appropriate to use aggregate beneficiary information (that is, average weight loss) in the proposed performance-based payment methodology.

(2) Overall Approach to Setting Performance Payment Amounts

We proposed to establish the rules governing payment for MDPP services at new § 414.84. At proposed § 414.84(a), we proposed to define ''performance goal'' as an attendance or weight loss goal that an MDPP beneficiary must achieve for an MDPP supplier to be paid a performance payment. We proposed to define ''performance payment'' as a payment to an MDPP supplier for furnishing certain MDPP services when an MDPP beneficiary achieves the applicable performance goal. These definitions were used in our proposals for payment of MDPP services.

To align with the once-per-lifetime policy, we proposed at § 414.84(b) that each performance payment made based on attendance of a specified number of core sessions, for a specific 3-month core maintenance or ongoing maintenance interval during the MDPP services period, or for achieving a weight loss performance goal, would be made only once per MDPP beneficiary.

The following is a summary of the public comments received on the proposals for the definitions of performance goal and performance payment for MDPP services and our responses:

Comment: Several commenters recommended that CMS use additional outcome measures other than weight loss or use other measures of performance in addition to attendance as performance goals in the performance-based payment methodology for MDPP services. The commenters urged CMS to use laboratory values, such as a reduction in hemoglobin A1c or fasting blood glucose, either in addition to or instead of weight loss as measures of a DPP organization's effectiveness, noting that changes in these laboratory values would reflect improvement in the blood values that are used to diagnose diabetes. The commenters reasoned that if a DPP organization can help a beneficiary improve on these lab values, the beneficiary's risk of type 2 diabetes would be reduced. One commenter added that although body weight was the measurement of success in the DPP Randomized Control Trial and is a DPRP standard, due to it being a non-invasive and cost-effective measurement of reduction in risk of type 2 diabetes, there is also an evidence-based correlation between a reduction in hemoglobin A1c value and the risk of developing type 2 diabetes. Another commenter, who cited that its own DPP organization has experienced numerous examples of individuals who did not meet the milestone of a 5 percent weight loss but were able to reduce their hemoglobin A1c value into a lower prediabetes zone or, in some instances, to a normal range, recommended that the proposed weight loss performance

[18] RF Hamman et al., ''Effects of Weight Loss with Lifestyle Intervention on Risk of Diabetes,'' *Diabetes Care* 29, no. 9 (2006): 2102–2107.

[19] Hinnant L, Razi S, Lewis R, Sun A, Alva M, Hoerger T, Jacobs S, Halpern M. Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring, Annual Report 2015. Awardee-Level Findings: YMCA of the USA; 2016. Table 17. Average/Frequencies Health Outcomes of all Participants through Q11, p. 36. RTI Project Number 0212790.010.001.004, Contract HHSM–500–2010–00021I. Sponsored by the Centers for Medicare & Medicaid Services.

payments be tied to weight loss *or* a reduction in hemoglobin A1c.

Other commenters expressed concern that the focus on weight loss as the MDPP supplier's outcome valued in the performance-based payment methodology could lead to weight cycling, which could in turn lead to health risks for beneficiaries other than type 2 diabetes. The commenters claimed that weight loss and attendance are confounded measures when both are used as performance goals in the payment methodology because they are linked. They urged CMS to avoid double counting by using attendance alone as the performance goal for performance payments instead of both weight loss and attendance.

Some commenters encouraged CMS to focus the performance goals valued in the payment methodology on improving beneficiary behaviors rather than weight loss. Several commenters recommended that certain DPP organizations, including tribal health programs, have the flexibility to determine their own diabetes prevention measures of success that would be the performance goals upon which payment would be based. In addition to advocating that CMS utilize hemoglobin A1c blood values to assess DPP outcomes, a few commenters suggested that CMS consider adopting other variables, including reduced hypertension risk, lower BMI, increased intake of healthy foods, increased rate of physical activity, or successful reduction of other risk factors. The commenters claimed that incorporating these variables in the MDPP expanded model performance-based payment methodology would reflect beneficiary adherence to healthy behaviors taught in the DPP curriculum. One commenter recommended that CMS supplement performance payments for core sessions with an additional payment for those sessions that include physical activity, in order accommodate and recognize beneficiaries who may fluctuate in weight loss due to thyroid and hormonal imbalances, stress, sleep disorders, or gastrointestinal issues, but who are otherwise achieving improved healthy behaviors through physical activity. Finally, another commenter urged CMS to explore, via a pilot, additional measures that reflect a possible mechanism associated with an MDPP supplier's success in furnishing MDPP services, such as increased beneficiary self-efficacy or activation and reduced social isolation, which the commenter noted would be likely to have spillover benefits for general health.

Response: We appreciate the commenters' recommendations about additional outcomes and other parameters that could be used as performance goals in the MDPP expanded model payment model to recognize a DPP organization's success that benefits the health of beneficiaries. As we stated in the proposed rule (82 FR 34189), we considered linking other criteria such as hemoglobin A1c level to MDPP performance payments. However, the MDPP expanded model was determined to meet the statutory requirements for expansion, with certification of the DPP model test based on findings that demonstrated that weight loss was associated with reductions in Medicare expenditures. Although elevated hemoglobin A1c levels were included as part of the beneficiary eligibility criteria in the DPP model test, hemoglobin A1c levels were not evaluated post-intervention in that model so we do not have information from the DPP model test about the relationship between hemoglobin A1c levels and reductions in Medicare expenditures upon which a determination about whether the MDPP expanded model meets the statutory requirements for expansion could be made. In addition, the CDC does not require post-MDPP services hemoglobin A1c blood values to be determined as part of its 2015 DPRP Standards, or the proposed 2018 DPRP Standards, and we aim to align with the CDC's DPRP Standards as much as possible. Therefore, we will not use hemoglobin A1c blood values as a performance goal in the performance-based payment methodology for MDPP services.

In response to the commenters who expressed concern about the potential for negative health effects of a focus on weight loss as a performance goal for the MDPP expanded model, we note that certification of the DPP model test was based on findings that demonstrated that weight loss was associated with reductions in Medicare expenditures, and the DPP Randomized Control Trial showed that people at risk for developing type 2 diabetes can prevent or delay the onset of type 2 diabetes by losing a modest amount of weight through diet and exercise. The CDC's DPRP Standards, where 5 percent weight loss is considered a performance measure, were developed with this science in mind. Therefore, we continue to believe that weight loss is an appropriate performance goal for use in the MDPP expanded model performance-based payment methodology.

In addition, while we acknowledge that there is an association between attendance and weight loss, the two performance goals proposed for use in the MDPP payment methodology, we remain committed to valuing weight loss in the methodology based on the evidence that achievement of the required minimum weight loss leads to a reduction in the incidence of type 2 diabetes. Weight loss is a key indicator of success among individuals enrolled in a DPP due to the strong association between weight loss and reduction in the risk of type 2 diabetes.[20] The MDPP expanded model was determined to meet the statutory requirements for expansion, with certification of the DPP model test based on findings that demonstrated that weight loss was associated with reductions in Medicare expenditures. We note that while there is a positive association between attendance at MDPP sessions and weight loss, which underpins the rationale for offering MDPP services to Medicare beneficiaries in the MDPP expanded model, attendance is not a full proxy for the required minimum weight loss outcome that leads directly to a reduction in the incidence of type 2 diabetes. For example, while in the DPP model test the number of DPP sessions attended had a statistically significant marginal effect on the percent of weight loss, session attendance did not fully account for the percent of weight loss.[21] Specifically, the average effect of attending one additional session was a 0.43 percentage point increase in weight loss. However, the results showed that a participant who attended 9 or more sessions on average experienced a 6.24 percentage increase in weight loss compared to participants attending fewer than 9 sessions, which is a higher percentage point increase in weight loss than would be predicted based on the number of sessions attended alone. Therefore, we continue to believe it is appropriate to use both attendance and weight loss as the MDPP expanded model performance goals in the MDPP performance-based payment methodology, so we are finalizing these performance goals.

For the same reasons that we are not using hemoglobin A1c as a performance goal for the MDPP expanded model, we also will not include any of the other additional parameters recommended by the commenters to value a DPP

[20] RF Hamman et al., ''Effects of Weight Loss with Lifestyle Intervention on Risk of Diabetes,'' Diabetes Care 29, no. 9 (2006): 2102–2107.

[21] RTI International.Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring, Third Annual Report Addendum 2017: Awardee-Level Findings: YMCA of the USA. Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring Third Annual Report—March 2017.

organization's success in the MDPP performance-based payment methodology, nor will we allow each DPP organization to develop its own measures of success for Medicare payment purposes under the MDPP expanded model. None of these parameters related to healthy beneficiary behaviors, such as an increased rate of physical activity or increased intake of health foods, were evaluated in the DPP model test to assess their potential relationship to reductions in Medicare expenditures. Therefore, they are not being adopted for use in the MDPP expanded model because they were not used in the determination that the MDPP expanded model meets the statutory requirements for expansion. However, we encourage each MDPP supplier to assess the needs and experiences of the beneficiaries it serves in the context of the MDPP services furnished by the supplier to create, implement, and evaluate its own DPP organization's performance metrics, including process and outcome measures, in the context of the goals of the MDPP expanded model so that the MDPP supplier can identify areas of success and opportunities for improvement in its DPP services.

We will not supplement performance payments for core sessions with additional payments for specific modalities (such as physical activity) offered during sessions, because the MDPP expanded model methodology is already performance-based in nature. Although health behavior changes, including dietary changes and physical activity, are components of the DPP curriculum taught during sessions, the MDPP expanded model was certified based on the close link between weight loss outcomes and a reduced incidence of type 2 diabetes and lower Medicare expenditures. Therefore, it would not be appropriate for us to specifically value in the performance-based payment methodology intermediate health behavior changes such as physical activity changes. Moreover, we are finalizing the requirements for the MDPP expanded model in this final rule, and therefore, are not pursuing through this rulemaking other models or pilots that reflect possible additional mechanisms associated with an MDPP supplier's success in reducing a beneficiary's incidence of type 2 diabetes.

After considering the public comments received, we are finalizing the proposals, without modification, for the definitions of performance goal and performance payment at § 414.84(a).

(a) Total Amount and Distribution of Performance Payments Across the Set of MDPP Services

As displayed in Table 28, we proposed a maximum total performance payment amount per beneficiary for the set of MDPP services of $810. This amount is the aggregate of the maximum proposed performance payments for core sessions, core maintenance sessions, and ongoing maintenance sessions furnished to MDPP beneficiaries who achieve weight loss of at least 9 percent over the proposed 36 months of the MDPP services period. This performance payment amount would be made for a minimum of 46 MDPP sessions required to be offered to the beneficiary in the set of MDPP services. Although CMS would make performance payments to MDPP suppliers at intervals throughout the MDPP services period in varying amounts, payment for each session furnished would be included in the total performance payment amount a supplier was paid for the set of MDPP services furnished to an MDPP beneficiary.

Although we did not propose that payment for MDPP services utilize a fee-for-service payment methodology, we noted that, estimated on a per-session basis, the maximum MDPP payment amount for achievement of all the performance goals would equate to approximately $18 per session. For comparison, Medicare pays under the PFS approximately $10 (excluding physician work and malpractice) for CPT code 98962 (Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 5–8 patients), a service that may bear some resemblance to an MDPP session furnished by an MDPP supplier, although an MDPP session would be furnished by a coach (not necessarily a health care professional), has a duration of 1 hour, and has no explicit limitation on group size.

However, this estimated per-session MDPP payment amount would result only from the furnishing of MDPP services to those beneficiaries who achieve all of the attendance and weight loss performance goals under the proposed performance-based payment methodology for MDPP services. For beneficiaries who do not achieve all of the performance goals, the estimated per-session MDPP payment amount would generally be significantly lower, with the amount based upon the actual attendance and weight loss performance of the beneficiary. The differences between the estimated MDPP per-session payment amounts and between the MDPP and PFS payment amounts would result from the proposed performance-based methodology for MDPP services based on the MDPP beneficiary's achievement of performance goals, that differs from the PFS where payments are based on suppliers' relative resources used to furnish services. We believed that the estimated per-session MDPP payment amounts under our proposal for beneficiaries who achieve specified attendance and weight loss performance goals were appropriate in the context of a performance-based payment methodology for the set of MDPP services.

Finally, we noted that there are also some administrative costs that MDPP suppliers would bear to enroll in Medicare and ensure compliance with the requirements for furnishing MDPP services. The total MDPP performance payment across all Medicare beneficiaries would provide some payment for the resources that would be used by MDPP suppliers to meet the administrative requirements for furnishing MDPP services.

In terms of the proposed distribution of the maximum total performance payment amount for MDPP services across the types of performance payments, as discussed in detail in sections III.K.2.d.iii.(3) and (4) of the proposed rule (82 FR 34141 through 34145) and displayed in Table 28, we proposed that, for those beneficiaries achieving the highest core services period performance goals, approximately 13 percent of the maximum of $810 would be paid for attendance at core sessions during the initial 6 months of the core services period, while approximately 15 percent would be paid for core maintenance sessions during months 7 to 12 of the core services period. We believed that payment of a similar percentage of the maximum total performance payment amount during the initial 6 months of the core services period for beneficiaries who meet attendance performance goals and during months 7 to 12 for beneficiaries who meet both weight loss and attendance performance goals would be appropriate to balance performance payment for attendance and weight loss throughout the core services period.

In addition, as discussed in detail in section III.K.2.d.iii.(5) of the proposed rule (82 FR 34145 through 34146), we proposed that approximately 49 percent of the maximum of $810 would be paid for ongoing maintenance sessions over a

24-month period, or 24.5 percent per each 12-month period, for those beneficiaries who maintain the required minimum weight loss. The focus of ongoing maintenance sessions is on maintenance of weight loss that has already been achieved, and there would typically be an established relationship between the MDPP supplier and the MDPP beneficiary during the ongoing services period. Therefore, the totality of MDPP sessions furnished during this 24-month period would result in a slightly lower performance payment per 12-month period than the totality of those sessions furnished when the required minimum weight loss is achieved during the 12 months of the core services period, when 28 percent of the maximum total performance payment amount would be paid.

Finally, due to the importance of weight loss as a meaningful outcome of MDPP services because of its association with a reduction in the incidence of type 2 diabetes, as discussed in detail in section III.K.2.d.iii.(6) of the proposed rule (82 FR 34146), we proposed that 23 percent of the maximum total performance payment amount would be paid for weight loss performance payments to provide additional payments for MDPP sessions that are effective (that is, lead to specified percentages of weight loss). We noted that, in the DPP model test, 44.7 percent of participants achieved 5 percent weight loss, which under our proposal would result in a weight loss performance payment of approximately 20 percent of the maximum total performance payment amount.[22] Moreover, according to estimates from CDC's DPRP, approximately 12 percent of program participants attending at least 2 sessions achieved 9 percent or greater weight loss.[23]

Table 28 summarizes the proposed maximum total amount and distribution of performance payments for the set of MDPP services.

TABLE 28—PROPOSED MAXIMUM TOTAL AMOUNT AND DISTRIBUTION OF PERFORMANCE PAYMENTS FOR THE SET OF MDPP SERVICES

Type of performance payment	Maximum performance payment for achieving attendance and/or weight loss performance goals	Percentage of maximum total performance payment amount (%)
Core sessions	$105	13
Core maintenance session intervals	120	15
Ongoing maintenance session intervals	400	49
Weight loss	185	23
Total performance payment	810	100

We invited public comments on our proposals for the maximum total performance payment amount and the distribution of performance payments for MDPP services across the set of MDPP services.

The following is a summary of the public comments received on the proposals for the maximum total performance payment amount and the distribution of performance payments for MDPP services across the set of MDPP services and our responses:

Comment: Many commenters supported the proposal of a performance-based payment methodology for MDPP services based on the performance goals of session attendance and weight loss. The commenters agreed that incentivizing MDPP suppliers, including coaches, and MDPP beneficiaries to work toward achievement of these performance goals would be valuable to the success of MDPP services in reducing the incidence of type 2 diabetes among MDPP beneficiaries. Several commenters further stated that the MDPP expanded model is consistent with other value-based payment models and would be an improvement over fee-for-service payment, although they acknowledged that the proposed payment structure was more complicated.

A few commenters recommended that CMS make a payment for each MDPP session, at least for the first 12 months of the MDPP services period. In addition, several of the commenters urged CMS to couple this payment policy with a bonus for achievement of the required minimum weight loss at the end of the core services period. Another commenter requested that CMS provide information on how the proposed performance payment amounts were determined, similar to information published in the Medicare PFS rules for any services covered under the Part B Medicare program. The commenter observed that the proposal for the MDPP expanded model contained extensive information on payment amounts but did not clearly explain the derivation of the proposed performance payment amounts. One commenter stated that services reported under the Medicare program using CPT code 98962 (Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 5–8 patients), a CPT code CMS referenced in the proposed rule, have been proven to be ineffective in changing behavior, yet the supplier is paid the full PFS amount regardless of outcomes. The commenter noted that trained DPP coaches have shown excellent results and, therefore, should be paid equal to or more on an hourly basis as the service reported under this CPT code, which the commenter stated would equate to $20 per hour.

One commenter urged CMS to reconfigure the proposed performance-based payment methodology to allow for add-on payments based on practice size and geographic location. The commenter noted that an additional payment for solo or small practices, as well as for practices in rural or underserved areas, would significantly expand the reach and effectiveness of MDPP services and enable primary care physicians to continue to drive the health care system through a focus on

[22] National Council of Young Men's Christian Associations, Measurement and Monitoring Report. CMS Health Care Innovation Awards, Round One, Sixteenth Quarterly Reporting Period (16QR), April, May, and June 2016.

[23] CDC's Diabetes Prevention Recognition Program dataset as of March 1, 2017.

preventive services that reduce costs and improve care.

Another commenter recommended that CMS pay all MDPP suppliers, or at a minimum community-based organizations and small suppliers, based on aggregate, rather than individual, beneficiary performance on attendance and weight. Several commenters emphasized their perspective that performance-based payment that relies heavily on individual patient outcomes would be most likely to succeed when directed at large institutions with multiple sources of revenue where reallocation, cross-subsidy, and assuming financial risk are possible. The commenters noted that small MDPP suppliers would be unlikely to be able to support performance-based payment structures such as CMS proposed for the MDPP expanded model that are premised on a very low payment per evidence-based service, with small sample sizes that make performance payments based on individual beneficiary achievement of performance goals unreliable.

Another commenter noted that evidence to support the effectiveness of pay-for-performance through using the achievement of individual patient outcomes to financially incentivize the appropriate delivery of evidence-based services is mixed. The commenter claimed that there are some reports of no impact on the delivery of evidence-based services and other reports of initial improvements that fail to be sustained in comparison with changes in the practices of other providers over time. The commenter stated that pay-for-performance methodologies for individual health care providers have largely been based on process measures about the delivery of appropriate services, rather than the patient outcomes that result. They concluded that moving to pay-for-performance for an outcome measure like weight loss for Medicare payment as CMS proposed for the MDPP expanded model is an experimental rather than an evidence-based payment strategy, while MDPP services themselves are evidence-based and, therefore, should be paid through an evidence-based approach.

Response: We continue to believe that a comprehensive performance-based payment methodology is appropriate for the MDPP expanded model, where all payments are made in direct relation to the achievement of performance goals, rather than on a per-session basis. The MDPP performance-based payment methodology makes available performance payments for the achievement of weight loss, specifically the required minimum weight loss in the first 12 months of the MDPP services period and the achievement of 9 percent weight loss any time during the MDPP services period. This is consistent with the recommendations of several commenters that a weight loss ''bonus'' be available, although we are not accompanying weight loss performance payments with per-session payments as further recommended by those commenters.

Given the differences between such a performance-based payment methodology and payment under the FFS Medicare payment methodologies, we are not able to provide information on determining MDPP performance payment amounts that is similar to information published in the Medicare PFS rules for other Part B services where payments are related to the relative resources used by suppliers to furnish those services, nor are comparisons to payment on an hourly basis with PFS services possible. The MDPP expanded model uses a fundamentally different payment methodology than the FFS Medicare payment methodologies because it provides a balance of performance-based payments related to weight loss and session attendance, and does not use a resource-based payment methodology for MDPP services. We respond specifically to comments on the proposed distribution of performance payments across the set of MDPP services in the subsequent response in this section and provide more information about our final performance payment and bridge payment amounts in sections III.K.2.d.iii.(3) through (6) and III.K.2.d.v. of this final rule.

Under the performance-based methodology, we believe it is appropriate to pay MDPP suppliers, regardless of size or geographic location, the same performance payment for each beneficiary who achieves the same performance goals because achievement of the required minimum weight loss leads to a reduced incidence of type 2 diabetes for beneficiaries.

Moreover, payment of performance payments based on aggregate beneficiary achievement of performance goals would not sufficiently incentivize MDPP suppliers to engage all beneficiaries in working to achieve the performance goals of the MDPP expanded model. We acknowledge that MDPP suppliers furnishing MDPP services to a small number of beneficiaries may experience more payment variation than larger suppliers under our proposed methodology that relies on the achievement of performance goals by individual beneficiaries to determine the payment amounts. However, we maintain our strong interest in incentivizing MDPP suppliers to work to engage all beneficiaries in achieving the attendance and weight loss performance goals of the MDPP expanded model, despite our understanding that this may put some suppliers at greater financial risk than others. Therefore, we will not provide performance payments based on aggregate beneficiary achievement of performance goals.

We note that the MDPP expanded model was determined to meet the statutory requirements for expansion, with certification of the DPP model test based on findings that weight loss was associated with reductions in Medicare expenditures. In response to the commenter who was concerned that the MDPP expanded model performance-based payment methodology is not evidence-based, we emphasize that we intend to evaluate the MDPP expanded model, which will pay for MDPP services under this payment methodology, using a combination of encounter and claims data to analyze the long-term utilization of services by beneficiaries who have received MDPP services. Moreover, we will continue to assess whether the MDPP expanded model is expected to improve the quality of care without increasing spending, reduce spending without reducing the quality of care, or improve the quality of care and reduce spending, and we will terminate or modify the MDPP expanded model if the expanded model is not expected to meet these criteria.

Comment: While many commenters supported the proposed maximum performance payment of $810 per MDPP beneficiary, multiple commenters opposed the proposed distribution of performance payments over the set of MDPP services. The commenters noted that the sum of the proposed performance payments for the first 12 months of the MDPP services period was too low, especially for beneficiaries who did not achieve the required minimum weight loss but to whom MDPP suppliers would be required to offer sessions throughout that time period. The commenters noted that the MDPP payment structure should take into account the weight loss trajectory of typical individuals receiving DPP services, where weight loss occurs slowly over many months, and should also ensure ongoing financial support for the MDPP supplier that must provide access to MDPP services and teach the DPP curriculum to beneficiaries while the beneficiaries are working to lose weight.

Many commenters acknowledged that they anticipated significant attrition of MDPP beneficiaries over the maximum 36-month MDPP services period. The commenters expected that MDPP suppliers would not receive the full $400 that CMS proposed as the maximum aggregate performance payment for ongoing maintenance session intervals in the ongoing services period during months 13 to 36 as Medicare beneficiaries reduced their participation in MDPP services because they were no longer eligible for coverage based on their lack of adherence to attendance requirements over the long duration of the period. Most commenters with this perspective also urged CMS either not to include ongoing maintenance sessions in the MDPP expanded model or to reduce the proposed 24 months of the ongoing services period to 12 months. Under both scenarios, the commenters urged CMS to redistribute the performance payments that would have been made for ongoing maintenance session intervals to increase performance payments during the first 12 months of the MDPP services period, especially to core session performance payments.

Multiple commenters requested that MDPP suppliers be paid when MDPP supplier resources are used. They stressed that MDPP suppliers incur significant cost prior to the first core session, including hiring and training coaches, printing the CDC curriculum and nutrition logs, and potentially securing class space. The commenters claimed that most MDPP supplier costs (for example, administration, staffing, beneficiary engagement, marketing, materials, and recruitment) are expended up front in the initial 6 months of the MDPP services period, regardless of whether beneficiaries achieve the required minimum weight loss performance goal. Under the proposal, the commenters concluded that MDPP suppliers would be faced with covering their initial DPP expenses without timely payment, which could preclude some entities from becoming MDPP suppliers.

Several commenters urged CMS to pay MDPP suppliers based on attendance alone for the full 12-month core services period, with higher amounts in the first 6 months because they claimed that the majority of the costs associated with professional staff labor are incurred in this time period due to the DPP curriculum being delivered in weekly sessions. Other commenters recommended that the large majority of payment for MDPP services, up to 70 percent for those beneficiaries achieving 5 percent weight loss, be paid during the first 12 months of a beneficiary's MDPP services period. Some commenters stated that the performance payment should be based on completion of the 12-month core services period, rather than on the achievement of weight loss goals that may be affected by factors outside the MDPP beneficiary's or MDPP supplier's control.

A number of commenters estimated the MDPP supplier cost of furnishing MDPP services for the core services period as greater than $500 per beneficiary. One commenter claimed that payment to DPP organizations in the DPP model test, in the NIH Randomized Control Trial, and the private sector were all substantially higher than the average proposed first year per beneficiary payment of $255 that a high-performing DPP organization would anticipate under the MDPP expanded model (to calculate the $255 average payment, the commenter assumed 50 percent of beneficiaries achieve 5 percent weight loss, and all beneficiaries attend 16 sessions in months 1 to 6 and 6 sessions in months 7 to 12). Another commenter further observed that the DPP model test did not include the significant administrative, operational, and reporting requirements necessary to become a Medicare supplier and adhere to the MDPP expanded model requirements that CMS proposed. The commenters concluded that the significant disparity between the proposed payment for MDPP services and actual needed MDPP supplier investment would impact the MDPP expanded model outcomes, including the MDPP beneficiary's achievement of performance goals and the MDPP supplier's fidelity to the quality of its DPP, in addition to reducing the cost-effectiveness and efficiency of MDPP services.

Moreover, several commenters claimed that the significant MDPP supplier infrastructure that would be required by CMS' proposals and the associated administrative costs to sustain a 12- to 36-month MDPP services period for each MDPP beneficiary would create a burden for most community-based DPP organizations, resulting in barriers to participation in the MDPP expanded model for small or new DPP organizations. Therefore, they reasoned that the proposed distribution of performance payments may be inadequate to support MDPP suppliers in general and may be biased towards organizations with greater resources. The commenters concluded that this bias could further restrict an already limited in-person network of DPP organizations and reduce the opportunity for competition among DPP organizations.

Other commenters reported that a typical performance bonus is 10 to 20 percent of a person's salary for achieving exemplary results, whereas CMS proposed that 85 percent of the maximum total performance payment amount for MDPP services would be based on the achievement of the required minimum weight loss. Several commenters stated that the goal of securing CDC's DPRP full recognition should be a sufficient incentive for MDPP supplier engagement in beneficiary weight loss efforts, because ultimately without this recognition, the DPP organization would not be eligible to be an MDPP supplier that can furnish and bill for MDPP services.

Response: We refer readers to sections III.K.2.d.iii.(3) through (6) of this final rule for discussion of our final policies and payment amounts for the specific types of performance payments under the MDPP expanded model. We also refer readers to section III.K.2.b.i. of this final rule for discussion of our final policy that establishes a maximum 12-month ongoing services period, rather than the 24-month timeframe we proposed. In addition, in a previous response to public comments in this section, we provided our rationale for adopting a performance-based payment methodology for MDPP services in general, where payment will be based on the achievement of attendance and weight loss performance goals.

We appreciate the information provided by the commenters about the amount of payment made by other payers for DPP services, as well as their estimates of MDPP supplier costs for furnishing MDPP services. However, we note that unlike FFS Medicare payment methodologies, we are not providing payments for MDPP services based on the relative resources used by MDPP suppliers but rather using a performance-based payment methodology that is based on the individual MDPP beneficiary's achievement of performance goals. We also do not believe that it would be appropriate to set payment for MDPP services based primarily on historical payments received by DPP organizations under clinical trials or other models where the beneficiary population and other program requirements and activities were not the same as those under the MDPP expanded model. For example, the design features of the NIH Randomized Control Trial differ from the MDPP expanded model, including the personnel teaching the curriculum

and the settings where DPP services were furnished. Moreover, we are aware of similar payment structures being used by commercial insurers and accepted by DPP organizations; however, the specific payment amounts vary substantially, and we continue to believe the performance payment amounts for MDPP services are appropriate under the MDPP expanded model.

However, we agree with commenters that the distribution of the maximum total performance payment amount over the set of MDPP services should be revised to shift a higher percentage to the core services period, especially the first 6 months of the MDPP services period. We believe this shift is appropriate in view of the frequent sessions that must be offered to MDPP beneficiaries by MDPP suppliers during months 1 to 6 for beneficiary achievement of attendance performance goals and the aggressive pursuit of performance goals that we expect to occur during the first 12 months of the MDPP services period, where coverage for MDPP services ends altogether if the beneficiary does not achieve the required minimum weight loss within that 12-month time period. Based on the information provided by the commenters, we believe this revised distribution better accounts for the weight loss trajectory of the typical MDPP beneficiary, where weight loss occurs slowly over many months, while ensuring ongoing financial support for the MDPP supplier that must provide access to MDPP services and teach the DPP curriculum to beneficiaries while the beneficiaries are working to lose weight.

We are specifically increasing the performance payments for attendance at 4 and 9 core sessions and the core maintenance session interval performance payments for those beneficiaries who do not achieve or maintain the required minimum weight loss, consistent with the requests of some commenters as discussed in detail in sections III.K.2.d.iii.(3) and (4) of this final rule, respectively. In comparison with the approximately 50 percent that we proposed, these changes result in about 70 percent of the maximum total performance payment amount for the MDPP services period being available during the first 12 months of the MDPP services period for beneficiaries who achieve the required minimum weight loss within the first 6 months, as some commenters also requested.

We considered making the distributional changes to shift a higher percentage of the maximum total performance payment amount for the set of MDPP services to the core services period by redistributing only those performance payments that would have been made during months 1 to 24 of the MDPP services period, in order to shift a higher percentage of those payments to the first 6 months of the core services period. However, such a redistribution would have required reducing the performance payments for core maintenance and ongoing maintenance session intervals from the amounts we proposed, while commenters supported the proposed amounts or recommended higher payment amounts, as discussed in sections III.K.2.d.iii.(4) and (5) of this final rule. It would also have reduced the maximum total performance payment amount to $610 from the $810 that we proposed, due to the elimination of ongoing maintenance session interval performance payments of $50 per interval for the 4 intervals that would have occurred during months 25 to 36 of the MDPP services period.

Instead, we are shifting a higher percentage of the maximum total performance payment amount to the core services period by partially redistributing the performance payments that would have been made during months 25 to 36 of the MDPP services period to the core services period because the ongoing services period has been reduced from 24 to 12 months. This approach allows us to finalize performance payments for core maintenance and ongoing maintenance session intervals that are no lower than the amounts we proposed and results in a smaller reduction to $670 for the maximum total performance payment amount.

In considering opportunities to revise the performance payment amounts in response to the perspectives provided by the commenters, we intend for our redistribution to have a minimal impact on the estimated Medicare expenditures for MDPP services; therefore, we are not redistributing the full amount of $200 that would have been the maximum performance payment amount for months 25 to 36 of the MDPP services period. Rather, we are only partially redistributing payments from the full amount of $200 because our expectation (based on the results of the DPP model test and information from the commenters) is that a higher number of beneficiaries will attend the sessions during the core services period than the number who would have attended the sessions during months 25 to 36 of the ongoing services period, due both to beneficiary attrition over the long duration of the MDPP services period and the coverage requirements for beneficiaries during the ongoing services period. Thus, we believe that redistributing the full amount of $200 to the core services period would result in significantly higher expenditures for the MDPP expanded model than a partial redistribution that more closely reflects performance payments we would have made if the ongoing services period continued through month 36. Therefore, in order to maintain a similar estimate of aggregate Medicare expenditures for MDPP services under our final distribution of performance payments, the final maximum total performance payment amount is necessarily lower than the $810 we proposed.

The partial redistribution of $60 to the performance payments for attendance at 4 and 9 core sessions and $10 to the core maintenance session interval performance payments for beneficiaries who do not achieve or maintain the required minimum weight loss means that the final maximum total performance payment amount for a beneficiary is $670 under the MDPP expanded model. As was also true for our proposals, in the context of estimates of future Medicare savings from the MDPP expanded model, the redistribution of dollars across the set of MDPP services under our final policies takes into account estimates of total Medicare expenditures under the MDPP expanded model for MDPP beneficiaries and estimates of future reductions in spending for those beneficiaries that would occur from their reduced incidence of type 2 diabetes.

Based on the final performance payments displayed in Table 29, and assuming 50 percent of an MDPP supplier's MDPP beneficiaries achieve the required minimum weight loss within the first 6 months of the core services period (the assumption made by one commenter for ease of estimation, which we also use because it is close to the 44.7 percent of participants in the DPP model test who achieved 5 percent weight loss and) [24] and maintain this weight loss through months 7 to 12, the average MDPP supplier total performance payment amount per beneficiary for the first 12 months of the MDPP services period is $320 under our final policies, compared with $255 under our proposed policies. In the MDPP expanded model performance-based payment methodology, this increase in the estimated average MDPP supplier total performance payment amount per

[24] National Council of Young Men's Christian Associations, Measurement and Monitoring Report. CMS Health Care Innovation Awards, Round One, Sixteenth Quarterly Reporting Period (16QR), April, May, and June 2016.

beneficiary for the core services period more substantially recognizes beneficiary achievement of the attendance and weight loss performance goals during this 12-month timeframe that result in a reduced incidence of type 2 diabetes. In addition, we note that these payment changes also result in the opportunity for MDPP suppliers, including those suppliers that are small or new DPP organizations, to receive a larger amount of performance payments in the first 12 months of a beneficiary's MDPP services period that may help reduce DPP organizations' financial barriers to enrollment in Medicare and, therefore, increase access to MDPP services for Medicare beneficiaries. We believe the revised distribution of performance payments shortens the time MDPP suppliers must bear the resource costs of enrolling in Medicare and furnishing MDPP services without receiving significant payments from Medicare, thereby increasing the likelihood that additional organizations with fewer resources will be able to enroll in Medicare and furnish MDPP services.

As explained previously, we are not redistributing to the other performance payments amounts the full amount of $200 that would have been the maximum total per-beneficiary performance payment for months 25 to 36 of the MDPP services period. This means that the final maximum total performance amount for a beneficiary is $670 under the MDPP expanded model, lower than the $810 we proposed. The final lower maximum total performance payment amount results from our expectation that the ongoing maintenance session interval performance payments for months 25 to 36 of the MDPP services period would have been made for fewer beneficiaries than the increased performance payments that will be made in the first 12 months of the MDPP services period under our final policies, due both to beneficiary attrition over the long duration of the MDPP services period and the policy that performance payments for ongoing maintenance session intervals require the beneficiary to meet both attendance and weight loss performance goals during each interval. As was also true for our proposals, in the context of estimates of future Medicare savings from the MDPP expanded model, the redistribution of dollars across the set of MDPP services under our final policies takes into account estimates of total Medicare expenditures under the MDPP expanded model for MDPP beneficiaries and estimates of future reductions in spending for those beneficiaries that would occur from their reduced incidence of type 2 diabetes.

After considering the public comments received, we are finalizing the proposals for the maximum total performance payment amount and the distribution of performance payments for MDPP services across the set of MDPP services, with modifications. Based on our discussions in sections III.K.2.d.iii.(3) through (6) of this final rule regarding weight loss performance payments and changes to the performance payments for core sessions, core maintenance session intervals for beneficiaries who do not achieve or maintain the required minimum weight loss, and ongoing maintenance session intervals to reflect the final 12-month ongoing services period policy (discussed in section III.K.2.b.i of this final rule), the final maximum total performance payment amount for the set of MDPP services is $670. The changes to the specific types of performance payments in this final rule that sum to the maximum total performance payment amount for the set of MDPP services result in a substantial increase in the percentage of the maximum total performance payment amount available during the 12-month core services period. The largest absolute percentage increase by type of performance payment is in the first 6 months of the MDPP services period when core sessions are furnished. There is also a significant absolute percentage decrease in the maximum total performance payment amount for ongoing maintenance session intervals, which reflects the shortening of the ongoing services period duration from 24 months to 12 months. The final maximum total performance payment amount and distribution of performance payments for MDPP services are displayed in Table 29.

TABLE 29—FINAL MAXIMUM TOTAL AMOUNT AND DISTRIBUTION OF PERFORMANCE PAYMENTS FOR MDPP SERVICES

Type of performance payment	Maximum performance payment for achieving attendance and/or weight loss performance goals	Percentage of maximum total performance payment amount (%)
Core sessions	$165	25
Core maintenance session intervals	120	18
Ongoing maintenance session intervals	200	30
Weight loss	185	27
Total performance payment	670	100

(b) Payment Considerations Related to Coverage of MDPP Services for Beneficiaries With Social Risk Factors

In the CY 2018 PFS proposed rule (82 FR 34141), we discussed our understanding that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support play a major role in health. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academies of Sciences, Engineering, and Medicine recently released reports on the issue of accounting for social risk factors in CMS programs.[25] [26] We have previously sought public comment on accounting for social risk factors in CMS programs, primarily on the topics of quality measurement and reporting, such as in the Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models published in the October 1, 2015 **Federal Register** (80 FR 59105, 59109, 59110, and 59113).

In the CY 2017 PFS final rule (81 FR 80466), we acknowledged commenters' concerns regarding the potential unintended consequences if the MDPP expanded model were to result in low-

[25] Available at *https://aspe.hhs.gov/sites/default/files/pdf/253971/ASPESESRTCfull.pdf.*

[26] Available at *http://nationalacademies.org/hmd/Reports.aspx?filters=inmeta:activity=Committee+on+Accounting+for+SES+in+Medicare+Payment+Programs.*

income or other disadvantaged populations having less access to ongoing maintenance sessions due to their failure to achieve or maintain the weight loss performance goal required for coverage of these sessions. In addition, through listening sessions, stakeholders provided us with anecdotal information suggesting that racial and ethnic minorities and low socioeconomic status populations lose about 1 percent less weight, on average, than higher socioeconomic groups and non-Hispanic whites.

We proposed an MDPP payment structure for the set of MDPP services that is similar to the structure presented in the CY 2017 PFS proposed rule (81 FR 46416), where performance payments are tied to attendance at MDPP sessions and/or weight loss. Based on information provided to us by stakeholders, we acknowledged that tying performance payment to a specific threshold of weight loss and/or attendance may make achieving the performance goals required for the highest performance payments and beneficiary eligibility for coverage of ongoing maintenance sessions more challenging for MDPP suppliers furnishing services to individuals with social risk factors. We noted that our proposal for beneficiary engagement incentives as discussed in section III.K.2.f. of the proposed rule (82 FR 34166 through 34171) would provide MDPP suppliers with the flexibility under certain conditions to furnish in-kind patient engagement incentives, such as transportation, to support beneficiaries in achieving the MDPP expanded model performance goals, including session attendance and weight loss. We expected that these beneficiary engagement incentives may be helpful to MDPP suppliers furnishing services to beneficiaries, including those with social risk factors that could increase their risk of not achieving the MDPP performance goals.

We did not propose to risk-adjust MDPP payments for social risk factors or to adopt additional special payment policies to specifically encourage MDPP suppliers to furnish sessions to beneficiaries with social risk factors because, for the MDPP expanded model, we do not believe that such approaches are necessary to ensure access to MDPP services for all beneficiaries. This is because we believe that the proposed performance goals upon which the performance payments for the set of MDPP services would be based, as well as the payment policies that recognize that weight loss is a gradual process that may occur slowly over the 12 months of the core services period, should allow MDPP suppliers sufficient time to work with all eligible beneficiaries, including beneficiaries with social risk factors, toward achieving the attendance and weight loss performance goals of the MDPP expanded model. However, we noted that we may consider proposing additional payment policies for the MDPP expanded model in the future, as appropriate.

We requested comments about social risk factors in the context of the set of MDPP services that could inform any future considerations of additional payment policies for the MDPP expanded model. We also invited public comments on other types of strategies that we could utilize throughout the testing of the MDPP expanded model to assist MDPP suppliers in providing robust access to MDPP services for beneficiaries with social risk factors, such as learning activities to share best practices among MDPP suppliers in providing the set of MDPP services.

The following is a summary of the public comments received on social risk factors in the context of MDPP services and other types of strategies that we could utilize through the testing of the MDPP expanded model to assist MDPP suppliers in providing access to MDPP services for beneficiaries with social risk factors and our responses:

Comment: Several commenters expressed concern that the proposed performance-based payment methodology did not include risk-stratification of payments for MDPP services. The commenters noted the proposed payment approach could potentially lead MDPP suppliers to cherry-pick beneficiaries and/or service delivery locations based on the probability that the patient population would attend more sessions, be more adherent to the education and counseling they receive, and be more likely to lose weight, while avoiding communities with a high percentage of beneficiaries with social risk factors who might find DPP attendance and adherence more challenging. The commenters noted that such MDPP supplier practices resulting from the proposed MDPP performance-based payment methodology could compromise the advancement of the goals of the MDPP expanded model, and may generate greater inequities and lack of MDPP services access for individuals who already experience a disproportionately higher risk for type 2 diabetes. One commenter expressed concerns about the unknown relation of the proposed pay-for-performance strategy to health disparities and sought acknowledgement from CMS that the proposal is an experimental approach that has a weak evidence-base. The commenter requested that CMS include references to the data in the final rule regarding the effects on disparities on which the proposals for the MDPP expanded model were based.

The commenters urged CMS to take into account the socioeconomic status of MDPP beneficiaries and how this may impact their achievement of performance goals more generally, and risk-adjust for these factors. One commenter suggested that CMS provide a supplemental payment of 25 percent to MDPP suppliers for furnishing MDPP services in geographies or to groups who, based on the literature, have a higher prevalence of type 2 diabetes in their community, and/or are less likely to complete the set of MDPP services. The commenter recommended that this supplemental payment should be tied to aggregate attendance, rather than weight loss, in order to promote the delivery of MDPP services by community-based organizations that can make ancillary supportive services available to beneficiaries that the commenter stated may lead to greater success in priority communities. As an alternative to this approach, the commenter presented options for tying enhanced payments to individual MDPP suppliers that would pay suppliers different amounts based on the specific population enrolled with a DPP organization.

Other commenters who acknowledged that CMS did not propose to move forward with risk-adjustment for social risk factors in the MDPP expanded model in CY 2018 encouraged CMS to be mindful of how social influences may impact some MDPP beneficiaries and encouraged the Agency to consider risk-adjustment or other methods to appropriately account for social risk factors in future years in the performance-based payment methodology. In contrast, several commenters noted that risk-stratification of payments based on social risk factors is not necessary for the success of the MDPP expanded model and may lead to discrimination in the model.

Many commenters presented social factors that they state influence health, including income, education, race and ethnicity, employment, disability, and social supports. Other commenters cited research which suggested that addressing socioeconomic factors increases both the sustainability and impact on overall health of efforts to prevent and manage chronic conditions, particularly type 2 diabetes. One commenter identified the following social risk factors as potentially influencing patient outcomes

experience by DPP organizations: Transportation issues and their impact on consistent participation with face-to-face programs; socioeconomic status and its impact on access to healthy food choices and the ability to participate in safe physical activity; and educational and cognitive level and its impact on understanding key concepts of the DPP and decision-making skills. Another commenter stated that 22 percent of its DPP organization's participants are below the federal poverty guidelines and are achieving, on average, weight loss that is nearly a percentage point lower than participants with household income above the federal poverty line.

Several commenters stressed their commitment to furnishing MDPP services to all individuals who qualify for these services, regardless of their ability to pay or the timeline in which they achieve performance goals, including working hard to address issues like access and affordability that may make it difficult for people to enroll and continue to receive services from the DPP organization. The commenters emphasized that MDPP suppliers must be willing to put time and resources into additional or customized services to meet the needs of communities with social risk factors and drive people to enroll and continue to participate in a lengthy behavior change program like the set of MDPP services. Several commenters encouraged CMS to continue to align with the CDC's DPRP Standards to encourage and/or incentivize MDPP suppliers, through transparent policies, to furnish MDPP services in low-income areas.

One commenter recommended that CMS develop a list of social risk factors for MDPP suppliers to capture so suppliers can develop a process to query beneficiaries about these issues. Several commenters stated that while the MDPP expanded model proposals regarding beneficiary engagement incentives would provide MDPP suppliers with some flexibility to support different beneficiary needs, it is unclear if this policy will be sufficient to allow MDPP suppliers to appropriately assist low-income or other disadvantaged populations who have less access to programs and resources.

Response: We appreciate the feedback from the commenters on social risk factors in the context of MDPP services, as well as on strategies that we could utilize throughout the testing of the MDPP expanded model to assist MDPP suppliers in providing access to MDPP services for beneficiaries with social risk factors. We also appreciate the support of some of the commenters for our proposals regarding beneficiary engagement incentives to provide MDPP suppliers with additional flexibility to support different beneficiary needs.

In response to the commenter who requested that CMS present references to the data about the effects on disparities on which the proposals for the MDPP expanded model were based, we note that we have adapted model policies to support national expansion and in response to public comments; therefore, we do not currently have existing evidence specific to the effects on disparities of the totality of model design parameters that are being finalized in this final rule. To the extent possible with existing data, sub-group analyses, including beneficiary characteristics such as race and ethnicity, will be conducted at part of the evaluation of the MDPP expanded model.

We will review the information about social risk factors provided by the commenters, as well as our early implementation experience with the MDPP expanded model and other information we receive in the future from stakeholders, as we consider potential proposals for additional payment policies for the MDPP expanded model in the future.

(3) Performance Payments for Core Sessions

The payment structure presented in the CY 2017 PFS proposed rule (81 FR 46415 through 46416) would have made attendance-based payments of $25 for the first core session, $50 for 4 total core sessions, and $100 for 9 total core sessions. Based on our consideration of information provided in the public comments on CY 2017 PFS proposed rule and our increased emphasis in the performance payments on the achievement and maintenance of the required minimum weight loss as the outcome of MDPP services, our proposal for the attendance-based performance payments for 4 and 9 core sessions differed from these payment amounts. We proposed that an MDPP supplier would be paid a $25 performance payment the first time it furnishes an MDPP session to an MDPP beneficiary as displayed in Table 30. This performance payment would be available once per beneficiary for the beneficiary's first core session.

We proposed that an MDPP supplier would be paid the performance payment upon furnishing the first core session to a beneficiary who initiates the MDPP services period, regardless of whether the MDPP supplier qualifies for any of the additional performance payments for that beneficiary. Additional performance payments would depend upon the beneficiary's achievement of the performance goals for attendance and/or weight loss. We believed that making the first performance payment based on beneficiary attendance at the first core session would be appropriate because the MDPP supplier would use significant resources to furnish the first session, including collecting administrative information on the beneficiary who is not already known to the supplier, regardless of whether the beneficiary goes on to receive further MDPP services from that supplier.

On a per-session basis, the performance payment for the first MDPP core session would be the highest performance payment amount for any core session during the core services period. Of note, the first core session performance payment also would provide some payment for MDPP supplier activities to encourage the beneficiary's attendance at additional core sessions following the first session. Such supplier activities could include sending electronic messages or making reminder phone calls about upcoming sessions or providing transportation to the next session under the beneficiary engagement incentives policy proposed in section III.K.2.f. of the proposed rule (82 FR 34166 through 34171). It is only through attendance at the first core session with an MDPP supplier that a beneficiary initiates the MDPP services period and has the potential to achieve weight loss through receiving MDPP services.

Further, we proposed that suppliers would be paid a performance payment for the interval (which we refer to as an ''interval performance payment'' to distinguish it from other performance payments, such as the performance payment upon an MDPP beneficiary's achievement of the required minimum weight loss, that would not require attendance at multiple sessions) upon a beneficiary's attendance at 4 total core sessions, and again upon a beneficiary's attendance at 9 total core sessions—that is, attendance of 5 more core sessions after having attended his or her first 4. We proposed an interval performance payment of $30 upon a beneficiary attending 4 core sessions and an interval performance payment of $50 upon a beneficiary attending 9 core sessions as displayed in Table 30. Although an MDPP supplier must offer at least 16 core sessions to a beneficiary during the initial 6 months of the MDPP core services period, we did not propose any other interval performance payment for the core sessions after the performance payment for attendance at 9 core sessions. We noted that while these

payment amounts would be somewhat lower than the payment amounts for these milestones presented in the CY 2017 PFS proposed rule (81 FR 46415 through 46416), they follow a similar pattern of a higher payment amount associated with attendance at a larger cumulative number of core sessions to provide a significant financial incentive for MDPP suppliers to encourage MDPP beneficiary attendance at core sessions in the first 6 months of the core services period.

On a per-session basis, the payments for attendance at 4 total core sessions and 9 total core sessions would be approximately $10 and $4 to $10, respectively, depending upon the number of sessions attended by the beneficiary beyond the 9 required for the second interval performance payment up to the maximum of 16 core sessions that must be offered to the beneficiary by the MDPP supplier during the initial 6 months of the MDPP core services period. Because the performance payments for core sessions would be based solely on the achievement of attendance performance goals, we believed that these per-session performance payment amounts that would be lower than the proposed performance payment amount for the first core session would still be appropriate because we expected that fewer MDPP supplier resources would be used to furnish sessions to beneficiaries with whom the MDPP supplier has an established relationship. The per-session payment amounts for core sessions were set based on attendance at these sessions, which is associated with ultimate achievement of the required minimum weight loss.

We proposed to make the first interval performance payment for core sessions when the beneficiary has attended 4 core sessions for the following reasons. First, beneficiary attendance at 4 core sessions was a significant attendance milestone in the evaluation of the DPP model test, which provided evidence that meeting this milestone is tied to weight loss outcomes.[27] According to the second year independent evaluation of the DPP model test, those beneficiaries who attended at least 1 core session lost an average of 7.6 pounds while beneficiaries who attended at least 4 core sessions lost an average of 9 pounds. BMI was reduced from 32.9 to 31.5 among Medicare beneficiaries who attended at least 4 core sessions. Second, in examining CDC's DPRP participant trend data, we found that a higher percentage of participants drop out after 3 core sessions as compared to those who drop out after 4 core sessions, meaning that if a beneficiary completes the 4th core session, he or she is more likely to remain in the DPP for the 12-month program.[28] Therefore, we believed that making the first interval performance payment after beneficiary attendance at 4 core sessions would be appropriate.

We proposed to make the second interval performance payment when the beneficiary has attended 9 core sessions because attending a higher amount of sessions in the initial 6 months of the MDPP core services period, beginning at session 9, has been shown to greatly improve weight loss outcomes. Specifically, according to CDC data, there is a 125 percent increase in weight loss comparing beneficiaries who attend 4 to 8 sessions (1.6 percent weight loss on average) and beneficiaries who attend 9 to 16 sessions (3.6 percent weight loss on average).[29] Therefore, we believed that attendance at 9 sessions reflects clinically meaningful attendance at core sessions and would provide an incentive to MDPP suppliers to encourage beneficiaries to continue into the second 6 months of the MDPP core services period, which is when the 5 percent weight loss from baseline is usually achieved or exceeded. Additionally, 9 is the number of core sessions, on average, that a participant must attend in CDC's National DPP in the first 6 months for a CDC-recognized organization to achieve full CDC recognition.

MDPP suppliers would be paid these performance payments when beneficiaries achieve these core session attendance performance goals, regardless of weight loss. Although we proposed to base performance payments during the MDPP services period substantially on weight loss, which is directly associated with a significant decrease in the incidence of type 2 diabetes, we recognized that weight loss is a gradual process and that MDPP suppliers would utilize resources to furnish MDPP services during the period of time when the beneficiary is losing weight. Therefore, we proposed that performance payments for beneficiary attendance at core sessions during the first 6 months of the core services period be based on attendance only.

The proposed maximum total performance payment to MDPP suppliers for furnishing MDPP core sessions would be $105 per beneficiary, as displayed in Table 30.

TABLE 30—PROPOSED ATTENDANCE-BASED PERFORMANCE PAYMENTS FOR MDPP CORE SESSIONS

Performance goal	Attendance-based performance payment per beneficiary
1st core session attended (performance payment)	$25
4 total core sessions attended (interval performance payment)	30
9 total core sessions attended (interval performance payment)	50
Maximum total performance payment for core sessions	$105

We considered alternatives to this payment structure for core sessions, such as making higher payments for attendance at the earlier sessions to provide MDPP suppliers with additional funds for the resources necessary for start-up of the MDPP expanded model. We stated that although we understood that there are some up-front supplier costs associated with implementing the MDPP expanded model, we believed that these costs would disproportionately be related to start-up and not generally be ongoing costs borne by the MDPP supplier. In

[27] Hinnant L, Razi S, Lewis R, Sun A, Alva M, Hoerger T, Jacobs S, Halpern M. Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring, Annual Report 2015. Awardee-Level Findings: YMCA of the USA; 2016. Table 17. Average/Frequencies Health Outcomes of all Participants through Q11, p. 36. RTI Project Number 0212790.010.001.004, Contract HHSM–500–2010–00021I. Sponsored by the Centers for Medicare & Medicaid Services.

[28] CDC's Diabetes Prevention Recognition Program dataset as of March 1, 2017.

[29] CDC's Diabetes Prevention Recognition Program dataset as of February 28, 2017.

addition, because we expected that many MDPP suppliers are currently offering DPPs through contracts with commercial payers, MDPP suppliers may be able to minimize start-up costs by relying on their relevant experience with offering other DPPs. Finally, we believed that our proposal for payment of MDPP core sessions already included substantial payment for session attendance early in a beneficiary's participation with the MDPP supplier, considering that MDPP suppliers would be paid an initial $25 performance payment for the first core session attended by the beneficiary and would then be paid performance payments for beneficiary attendance of up to 9 core sessions, regardless of weight loss. We noted that increasing the initial payments for attendance at MDPP sessions would shift the nature of the payment for the set of MDPP services from a performance-based structure based on a balance of attendance and weight loss considerations toward a payment structure that is based on attendance at each session furnished.

The proposed attendance-based performance payments for MDPP core sessions were included at proposed § 414.84(b)(1), (2), and (3). We invited public comments on these proposals. We also invited public comments on the alternative considered.

The following is a summary of the public comments received on the proposals for attendance-based performance payments for MDPP core sessions and the alternative considered and our responses:

Comment: Many commenters urged CMS to increase the proposed $25 performance payment for the first core session. They explained that many potential MDPP suppliers are not medical providers in a way similar to most clinicians who commonly work within practices already set up for Medicare, where the practice is fully HIPAA compliant and staff have already been trained in fraud, waste and abuse, false claims, and other policies specific to governmental programs. The commenters claimed that there is a necessary and essential MDPP supplier cost to being Medicare ''ready'' that is not always similarly incurred in the commercial payer context, especially when in some circumstances the billing of commercial payers is conducted by invoice, not claim, and those payment arrangements are therefore less costly to the DPP organization than submitting claims for Medicare payment. The commenters stated that each MDPP supplier will have additional set up costs, not only in areas of staffing and training, but in meeting basic requirements of the MDPP expanded model such as the acquisition of medical record systems and Medicare enrollment.

Several commenters requested that CMS review its proposed payment structure for core sessions and, in their view, better balance the amount of money an MDPP supplier would receive for the first session by moving portions of the proposed performance payments for attendance at the fourth session and ninth core session, as well as for core maintenance session intervals, earlier in a beneficiary's MDPP services period to increase payment for the first core session. Another commenter urged CMS to rebalance the attendance-based performance payments for the core sessions to provide 25 percent for the first core session to cover outreach and other start-up costs.

Response: We note that some of the costs identified by the commenters are one-time set up costs, such as the acquisition of medical record systems, that will not be incurred again once the organization is enrolled as an MDPP supplier and furnishing MDPP services on an ongoing basis. We do not believe that increasing the performance payment for the first core session for all MDPP beneficiaries would be appropriate to provide organizations with additional funds for these startup costs in a performance-based payment methodology.

As discussed in section III.K.2.d.ii. of this final rule, we will provide payment for the set of MDPP services through a performance-based payment methodology that makes periodic performance payments to MDPP suppliers during the MDPP services period. The aggregate of all performance payments constitutes the total performance-based payment amount for the set of MDPP services. We understand that MDPP suppliers will experience some early set up costs and ongoing costs for activities such as outreach to get Medicare beneficiaries to obtain MDPP services from the supplier and that the MDPP supplier may need to bear these resource costs before receiving significant payment from Medicare for MDPP services. We appreciate that the timing of the performance payments and MDPP suppliers' use of resources for furnishing MDPP services are not fully aligned. Because the MDPP expanded model relies on a performance-based payment methodology that is heavily weighted toward the outcome of the required minimum weight loss that is associated with a reduced incidence of type 2 diabetes, MDPP suppliers will need to bear these resource costs until suppliers begin to receive significant performance payments from CMS. However, we expect that the total performance payment amounts received by MDPP suppliers for the set of MDPP services will provide funds to MDPP suppliers for carrying out these initial and ongoing activities, not just the payment for the first core session furnished to an MDPP beneficiary in the MDPP services period.

We note that the proposed performance payment for the first core session of $25 was the highest performance payment, on a per-session basis, of any of the other proposed core session performance payments. As discussed in the subsequent response to comments, we are finalizing higher performance payments for attendance at 4 and 9 core sessions than we proposed, but $25 is still higher than those final core session performance payments on a per-session basis. Therefore, we believe that the $25 performance payment for beneficiary attendance at the first core session already recognizes some of the startup costs and the more intense resources used by MDPP suppliers early in their participation as MDPP suppliers and in the beneficiary's MDPP services period, respectively.

In addition, given the performance goal of attendance at only one core session for the first core session performance payment, we believe that a performance payment higher than $25 for the first core session could incentivize MDPP suppliers to furnish the first core session to a large number of beneficiaries who are eligible for MDPP services but who may not have a full understanding of the DPP and its expectations or who are not ready to commit to the full DPP. Such an MDPP supplier practice could result in fewer beneficiaries benefiting from MDPP services by achieving the required minimum weight loss that reduces their risk of type 2 diabetes. Thus, we continue to believe that a performance payment of $25 for attendance at the first core session is the most appropriate payment amount for beneficiary achievement of this attendance performance goal.

Comment: Several commenters urged CMS to make significantly higher core session performance payments, noting that the most intense MDPP supplier administrative activities occur during the first 6 months of the core services period, specifically teaching the health behavior change, motivating individuals to lose 5 percent of their weight, and encouraging session attendance. The commenters emphasized that significant MDPP supplier activities are required to furnish the weekly core sessions that

must be offered in the first 6 months of the MDPP services period, further noting that these activities lessen beginning in month 7 when sessions must be offered only a minimum of monthly. They claimed that most supplier costs, such as administrative costs, staffing, beneficiary engagement, marketing, materials, and recruitment are incurred up front in the initial 6 months of the MDPP services period and are experienced by the MDPP supplier regardless of beneficiaries' achievement of the required minimum weight loss in that 6-month time period. Under the proposal, the commenters expressed concern that MDPP suppliers would be faced with covering the initial overhead expenses without the opportunity to receive sufficient, timely performance payments.

Therefore, the commenters recommended that CMS reallocate performance payments from the performance payments for 5 percent weight loss and core maintenance session intervals to the first 16 weeks of the MDPP services period when the majority of costs are incurred by the DPP organization. Some commenters specifically recommended the redistribution of $60 to payment for core sessions from the proposed $160 performance payment for achievement of the required minimum weight loss, which would result in a total performance payment for attendance at core sessions of $165, compared to the $105 that CMS proposed (the sum of the performance payments for attendance at the first, 4, and 9 core sessions).

Some commenters supported making core session performance payments after beneficiary attendance at the fourth and ninth core sessions as CMS proposed, based on the evidence cited by the commenters that if a beneficiary completes his or her fourth core session, he or she is more likely to remain in the DPP for the full 12-month core services period.

Response: We agree with the commenters that the 4 and 9 core session attendance performance goals represent milestones that reflect the increased likelihood that the MDPP beneficiary will complete the 12-month core services period and, therefore, achieve the required minimum weight loss.

We appreciate the detailed information presented by the commenters on the critical need to appropriately engage beneficiaries in the first 6 months of the MDPP services period in order to support beneficiaries in achieving the core session attendance performance goals, as well as the information on the number and intensity of MDPP supplier activities necessary during this period in order to meet these goals. After reviewing these descriptions, we believe that it is appropriate to increase the final performance payment amounts from the proposed $30 and $50 for attendance at 4 and 9 core sessions, respectively. The increased core session attendance-based payment amounts reflect the importance of these core session attendance milestones to ultimate MDPP beneficiary achievement of the required minimum weight loss, given the association between greater session attendance and achievement of weight loss. In addition, we note that as a result of these performance payment increases during the first 6 months of the MDPP services period, greater payment for beneficiaries who achieve the performance goals will be available to MDPP suppliers in months 1 to 6 of the core services period that may result in more timely and substantial financial support during that time period for the high intensity of supplier activities needed to promote further beneficiary achievement of performance goals. We recognize that MDPP suppliers will be working diligently throughout this 6-month period to engage beneficiaries, encourage attendance, teach the weekly DPP curriculum, and support beneficiary behavior change through beneficiary engagement incentives and other activities.

Therefore, in view of our final policy that shortens the maximum ongoing services period from 24 to 12 months as discussed in section III.K.2.b.i. of this final rule, we will redistribute some of the funds that would have been available for ongoing maintenance session interval performance payments for months 25 to 36 of the MDPP services period to the 4 and 9 core session attendance-based performance payments.

Because we consider both these milestones to be of similar importance in recognizing beneficiary achievement of attendance performance goals that are associated with completion of the 12-month core services period and achievement of the required minimum weight loss, we are increasing both performance payments by 70 to 80 percent from the proposed amounts, resulting in final attendance-based performance payments for 4 and 9 core sessions of $50 and $90, respectively. While the commenters did not specifically recommend these payment amounts for attendance at 4 and 9 core sessions, several commenters specifically urged us to increase the total payment for core sessions (attendance at the first, 4, and 9 core sessions) from the $105 that we proposed to $165, which would represent a substantial increase in the performance payments for core session attendance. As discussed in the previous response to comments, we are not increasing the performance payment for attendance at the first core session from the $25 payment amount that we proposed. However, we will increase the total attendance-based payment for core sessions from $105 to $165 as recommended by the commenters through proportionately similar increases in the performance payments for attendance at 4 and 9 core sessions.

We believe that increasing the final 4 and 9 session attendance-based performance payments by 70 to 80 percent from the proposed amounts represents a significant increase in the performance payments for attendance at 4 and 9 core sessions that is consistent with the requests of the commenters for increased total payment for attendance at core sessions. Moreover, the final performance payment amounts appropriately recognize the importance of meeting these core session attendance milestones that are linked to the achievement of the required minimum weight loss that leads to a reduction in incidence of type 2 diabetes and reduced Medicare expenditures.

After considering the public comments received, we are finalizing the proposals for the performance payments for core sessions at § 414.84(b)(1), (2), and (3), with modifications. We are finalizing the performance payment for the first core session attended at $25 as we proposed. We are increasing the performance payment for 4 core sessions attended to $50 and the performance payment for 9 core sessions attended to $90. These final performance payment amounts result in a total attendance-based performance payment amount for MDPP services furnished to an MDPP beneficiary in the first 6 months of the core services period of $165, an increase of approximately 60 percent over the proposed total performance payment amount of $105 for the 6-month period of core sessions. The final attendance-based performance payments for MDPP core sessions are displayed in Table 31.

TABLE 31—FINAL ATTENDANCE-BASED PERFORMANCE PAYMENTS FOR MDPP CORE SESSIONS

Performance goal	Attendance-based performance payment per beneficiary
1st core session attended (performance payment)	$25
4 total core sessions attended (interval performance payment)	50
9 total core sessions attended (interval performance payment)	90
Maximum total performance payment for core sessions	165

(4) Performance Payments for Core Maintenance Session Intervals

We proposed that performance payments for core maintenance sessions would be tied to the beneficiary's achievement of attendance and weight loss performance goals during a core maintenance session interval. A core maintenance session interval, as we proposed to define it at § 410.79(b), would mean 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 at least 1 core maintenance session per month to an MDPP beneficiary.

The payment structure presented in the CY 2017 PFS proposed rule (81 FR 46415 through 46416) would have required the MDPP beneficiary to attend 3 core maintenance sessions and achieve or maintain a minimum 5 percent weight loss for a $45 payment to be made to an MDPP supplier for the core maintenance session interval. If 5 percent weight loss was not achieved or maintained during the core maintenance session interval, no separate performance payment would be made. MDPP suppliers would still have been required to offer (and furnish if the beneficiary attended) MDPP services during core maintenance intervals to beneficiaries regardless of weight loss. Based on our consideration of information provided in the public comments on the CY 2017 PFS proposed rule and our increased emphasis in the performance payments on the achievement and maintenance of the required minimum weight loss as the outcome of MDPP services, our proposal for the performance payments for core maintenance sessions differed from the payment amounts included in the CY 2017 PFS proposed rule (81 FR 46415 through 46416).

For the MDPP expanded model, we proposed performance payments amounts for core maintenance session intervals that would value achievement of both session attendance and the required minimum weight loss, with an emphasis on achieving the weight loss performance goal. We proposed that an MDPP supplier would be paid a performance payment for a core maintenance session interval if a beneficiary achieves the performance goal of attending at least 3 core maintenance sessions during the interval. The specific performance payment amount would be determined by whether the beneficiary has also achieved or maintained the required minimum weight loss within the interval. The achievement or maintenance of the required minimum weight loss within the 3-month core maintenance session interval would be determined based on a measurement taken in-person during any 1 session within that 3-month interval. We proposed that MDPP suppliers would be paid a performance payment for no more than 2 core maintenance session intervals for each MDPP beneficiary.

As discussed previously, we recognized that weight loss is a process that may still be ongoing for some beneficiaries during the final months of the core services period. According to an analysis of participant data from CDC's DPRP, the longer a participant remains in the lifestyle change program, the greater his or her average weight loss achieved.[30] Findings indicate that it takes an average of 17 DPP sessions attended to exceed the required minimum weight loss, and the 9 percent or greater weight loss goal is more likely to be achieved upon attending 19 sessions on average. This average number of sessions exceeds the 16 core sessions that must be offered to the MDPP beneficiary during the first 6 months of the MDPP services period and emphasizes the importance of core maintenance sessions to achievement of meaningful weight loss goals.

Of further note, the National DPP's core maintenance sessions were developed based on results from the original 2002 DPP Randomized Control Trial and CDC's DPRP Standards were developed with this science in mind.[31] Core maintenance sessions are integral for the expected reduction in the incidence of type 2 diabetes to be experienced by MDPP beneficiaries. These findings were recently confirmed in a literature review on combined diet and physical activity programs to prevent type 2 diabetes conducted by the Community Preventive Services Task Force that reiterated the year-long intensity and duration of the National DPP.[32]

Therefore, we believed that providing no performance payment to MDPP suppliers for furnishing core maintenance sessions to beneficiaries who have not achieved the required minimum weight loss prior to or during months 7 to 12 of the core services period could reduce the opportunity for MDPP beneficiaries to achieve the weight loss performance goal. Such a payment methodology could reduce the likelihood that MDPP suppliers would continue to work to engage beneficiaries in the weight loss process if those beneficiaries had not achieved the required minimum weight loss after completion of the initial 6 months of the MDPP core services period. We noted that, as finalized in the CY 2017 PFS final rule (81 FR 80459), suppliers must offer a minimum of 1 core maintenance session per month in months 7 to 12 of the core services period to eligible beneficiaries, regardless of the beneficiary's weight loss. We further believed that it would be possible for some beneficiaries to have achieved the required minimum weight loss performance goal by the time the core sessions have been completed, and we wanted to incentivize MDPP suppliers to work toward the weight loss performance goal in that timeframe. However, we believed that it would also be appropriate to place some value on achieving attendance performance goals alone through performance payments for core maintenance session intervals so that MDPP suppliers continue to work to engage all beneficiaries in striving to achieve the required minimum weight loss performance goal.

[30] CDC's Diabetes Prevention Recognition Program dataset as of March 1, 2017.

[31] Available at *https://www.niddk.nih.gov/about-niddk/research-areas/diabetes/diabetes-prevention-program-dpp/Documents/DPP_508.pdf.*

[32] Available at *http://www.thecommunityguide.org/diabetes/combineddietandpa.html.*

As discussed in section III.K.2.d.iii.(2)(a) of the proposed rule (82 FR 34139 through 34141), we proposed that the maximum total performance payment for MDPP core maintenance sessions would be $120 for beneficiaries who achieve both the attendance and weight loss performance goals during months 7 to 12 of the core services period. Specifically, we proposed to pay MDPP suppliers $60 for a core maintenance session interval if a beneficiary attends 3 sessions and achieves or maintains the required minimum weight loss during that interval, and to pay MDPP suppliers $10 for a core maintenance session interval if the beneficiary attends 3 sessions but does not achieve or maintain the required minimum weight loss during that core maintenance session interval.

As compared to the payment amounts with and without achievement or maintenance of the required minimum weight loss that were presented for core maintenance session intervals in the CY 2017 PFS proposed rule (81 FR 46415 through 46416), these proposed payment amounts are both higher. As discussed previously, we believed that it would be appropriate in months 7 to 12 of the core services period to provide some performance payment for achievement of attendance performance goals even if the required minimum weight loss is not achieved, in order to provide the greatest opportunity for beneficiaries to achieve the required minimum weight loss over the full core services period. In addition, we proposed a higher payment amount for core maintenance session intervals with achievement or maintenance of the required minimum weight loss to recognize that achievement and maintenance of the required minimum weight loss are necessary for the reduced incidence of type 2 diabetes and to encourage MDPP suppliers to work to engage beneficiaries in achieving weight loss and sustaining their weight loss over time.

Proposed performance payments for the core maintenance session intervals are displayed in Table 32. On a per-session basis, these payments would be approximately $20 and $3, respectively. Although both of these payment amounts would provide payment to MDPP suppliers for the resources involved with furnishing core maintenance sessions, we believed that the relatively high per-session performance payment of $20 in comparison to the per-session performance payment amounts for core sessions would be appropriate due to the achievement or maintenance of both the required minimum weight loss and beneficiary attendance at core maintenance sessions, as compared to core sessions where the performance payment would be based solely on attendance. On the other hand, we believed that the relatively low per-session payment amount in our core maintenance session interval performance payment proposal for core maintenance sessions for those beneficiaries who do not achieve the weight loss performance goal, while providing some performance payment for attendance at core maintenance sessions by beneficiaries still working to achieve the required minimum weight loss, would be appropriate because these sessions have not yet resulted in those beneficiaries achieving the weight loss performance goal.

TABLE 32—PROPOSED PERFORMANCE PAYMENTS FOR CORE MAINTENANCE SESSION INTERVALS

Performance goal	Performance payment per beneficiary (*with* achievement or maintenance of required minimum weight loss)	Performance payment per beneficiary (*without* achievement or maintenance of required minimum weight loss)
3 sessions attended in first core maintenance session interval (months 7–9 of the MDPP core services period)	$60	$10
3 sessions attended in second core maintenance session interval (months 10–12 of the MDPP core services period)	60	10
Maximum total performance payment for core maintenance session intervals (two consecutive 3-month intervals over months 7–12 of the MDPP core services period)	120	20

The proposed core maintenance session interval performance payments for core maintenance sessions were included at proposed § 414.84(b)(4). We invited public comments on these proposals.

The following is a summary of the public comments received on the proposals for core maintenance session interval performance payments for core maintenance sessions and our responses:

Comment: Many commenters disagreed with the proposal that an MDPP beneficiary must attend 3 core maintenance sessions in each 3-month core maintenance session interval for an MDPP supplier to be paid the core maintenance session interval performance payment for that interval. The commenters observed that because MDPP suppliers must offer, at a minimum, monthly sessions to MDPP beneficiaries during months 7 to 12 of the core services period, the payment proposal would require a beneficiary to achieve 100 percent attendance every 3 months in order for the MDPP supplier to be paid the performance payment. The commenters stated that this is a very high attendance goal that is unlikely to be met, which would result in MDPP suppliers not being paid for MDPP services they are required to offer and some of which the beneficiary attended. One commenter further reasoned that this attendance performance is unnecessary because it was not required in the DPP model test which still realized cost savings for Medicare.

The commenters speculated that in order to promote 100 percent attendance of 3 sessions in a 3-month core maintenance session interval, MDPP suppliers might have to offer more sessions in that interval to accommodate the schedules of the MDPP beneficiaries. They added that offering additional sessions would lead to greater MDPP supplier cost that would not be covered by the proposed performance payments for core maintenance session intervals. Therefore, the commenters urged CMS to change the attendance requirement for core maintenance session intervals from 3 to 2 sessions in order for performance payments to be made, in order to address scenarios where beneficiaries were unable to attend one monthly session in a 3-month period of

time during months 7 through 12 of the core services period.

Several commenters recommended that CMS increase the performance payments for core maintenance session intervals, especially for beneficiaries who have not achieved or maintained the required minimum weight loss. The commenters opposed the use of combined weight loss and attendance performance goals to determine the performance payment amount for the interval during months 7 through 12 of the core services period. Most commenters addressing this issue recommended that CMS make the same performance payment, suggesting values that ranged from the proposed $60 to higher amounts such as $72.50, for core maintenance session intervals for beneficiaries who achieved or maintained the requirement minimum weight loss and those who did not meet the weight loss performance goal because MDPP suppliers are required to offer these sessions to all MDPP beneficiaries.

The commenters stated that providing the same payment for core maintenance session intervals, regardless of the achievement of the weight loss performance goal, would better align beneficiary eligibility with payment for core maintenance sessions. Under such an approach, similar to the first 6 months of the core services period, performance payments in months 7 through 12 would be attendance-based in order not to penalize MDPP suppliers financially for the MDPP beneficiary's weight loss performance because weight loss could reasonably occur over the first 12 months of the MDPP core services period, not just the first 6 months. The commenters described significant administrative costs for necessary MDPP supplier activities during months 7 through 12, including the required tracking of Medicare beneficiaries, in-person weigh-ins, and outreach to enrollees to ensure attendance is high. The commenters stated that these administrative activities could actually increase the MDPP supplier's per-session costs in comparison with months 1 through 6 of the core services period where core sessions must be offered weekly to MDPP beneficiaries.

Response: We appreciate the recommendations of the commenters regarding the performance goals for core maintenance session interval performance payments, as well as the performance payment amounts for beneficiaries who have achieved or maintained the required minimum weight loss and those who have not achieved the weight loss performance goal. In terms of promoting alignment between beneficiary eligibility and payment during months 7 to 12 of the core services period, because we are using a performance-based payment methodology for payment of MDPP services and MDPP services are covered for all beneficiaries in months 7 to 12 of their MDPP services period, it is not possible to fully align eligibility and payment. This contrasts with ongoing maintenance session interval performance payments discussed in section III.K.2.d.iii.(5) of this final rule where the performance payment for a given interval and beneficiary coverage of the subsequent ongoing maintenance session interval are aligned because both depend upon beneficiary maintenance of the required minimum weight loss and attendance at 2 sessions in the ongoing maintenance session interval.

We continue to believe that it is important after making attendance-based performance payments for months 1 to 6 of the MDPP services period to begin to base performance payments in part on the achievement of weight loss beginning in month 7 of the core services period, a time by which we expect some beneficiaries to have achieved the required minimum weight loss outcome goal for MDPP services. Our expectation is supported by findings from the CDC's DPRP that it takes an average of 17 DPP sessions attended to exceed the required minimum weight loss.[33] Given that MDPP suppliers must offer a minimum of 16 sessions during the first 6 months of the MDPP services period, we believe it is reasonable to expect that a number of MDPP beneficiaries will have achieved the required minimum weight loss by month 7 of the core services period. On the other hand, we recognize that weight loss is a process that may still be ongoing for some beneficiaries during the final months of the core services period. Therefore, we believe it is appropriate to maintain performance goals for performance payment for core maintenance session intervals that rely both on attendance and the achievement or maintenance of the required minimum weight loss to encourage high engagement of MDPP suppliers with the MDPP beneficiaries to whom they are offering sessions toward the goal of achieving or maintaining the required minimum weight loss.

Thus, we do not believe it would be appropriate to make a performance payment of $60 for session attendance alone in months 7 to 12 of the core services period at the same payment amount that we are finalizing for beneficiaries who meet both the attendance and weight loss performance goals. However, we appreciate the interest of the commenters in a substantial increase from the $10 that we proposed as the core maintenance session interval performance payment for beneficiaries who are attending sessions that must be offered by the MDPP supplier and still working to achieve the required minimum weight loss. Given the considerable expected engagement of MDPP suppliers with MDPP beneficiaries who are still working to achieve the required minimum weight loss at the end of the first 6 months of the core services period, we agree with the commenters that it would be appropriate to provide a higher core maintenance session interval performance payment for beneficiaries who meet the attendance performance goal for these intervals but have not yet achieved the required minimum weight loss. However, we also intend for our performance-based payment amounts for months 7 to 12 of the core services period to financially incentivize high engagement of MDPP suppliers with the MDPP beneficiaries to whom they are offering sessions toward the goal of achieving or maintaining the required minimum weight loss.

Therefore, we believe that a performance payment of $15 for core maintenance session interval performance payments for those beneficiaries who do not achieve or maintain the required minimum weight loss during the interval but meet the interval attendance performance goal appropriately balances these objectives. We note that this payment amount reflects a significant increase of 50 percent over our proposed payment amount, yet the sizeable difference between the $60 and $15 performance payments that continues to exist for core maintenance session interval performance payments for beneficiaries who do or do not achieve or maintain the required minimum weight loss, respectively, will strongly incentivize MDPP suppliers to engage with MDPP beneficiaries to work toward achieving or maintaining the required minimum weight loss throughout the 3-month core maintenance session intervals.

Because MDPP suppliers must offer, at a minimum, monthly core maintenance sessions to all MDPP beneficiaries during months 7 to 12, regardless of the beneficiary's attendance or achievement of weight loss, we agree with the commenters that it is appropriate to reduce the

[33] CDC's Diabetes Prevention Recognition Program dataset as of March 1, 2017.

attendance requirement for the performance payments during this time period from 3 to 2 sessions per interval. Lowering the required session attendance for the performance payments during this time will provide additional flexibility to beneficiaries to allow them to balance life events and MDPP session attendance, without beneficiary decisions resulting in financial consequences for MDPP suppliers that must offer sessions regardless of actual attendance. We believe that attendance of 2 sessions in a core maintenance session interval still represents substantial beneficiary engagement and, because we also provide payment that differs in relation to achievement of the weight loss performance goal during core maintenance session intervals, this flexibility does not discourage MDPP beneficiaries and MDPP suppliers from a high level of engagement during months 7 to 12 of the core services period.

Comment: Several commenters urged CMS to fully align eligibility and performance payment for core maintenance session intervals, similar to the proposal for eligibility and payment for ongoing maintenance session intervals. For example, if an MDPP beneficiary did not meet the attendance performance goal for the first core maintenance session interval performance payment, the commenters recommended that the beneficiary not be covered for the second core maintenance session interval. Under such an approach, the MDPP supplier would not be required to continue to use its resources to offer additional core maintenance sessions to the beneficiary whose attendance was too low to result in a performance payment being made to the MDPP supplier.

Response: As the commenters observed, eligibility and payment are aligned for ongoing maintenance session intervals where a beneficiary must meet the performance goals for the performance payment for an interval, namely attendance at 2 sessions and maintenance of the required minimum weight loss, to be eligible for the subsequent ongoing maintenance session interval as discussed in section III.K.2.c.iv.(1)(b) of this final rule. However, with respect to core maintenance sessions intervals, in the CY 2017 PFS final rule (81 FR 80465), we finalized the MDPP core benefit for all MDPP beneficiaries as 12 consecutive months consisting of at least 16 weekly core sessions over months 1 to 6 and at least 6 monthly core maintenance sessions over months 6 to 12 that must be offered to each MDPP beneficiary regardless of attendance or weight loss.

We made no proposals to change the coverage policy under circumstances where an MDPP beneficiary's attendance at sessions that must be offered by the MDPP supplier is too low to result in a performance payment to that supplier. We further note that the CDC DPRP Standards require that DPP-eligible individuals be able to access the core maintenance sessions, regardless of weight loss, in order for an organization to maintain CDC DPRP recognition. Our final policy at § 424.205(b)(1) specifies that to enroll in Medicare as an MDPP supplier, an entity must have and maintain MDPP preliminary recognition or full CDC DPRP recognition. Therefore, we are not requiring the achievement of attendance or weight loss performance goals during the first core maintenance session interval for the MDPP beneficiary to have coverage of the second core maintenance session interval, which is consistent with the CDC DPRP Standards for core maintenance session access. Because the achievement of performance goals is required for performance payments for core maintenance session intervals, eligibility and payment are not aligned during months 7 through 12 of the MDPP services period.

After considering the public comments received, we are finalizing the proposals for core maintenance session interval performance payments for core maintenance sessions at § 414.84(b)(4), with modifications. We will pay MDPP suppliers $60 for a core maintenance session 3-month interval if a beneficiary attends at least 2 sessions during the interval and achieves or maintains the required minimum weight loss during that interval, and pay MDPP suppliers $15 for a core maintenance session interval if the beneficiary attends at least 2 sessions but does not achieve or maintain the required minimum weight loss during that core maintenance session interval. The final performance payments for core maintenance session intervals are displayed in Table 33.

TABLE 33—FINAL PERFORMANCE PAYMENTS FOR CORE MAINTENANCE SESSION INTERVALS

Performance goal	Performance payment per beneficiary (*with* achievement or maintenance of required minimum weight loss)	Performance payment per beneficiary (*without* achievement or maintenance of required minimum weight loss)
2 sessions attended in first core maintenance session interval (months 7–9 of the MDPP core services period)	$60	$15
2 sessions attended in second core maintenance session interval (months 10–12 of the MDPP core services period)	60	15
Maximum total performance payment for core maintenance session intervals (two consecutive 3-month intervals over months 7–12 of the MDPP core services period)	120	30

(5) Performance Payments for Ongoing Maintenance Session Intervals

Similar to our proposal for the payment of core maintenance session intervals described previously, we proposed to make performance payments to MDPP suppliers for 3-month ongoing maintenance session intervals. This payment would be made when suppliers furnish ongoing maintenance sessions during the 24 months of the ongoing services period after the 12-month MDPP core services period ends. We proposed that an MDPP supplier would be paid a performance payment for an ongoing maintenance session interval if an MDPP beneficiary achieves the performance goals of attending at least 3 ongoing maintenance sessions and maintaining the required minimum weight loss from baseline measured in-person during a session at least once within that interval. Under this proposal, an MDPP supplier would not be paid a performance payment unless the beneficiary has achieved both of these

performance goals within that 3-month interval. An ongoing maintenance session interval, as we proposed to define it at § 410.79(b), would mean one of the up to eight consecutive 3-month time periods during the ongoing services period, during which an MDPP supplier offers at least 1 ongoing maintenance session to an MDPP beneficiary per month.

The payment structure presented in the CY 2017 PFS proposed rule (81 FR 46415 through 46416) would have required the MDPP beneficiary to attend 3 ongoing maintenance sessions and maintain the required minimum weight loss for a $45 payment to be made to an MDPP supplier for the ongoing maintenance session interval. Based on our consideration of information provided in the public comments on the CY 2017 PFS proposed rule and our increased emphasis in the performance payments on the achievement and maintenance of weight loss as the outcome of MDPP services, our proposal for the performance payment for ongoing maintenance session intervals differed from that payment amount.

We proposed that MDPP suppliers could be paid up to 8 performance payments of $50 each for ongoing maintenance session intervals. Just like the other proposals for performance payments, we proposed this payment in CY 2018 dollars to ensure consistency in calendar year dollars among performance payments for a given calendar year. However, we noted that no ongoing maintenance session interval payments, available only for intervals in the ongoing services period during months 13 through 36 of an MDPP beneficiary's MDPP services period, would be made in CY 2018 based on our proposal discussed in section III.K.2.a. of the proposed rule (82 FR 34141) that MDPP services be available on April 1, 2018. Under this proposal, MDPP services would only be available for 9 months of CY 2018 so no MDPP beneficiaries would attend ongoing maintenance sessions in CY 2018. The first ongoing maintenance session interval performance payments would be made in CY 2019 and would equal $50 adjusted 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, 2018, as discussed in section III.K.2.d.iii.(9) of the proposed rule (82 FR 34147 through 34148).

This proposed payment amount would be somewhat higher than the potential payment discussed in the CY 2017 PFS proposed rule (81 FR 46415 through 46416) to recognize that maintenance of the required minimum weight loss is necessary for the reduced incidence of type 2 diabetes and to encourage MDPP suppliers to work to engage beneficiaries in sustaining their weight loss over time. The maximum total performance payment for MDPP ongoing maintenance sessions would be $400, as displayed in Table 34. On a per-session basis, this payment would be approximately $17, which we believed would be appropriate for MDPP suppliers that furnish ongoing maintenance sessions to beneficiaries who maintain the required minimum weight loss during ongoing maintenance session interval. We noted that this per-session payment amount would be somewhat lower than the $20 per-session payment amount included in the core maintenance session interval performance payment for beneficiaries who achieve attendance and weight loss performance goals during the 3-month intervals in months 7 to 12 of the MDPP core services period. Like the proposed performance payment for core maintenance session intervals, the proposed performance payment for ongoing maintenance session intervals would value both attendance and weight loss. However, we believed it is likely that the required minimum weight loss would be first achieved during core maintenance session intervals, and we also believed that a somewhat higher per-session payment amount would be appropriate under these circumstances. In contrast, we believed that a somewhat lower per-session payment amount for ongoing maintenance sessions during intervals where the required minimum weight loss is maintained, rather than achieved, would be appropriate.

We considered an alternative policy in which an MDPP supplier would receive a payment for an ongoing maintenance session interval so long as the beneficiary attended at least 1 ongoing maintenance session during the interval and maintained the required minimum loss. In this scenario, we considered that the MDPP supplier would still be required to offer at least 2 additional ongoing maintenance sessions (at least one per month) to the beneficiary over the 3-month interval. However, we believed that the goal of ongoing maintenance sessions is to promote both sustained beneficiary engagement and weight loss and, therefore, we believed that ongoing maintenance session interval performance payments should be tied to achieving both attendance and weight loss performance goals.

The proposed payment policy also would align with the coverage limitations for ongoing maintenance sessions at § 410.79(c)(1)(iii) in that beneficiaries also would be required to attend all 3 sessions within a given ongoing maintenance session 3-month interval to be covered for the subsequent 3-month interval. We noted that the proposed coverage and payment policies would be aligned for ongoing maintenance session intervals, where attendance at 3 sessions within an interval would be required for a performance payment as well as for coverage of ongoing maintenance sessions in the next interval. In contrast, MDPP suppliers would be required to offer core maintenance sessions in both core maintenance session intervals for all beneficiaries, regardless of a beneficiary's attendance at core maintenance sessions, although attendance would be required for a performance payment to be made for the core maintenance session interval.

TABLE 34—PROPOSED PERFORMANCE PAYMENTS FOR ONGOING MAINTENANCE SESSION INTERVALS

Performance goal	Performance payment per beneficiary (*with* maintenance of the required minimum weight loss)	Performance payment per beneficiary (*without* maintenance of the required minimum weight loss)
3 sessions attended in 1 ongoing maintenance session interval	$50	$0
Maximum total performance payment for ongoing maintenance session intervals (8 consecutive 3-month intervals over months 13–36 of the MDPP ongoing services period)	400	*0 to 350

* = The specific payment amount depends on whether the beneficiary has coverage of 1 to 7 ongoing maintenance session intervals, as well as whether the beneficiary meets the performance goals for the performance payment for that ongoing maintenance session interval.

The proposed ongoing maintenance session interval performance payments for ongoing maintenance sessions were included at proposed § 414.84(b)(5). We invited public comments on these proposals. We also invited public comments on the alternative considered.

The following is a summary of the public comments received on the proposals for ongoing maintenance session interval performance payments for ongoing maintenance sessions and the alternative considered and our responses:

Comment: Some commenters supported the proposed $50 ongoing maintenance session interval performance payment, which they believe is appropriate given the MDPP supplier resources that would be used to furnish sessions during those intervals. One commenter, who also advocated for an increase in the performance payments for core sessions in order to increase the maximum total performance payment amount available in the first 12 months of the MDPP services period to meet the MDPP supplier financial need for sustaining its DPP, further urged CMS to reduce the ongoing maintenance session interval performance payment from $50 to $45.

Several commenters expressed concern that if an MDPP beneficiary in an ongoing maintenance session 3-month interval does not achieve the 3 session attendance goal and/or does not maintain the required minimum weight loss, the MDPP supplier would not receive the performance payment for that interval. The commenters stated that MDPP suppliers would expend resources to furnish MDPP services to the MDPP beneficiary during the 3-month interval but bear the financial risk under the proposal of not getting paid if the beneficiary fails to attend at least 3 sessions and maintain the required minimum weight loss. They further noted that to achieve beneficiary attendance of 3 sessions during the 3-month interval, MDPP suppliers would likely have to offer more than 3 ongoing maintenance sessions to MDPP beneficiaries during that time period. The commenters urged CMS to change the attendance requirement for performance payment for ongoing maintenance session intervals to 2 of the 3 sessions that must be offered, in order to help more beneficiaries stay in the DPP and reduce the financial risk to the MDPP supplier. Particularly over the 24-month long ongoing services period that CMS proposed, the commenters stated that monthly beneficiary attendance could be hard to sustain and in actuality not be important, especially if the MDPP beneficiary maintains the required minimum weight loss throughout that time period.

Response: As discussed in section III.K.2.b.i. of this final rule, we are finalizing the ongoing services period as 12 months, rather than the 24-month duration that we proposed. In addition, as discussed in section III.K.2.c.iv., we are finalizing the policy that the eligibility for coverage of a subsequent ongoing maintenance session 3-month interval during months 16 to 24 of the MDPP services period depends both on beneficiary attendance at 2 ongoing maintenance sessions in the prior ongoing maintenance session interval and maintenance of the required minimum weight loss.

In the proposed rule (82 FR 34145), we considered an alternative policy in which an MDPP supplier would receive a performance payment for an ongoing maintenance session interval so long as the beneficiary attended at least 1 ongoing maintenance session during the interval and maintained the required minimum weight loss, which is similar to the requests of some of the commenters that the performance payment require attendance at 2 ongoing maintenance sessions, rather than 3. However, we note that we continue to believe that the goal of ongoing maintenance sessions is to promote both sustained beneficiary engagement and weight loss and, therefore, we believe that ongoing maintenance session interval performance payments should be tied to achieving both weight loss and significant attendance performance goals. However, because MDPP suppliers must offer, at a minimum, monthly ongoing maintenance sessions to all MDPP beneficiaries with coverage of each 3-month ongoing maintenance session interval during months 13 to 24 of the MDPP services period, regardless of the beneficiary's attendance or maintenance of weight loss, we believe it is appropriate to reduce the attendance requirement for the performance payments during this time period from 3 to 2 sessions per interval.

Our reasoning for this decision is similar to our rationale for finalizing a core maintenance session interval attendance performance goal of 2 sessions for the core maintenance session interval performance payments as discussed in section III.K.2.d.iii.(4) of this final rule. Lowering the required session attendance for the performance payments during the ongoing services period will provide additional flexibility to beneficiaries to allow them to balance life events and DPP session attendance, without the decisions of beneficiaries who maintain the required minimum weight loss resulting in financial consequences for MDPP suppliers that must offer sessions regardless of actual attendance. We believe that attendance of 2 sessions in an ongoing maintenance session 3-month interval still represents substantial beneficiary engagement that promotes the integration of behavior change longer-term into a beneficiary's lifestyle in order for him or her to maintain the required minimum weight loss.

We also believe that the final shorter ongoing services period makes beneficiary attendance at 2 sessions in each 3-month interval feasible. We acknowledge that the MDPP supplier bears some risk that an MDPP beneficiary who must be offered a minimum of 3 sessions during an ongoing maintenance session interval will not attend 2 sessions and/or will not maintain the required minimum weight loss during that interval so the MDPP supplier would not receive an ongoing maintenance session interval performance payment for that interval for that beneficiary. However, we pay for the set of MDPP services through a performance-based payment methodology that makes periodic performance payments to MDPP suppliers during the MDPP services period, and the aggregate of all performance payments constitutes the total performance-based payment amount for the set of MDPP services.

Moreover, we continue to believe that maintaining the required minimum weight loss is an appropriate performance goal that must be met for an ongoing services interval performance payment to be made, given that the first ongoing maintenance session interval begins 12 months after the beginning of the MDPP services period. At that point at least half way through the maximum length of the beneficiary's MDPP services period, providing a performance payment for attendance alone would not be consistent with our emphasis in the MDPP expanded model on the achievement of the outcome of weight loss.

We note that the final attendance and weight loss performance goals for ongoing maintenance session interval performance payments are aligned with beneficiary eligibility for the subsequent ongoing maintenance session interval, a consistency that will incentivize MDPP suppliers to sustain their efforts regarding beneficiary engagement and minimize MDPP supplier and beneficiary confusion about MDPP services during the ongoing services period. Due to this alignment, the MDPP

supplier financial risk during the ongoing services period is limited to a maximum of 3 sessions in a single ongoing maintenance service interval, because eligibility and performance payment are aligned during this period. If a beneficiary does not meet the attendance and weight loss performance goals for an interval performance payment, the beneficiary is not eligible for coverage of ongoing maintenance sessions in the next interval, so the MDPP supplier is not required to offer additional sessions to the beneficiary.

We appreciate the support of the commenters for the proposed ongoing maintenance session interval performance payment amount of $50. Given our emphasis in the MDPP expanded model on the achievement of the required minimum weight loss that results in a reduced incidence of type 2 diabetes, we believe it is appropriate to adopt this payment amount under the performance-based payment methodology because the performance payment is only made if the beneficiary maintains the required minimum weight loss. Reducing the payment amount would lessen our emphasis on maintaining weight loss, which would be contrary to our interest in improving the health of beneficiaries through MDPP services that ultimately lead to lower Medicare expenditures.

After considering the public comments received, we are finalizing the proposals for ongoing maintenance session interval performance payments for ongoing maintenance sessions at § 414.84(b)(5), with modifications. We will pay MDPP suppliers $50 for an ongoing maintenance session 3-month interval if a beneficiary attends at least 2 sessions during the interval and maintains the required minimum weight loss during that interval. The final performance payments for ongoing maintenance session intervals are displayed in Table 35.

TABLE 35—FINAL PERFORMANCE PAYMENTS FOR ONGOING MAINTENANCE SESSION INTERVALS

Performance goal	Performance payment per beneficiary (*with* maintenance of the required minimum weight loss)	Performance payment per beneficiary (*without* maintenance of the required minimum weight loss)
2 sessions attended in 1 ongoing maintenance session interval and required minimum weight loss maintained	$50	$0
Maximum total performance payment for ongoing maintenance session intervals (4 consecutive 3-month intervals over months 13–24 of the MDPP ongoing services period)	200	* 0 to 150

* = The specific payment amount depends on whether the beneficiary has coverage of 1 to 4 ongoing maintenance session intervals, as well as whether the beneficiary meets the performance goals for the performance payment for that ongoing maintenance session interval.

(6) Weight Loss Performance Payments

We proposed that if a beneficiary achieves the required minimum weight loss measured at any session attended during the core services period, an MDPP supplier would be paid the weight loss performance payment of $160 displayed in Table 36. As discussed in section III.K.2.d.iii.(2)(a) of the proposed rule (82 FR 34139 through 34141), we proposed that 23 percent of the maximum total performance payment amount for the set of MDPP services would be paid for the achievement of weight loss, regardless of session attendance, because weight loss is the most important outcome for the MDPP expanded model. The proposed performance payment of $160 for the required minimum weight loss, which constitutes approximately 90 percent of the maximum total weight loss performance payment, was proposed to be the large majority of the available weight loss performance payment based on the strong evidence for the association of the required minimum weight loss with a reduction in the incidence of type 2 diabetes.

We noted that this association is evidenced by the CDC's National DPP, which is based on the 2002 DPP Randomized Control Trial and follow-up efficacy trials.[34] All of the trials found that the greater the intensity and duration of the diabetes prevention program—with 1 year being the most effective program ''dose''—the greater the reduction in the incidence of type 2 diabetes. Specially, persons at high-risk for type 2 diabetes who participated in a year-long lifestyle change program, focused on modest weight loss (5–7 percent), experienced a 58 percent lower incidence of type 2 diabetes than those who did not receive the lifestyle intervention. The DPP Randomized Control Trial, as well as the DPP model test, involved the provision of 16 weekly core sessions and 6 monthly core maintenance sessions (all approximately 1 hour in length), similar to the set of core services in the MDPP expanded model. We recognized that not all beneficiaries would be able to achieve the required minimum weight loss within the first 6 months, which is the period when core sessions are furnished. Therefore, we believed that our proposed policy for payment of the performance payment upon achievement of the required minimum weight loss any time during the 12 months of the MDPP core services period would allow MDPP suppliers the greatest flexibility to work throughout the full MDPP core services period with beneficiaries who face difficulty in achieving this weight loss performance goal.

We also proposed that, in addition to the weight loss performance payment for the required minimum weight loss, an MDPP supplier would be paid an additional weight loss performance payment of $25 if the beneficiary achieves at least 9 percent weight loss from his or her baseline weight at any time during the MDPP services period as displayed in Table 36. We proposed this additional weight loss performance payment based on information from stakeholders that commercial payers paying for DPPs frequently include an incentive payment for 9 percent weight loss as an incentive to try to encourage greater and/or continued weight loss and behavior change. We believed that making an additional weight loss performance payment for 9 percent weight loss at any time during the MDPP services period would provide an additional incentive for MDPP suppliers to continue weight loss efforts with beneficiaries, especially during the ongoing services period, which may extend for a period of up to 24 months.

We proposed that MDPP suppliers may submit claims for these weight loss performance payments on the date when the beneficiary first reaches the

[34] Available at *https://www.niddk.nih.gov/about-niddk/research-areas/diabetes/diabetes-prevention-program-dpp/Documents/DPP_508.pdf.*

required minimum or 9 percent weight loss, as measured in-person during a session, respectively, and each weight loss performance payment would be paid to only one supplier and only once per beneficiary. In the unusual circumstance where the beneficiary achieved 9 percent weight loss as the first weight loss change measured from baseline, the MDPP supplier could bill and be paid both the 5 percent and 9 percent weight loss performance payments.

TABLE 36—PROPOSED WEIGHT LOSS PERFORMANCE PAYMENTS

Performance goal	Performance payment per beneficiary
5 percent weight loss (required minimum weight loss)	$160
9 percent weight loss	25
Maximum total performance payment for weight loss	185

The proposed weight loss performance payments were included at proposed § 414.84(b)(6) and (7). We invited public comments on these proposals.

The following is a summary of the public comments received on the proposals for weight loss performance payments and our responses:

Comment: While generally supportive of weight loss performance payments for the achievement of weight loss during the MDPP services period, several commenters recommended that CMS make performance payments for a lower percentage of weight loss than the 5 percent weight loss that CMS proposed, either as additional incremental weight loss performance payments or in place of the proposed performance payment for 5 percent weight loss. Those commenters advocating for additional incremental weight loss performance payments for lower percentages of weight loss believe this approach would allow MDPP suppliers to be paid for continued DPP support when a beneficiary achieves 3 percent and 4 percent weight loss. Under such a methodology, the commenters claimed that MDPP suppliers and MDPP beneficiaries would be able to work toward a more achievable early weight loss performance goal that would also sustain the MDPP suppliers' operations. The MDPP supplier would receive a performance payment when the early weight loss performance goal is achieved, thereby enabling the MDPP supplier to help beneficiaries reach even greater weight loss from baseline. A few commenters further urged CMS to make an additional performance payment for any MDPP beneficiary who achieves the required minimum weight loss and then maintains that level of weight loss at the end of the core services period.

Several commenters recommended that CMS gradually phase-in the percentage of weight loss required for the first weight loss performance payment during implementation of the MDPP expanded model, to allow MDPP suppliers to follow a learning curve in starting up their DPP. One scenario described by the commenters would provide a performance payment for 3 percent weight loss in the DPP organization's first year in the MDPP expanded model, 4 percent in the second year, and 5 percent in the third year and thereafter.

A few commenters requested that CMS eliminate the weight loss performance payment entirely to help avoid putting MDPP suppliers serving low-resources communities at immediate risk. Alternatively, the commenters suggested that CMS could guarantee the amount of weight loss performance payment for MDPP suppliers below a certain volume of beneficiaries, while making the payment for weight loss based on actual performance for MDPP suppliers of a larger size or to MDPP suppliers in a pooled group so that random variation in beneficiary weight loss could be overcome. Another commenter noted that a beneficiary's weight can fluctuate during the MDPP services period and, as such, a general downward trend in weight may be a more valid measure of progress than a percentage weight loss over a prescribed interval.

One commenter pointed out that professional care guidelines about weight loss do not translate population health averages to individual treatment targets, and in using 5 percent weight loss as the performance goal to determine payment for an individual Medicare beneficiary, the commenters observed that CMS did not value the significant health benefit for individual beneficiaries of lower levels of weight loss. The commenter further noted that the 5 percent weight loss performance payment per MDPP beneficiary did not align with the CDC's DPRP Standards, which are DPP-wide achievement of an average of 5 percent weight loss across those patients who attend 4 or more sessions.

Several commenters urged CMS to reduce the proposed amount of the 5 percent weight loss performance payment to approximately 10 percent of the maximum available total performance payment per beneficiary from the 20 percent CMS proposed and redistribute the dollars to attendance-based payments for sessions during the core services period.

Response: With regard to the potential for lowering the weight loss performance payment goal to 3 percent or 4 percent or, alternatively, making incremental weight loss performances for 3 percent, 4 percent, and 5 percent weight loss, we note that the MDPP expanded model was determined to meet the statutory requirements for expansion, where certification of the DPP model test was based on findings that demonstrated that 5 percent weight loss was associated with reductions in Medicare expenditures. Therefore, the goal of the MDPP expanded model is at least 5 percent weight loss for each beneficiary, which is expected to lead to a reduction in the incidence of type 2 diabetes. We do not have data to support an expanded model that does not require the achievement and maintenance of the required minimum weight loss, so we do not believe it would be appropriate to make a weight loss performance payment for achievement of weight loss that is less than 5 percent, to guarantee the weight loss performance payment for all beneficiaries served by small MDPP suppliers, or to eliminate the weight loss performance payment entirely in favor of solely attendance-based performance payments. In addition, we expect there to be some natural, small downward or upward fluctuations in a beneficiary's weight as measured over time, in relation to fluid intake, the composition of recent meals, hormonal changes, or other factors. We believe that making a weight loss performance payment based on a one-time in-person weight measurement at a session for less than a 5 percent weight loss would risk Medicare making a weight loss performance payment when a beneficiary has experienced a natural downward weight fluctuation rather than true weight loss that has the potential to be sustained.

Furthermore, because there is no specific number of beneficiaries per MDPP supplier, we do not believe it would be appropriate to make weight loss performance payments based on program-wide achievement of 5 percent weight loss, rather than individual beneficiary weight loss, because this would reduce an MDPP supplier's incentive to actively help each beneficiary to meet the required minimum weight loss, particular if a few beneficiaries lost a large percentage of their weight. While we aim to maintain consistency to the extent possible with CDC's DPRP Standards, we note that standards for full recognition status, which require

meeting weight loss and attendance standards that are measured at the aggregate rather than individual level, are set to ensure the quality and integrity of the services furnished by the DPP organization. In contrast, the performance-based payment methodology for the MDPP expanded model establishes performance goals for beneficiaries so Medicare can make performance payments based on claims submitted by MDPP suppliers for MDPP services furnished to individual beneficiaries who achieve those performance goals. We believe that these differences between the DPP organization-wide rationale for the DPRP Standards and the performance goals for payment for MDPP services furnished to individual MDPP beneficiaries under the MDPP expanded model lead to reasonable differences in the measurement of 5 percent weight loss for these two purposes.

In response to the commenters who urged us to reduce the proposed 5 percent weight loss performance payment from 20 percent to 10 percent of the maximum total performance payment amount per beneficiary and redistribute the dollars to attendance-based payments in the core services period, we continue to emphasize that the achievement and maintenance of the required minimum weight loss is the outcome of MDPP services that is associated with a reduction in the incidence of type 2 diabetes. Therefore, we do not believe it would be appropriate to reduce the amount of the performance payment for 5 percent weight loss to less than the $160 we proposed, because that would reduce the emphasis on the weight loss outcome in the performance payments.

However, as discussed in section III.K.2.d.iii.(5) of this final rule, the maximum total performance payment for ongoing maintenance session intervals has been reduced due to the shortening of the ongoing services period from the 24 months that we proposed to 12 months in this final rule. Dollars for performance payments that would have been made for ongoing maintenance session intervals in months 25 to 36 of the MDPP services period have been partially redistributed to attendance-based performance payments for core sessions during the first 6 months of the MDPP services period, as discussed in section III.K.2.d.iii.(3) of this final rule. This is consistent with the interests of the commenters who requested a redistribution of a portion of the 5 percent weight loss performance payment in order to increase attendance-based payments for sessions in the core services period. Finally, we note that because the maximum total performance payment amount per beneficiary is $670 as discussed in section III.K.2.d.iii.(2)(a) of this final rule, which is lower than the $810 that we proposed, the final $160 5 percent weight loss performance payment is actually a higher percentage (24 percent) than the proposed 20 percent of the maximum total performance payment amount.

Comment: While several commenters supported the proposal to make a weight loss performance payment for 9 percent weight loss at any point in time during the MDPP services period, a number of commenters opposed this additional weight loss performance payment that is in addition to the proposed performance payment for the required minimum weight loss. The commenters noted that the CDC DPRP target is 5 percent weight loss and, while they acknowledge the potential value to beneficiary health of greater weight loss beyond the 5 percent, they believe that making a performance payment for a weight loss of 9 percent under the MDPP expanded model goes beyond the core DPRP framework and initial research and may not be realistic or appropriate for many MDPP beneficiaries. One commenter who urged CMS not to finalize the 9 percent weight loss performance payment further suggested that the $25 represented in this performance payment be distributed to higher core maintenance session payments for beneficiaries who did not achieve or maintain the required minimum weight loss in the 3-month core maintenance session intervals.

Response: While we acknowledge the concerns of some commenters that the proposed $25 performance payment for 9 percent weight loss is not included as a standard in the CDC's DPRP, we continue to agree with other commenters that making an additional weight loss performance payment for 9 percent weight loss at any time during the MDPP services period will provide an additional incentive for MDPP suppliers to continue weight loss efforts with MDPP beneficiaries, especially during the ongoing services period which may extend for a period of up to 12 months after the end of the core services period. We also understand that commercial payers paying for DPPs frequently include an incentive payment for 9 percent weight loss as an incentive to try to encourage greater and/or continued weight loss and behavior change.

We recognize that 9 percent weight loss may not be realistic or appropriate for every MDPP beneficiary. However, by finalizing the performance payment for 9 percent weight loss as $25, which is less than 4 percent of the maximum total performance payment amount available for an MDPP beneficiary, we will not provide such a high incentive to MDPP suppliers that we risk MDPP suppliers encouraging continued weight loss for those beneficiaries who are unlikely to benefit from weight loss beyond the required minimum.

After considering the public comments received, we are finalizing our proposals, without modification, for the weight loss performance payments at § 414.84(b)(6) and (7). The final weight loss performance payments are displayed in Table 37.

TABLE 37—FINAL WEIGHT LOSS PERFORMANCE PAYMENTS

Performance goal	Performance payment per beneficiary
5 percent weight loss (required minimum weight loss)	$160
9 percent weight loss	25
Maximum total performance payment for weight loss	185

(7) Summary Table of Performance Payments for the Set of MDPP Services

In summary, for furnishing MDPP services during the MDPP services period, we proposed that MDPP suppliers could be paid a minimum of $25 per beneficiary (if the beneficiary attends the first core session) and a maximum total of $810 per beneficiary (if the beneficiary achieves all performance goals, maintains eligibility for 36 months, and does not change MDPP suppliers). Table 38 summarizes all of the proposed performance payments for the set of MDPP services that were discussed in sections III.K.2.d.iii.(3) through (6) of the proposed rule (82 FR 34141 through 34146).

TABLE 38—PROPOSED PERFORMANCE PAYMENTS FOR THE SET OF MDPP SERVICES

Performance goal	Performance payment per beneficiary (*with* the required minimum weight loss)	Performance payment per beneficiary (*without* the required minimum weight loss)
1st core session attended	$25	
4 total core sessions attended	30	
9 total core sessions attended	50	
3 sessions attended in first core maintenance session interval (months 7–9 of the MDPP core services period)	*60	10
3 sessions attended in second core maintenance session interval (months 10–12 of the MDPP core services period)	*60	10
5 percent weight loss achieved	160	0
9 percent weight loss achieved	25	0
3 sessions attended in ongoing maintenance session interval (8 consecutive 3–month intervals over months 13–36 of the MDPP ongoing services period)	*50	**0
Total performance payment	810	125

*The required minimum weight loss from baseline must be achieved or maintained during the core maintenance session 3-month interval or maintained during the ongoing maintenance session 3-month interval.

**A beneficiary attends at least 1 core session during the core services period to initiate the MDPP services period; must attend at least 1 session during the final core maintenance session 3-month interval; and must achieve or maintain the required minimum weight loss at least once during the final core maintenance session 3-month interval to have coverage of the first ongoing maintenance session interval. Then, a beneficiary must attend at least 3 sessions and maintain the required minimum weight loss at least once during an ongoing maintenance session 3-month interval to have coverage of the next ongoing maintenance session interval.

Comment: One commenter requested that MDPP services be paid at a higher payment amount when medical professionals, who currently already furnish other services to Medicare beneficiaries, furnish MDPP sessions than when unlicensed coaches teach the sessions, due to the additional training medical professionals have received.

Response: As finalized in the CY 2017 PFS final rule (81 FR 80479), MDPP services must be furnished by trained coaches, including trained community health workers and health professionals, who teach beneficiaries with prediabetes how to lower their risk of progressing to type 2 diabetes with methods that do not include medication or other interventions for beneficiaries diagnosed with diabetes. While any individual may be eligible to become a DPP coach, provided that they meet requirements and trainings as dictated by the CDC's DPRP Standards, an individual can only become an eligible coach for purposes of furnishing MDPP services after having their required identifying information submitted on an MDPP supplier's enrollment application, being screened by CMS or its contractors, and as a result, being determined to be eligible to furnish MDPP services on behalf of an MDPP supplier as discussed in section III.K.3.e.iv.(2) of this final rule. Thus, all DPP coaches, whether or not they are licensed health professionals who also furnish other services to Medicare beneficiaries, must meet the same DPRP Standards and the other requirements established in this final rule to be eligible coaches who can furnished MDPP services.

We proposed that the payment methodology for MDPP services be performance-based in relation to the achievement of the performance goals of session attendance and weight loss. While we acknowledge that licensed health professionals have training and a scope of practice that extends beyond community health workers who are trained DPP coaches, for purposes of the performance payments for MDPP services we see no reason to value in the payment methodology the MDPP beneficiary's achievement of the same performance goals differently based on additional credentials of the coach who furnished the session that resulted in the performance goal being met. The literature does not demonstrate that DPP sessions furnished by coaches with additional credentials result in greater achievement of patient outcomes than sessions furnished by coaches without additional credentials, where all coaches meet the CDC's DPRP Standards.[35] [36] [37] [38] Therefore, we expect that each MDPP supplier will consider the characteristics of the most effective coaches furnishing MDPP services to its MDPP beneficiaries, including whether or not specific coaches have additional credentials, in relation to the resources used by the MDPP supplier to pay those coaches, and the MDPP supplier will make decisions about the specific coaches to include on the supplier's roster accordingly.

Comment: Several commenters recommended that MA plans be given flexibility in making MDPP services available to their eligible plan enrollees, including, but not limited to, contracting directly with a vendor who in turn contracts with approved entities that furnish the CDC-approved DPP curriculum with payment arrangements that may or may not be the same as the payment methodology CMS proposed. With respect to payment for MDPP services furnished to MA plan enrollees, the commenters requested that MA plans be permitted to utilize the payment framework proposed by CMS, use a value-based performance contracting arrangement, or put in place any other alternative payment arrangement that meets the needs of the MA plan and their eligible plan enrollees in the communities in which

[35] D Vojta et al., ''A Coordinated National Model for Diabetes Prevention: Linking Health Systems to an Evidence-Based Community Program,'' *American Journal of Preventive Medicine* 44, no. 4 Suppl 4 (2013): S301–S306.

[36] Mohammed K. Ali et al., ''How Effective were Lifestyle Interventions in Real-World Settings that were Modeled on the Diabetes Prevention Program?'' *Health Affairs* 31, no.1 (2012): 67–75.

[37] L Ruggiero et al., ''Community-Based Translation of the Diabetes Prevention Program's Lifestyle Intervention in an Underserved Latino Population,'' *The Diabetes EDUCATOR* 37, no. 4 (2011); 564–572.

[38] JA Katula et al., ''The Healthy Living Partnerships to Prevent Diabetes Study 2-Year Outcomes of a Randomized Controlled Trial,'' *American Journal of Preventive Medicine* 44, no. 4S4 (2013): S324–S332.

they operate. The commenters urged CMS to clarify that the detailed proposed payment framework applies only to MDPP services furnished to Medicare fee-for-service beneficiaries.

Response: We appreciate the recommendations from the commenters about MA plan flexibilities that may be used in making MDPP services available to their eligible plan enrollees, including their requests for clarification about the relationship between the proposed performance-based payment methodology for MDPP services and payment for MDPP services furnished to MA plan enrollees. Under section 1854(a)(6)(B)(iii) of the Act, CMS is prohibited from requiring an MAO to contract with specific providers and from requiring specific price or payment structures under the contracts with network providers; these provisions are reflected in the regulation at § 422.256(a)(2)(ii). However, the Act, at sections 1852(a)(2) and (k)(1) and 1866(a)(1)(O) of the Act, also imposes requirements that MAOs pay out-of-network providers (that is, providers that do not contract with the MAO) and that such providers accept as payment in full the amount that would have been paid under original (fee-for-service) Medicare when the out-of-network provider furnishes covered services to an MA plan enrollee.

Therefore, we are not adopting any requirements to govern how an MAO pays its network providers—either in amount or structure—for MDPP services and believe that existing law adequately addresses when an out-of-network provider furnishes covered MDPP services. We note that as it appears unlikely that any MDPP services would be furnished as emergency or urgently needed services, we anticipate that the out-of-network payment requirements would be applicable only for MA private fee-for-service plans, MA point-of-service (POS) plans, or MA preferred provider organization (PPO) plans that regularly cover out-of-network services. Under these existing authorities, MA plans currently have flexibility in their payment methodologies for Part B services furnished to MA plan enrollees through network providers. Because MDPP services are covered under Part B, MA plans will have this same payment flexibility for MDPP services furnished by network providers to MA plan enrollees.

Table 39 summarizes all of the final performance payments for the set of MDPP services that were individually finalized in sections III.K.2.d.iii.(3) through (6) of this final rule.

TABLE 39—FINAL PERFORMANCE PAYMENTS FOR THE SET OF MDPP SERVICES

Performance goal	Performance payment per beneficiary (*with* the required minimum weight loss)	Performance payment per beneficiary (*without* the required minimum weight loss)
1st core session attended	$25	
4 total core sessions attended	50	
9 total core sessions attended	90	
2 sessions attended in first core maintenance session interval (months 7–9 of the MDPP core services period)	*60	15
2 sessions attended in second core maintenance session interval (months 10–12 of the MDPP core services period)	*60	15
5 percent weight loss achieved	160	0
9 percent weight loss achieved	25	0
2 sessions attended in ongoing maintenance session interval (4 consecutive 3-month intervals over months 13–24 of the MDPP ongoing services period)	*50	**0
Total performance payment	670	195

*The required minimum weight loss from baseline must be achieved or maintained during the core maintenance session 3-month interval or maintained during the ongoing maintenance session 3-month interval.

**A beneficiary attends at least 1 core session during the core services period to initiate the MDPP services period; must attend at least 1 session during the final core maintenance session 3-month interval; and must achieve or maintain the required minimum weight loss at least once during the final core maintenance session 3-month interval to have coverage of the first ongoing maintenance session interval. Then, a beneficiary must attend at least 2 sessions and maintain the required minimum weight loss at least once during an ongoing maintenance session 3-month interval to have coverage of the next ongoing maintenance session interval.

(8) Considerations Related to Potential Future Geographic Adjustment of MDPP Payments

Although Medicare is a national program, it frequently adjusts fee-for-service payments to hospitals, physicians, and other providers and suppliers according to the geographic locations in which they furnish services. These adjustments generally account for differences in the relative costs of doing business in different geographic areas compared to the national average. For example, section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. This adjustment factor for hospitals is the wage index, and we currently define hospital geographic areas (labor market areas) based on the definitions of Core-Based Statistical Areas (CBSAs) established by the Office of Management and Budget. Similarly, a geographic adjustment is also made for services paid under the PFS, and a geographic practice cost index (GPCI) has been established for every Medicare PFS payment locality, many of which are statewide, for each of the three components of a service's relative value units (that is, the relative value units for work, practice expense, and malpractice).

We proposed to make performance-based payments to MDPP suppliers in intervals based on achievement of performance goals, rather than fee-for-service payments for individual services furnished. Although we intended for those performance payments to make

payment to MDPP suppliers for MDPP services that involve the use of supplier resources, we stated that we were unsure if there is notable variation in the relative costs of furnishing MDPP services among geographic areas. Because the DPP model test was carried out in only eight states, we did not have the data to determine whether there are geographic differences nationwide. In addition, because a substantial portion of the proposed MDPP performance payments would be based on the beneficiary's achievement of weight loss performance goals, we were uncertain about the appropriateness of geographically adjusting such performance-based payments.

Therefore, we did not propose geographic adjustment of performance payments for MDPP services. However, we invited public comments on issues related to geographic adjustment of payment for MDPP services in the context of the MDPP performance-based payment methodology, including appropriate sources of information for determining any geographic cost differences. We noted that we may consider proposing additional payment policies for the MDPP expanded model in the future. We requested that commenters submitting information on these issues provide justification, including any relevant analysis, to support any suggestions regarding potential future geographic adjustment of performance-based payments for MDPP services.

The following is a summary of the public comments received on issues related to geographic adjustment of payment for MDPP services in the context of the proposed MDPP performance-based payment methodology, including appropriate sources of information for determining any geographic cost differences, and our responses:

Comment: Several commenters recommended that CMS consider varying the payment structure for MDPP suppliers in differing geographic markets in which MDPP suppliers operate, given the potential effects the region may have on operating costs. One commenter explained that any business, including an MDPP supplier, relies on varying market analyses based on region, such as urban versus rural, and on factors such as environment, legislation and competition, in establishing the parameters of the business. The commenter stated that business processes result in differing administrative and operational costs based on region and organizational structure that the commenter noted, if not addressed through the MDPP payment structure, would impact MDPP supplier sustainability and network adequacy, including the delivery of MDPP services to populations of greatest need. Another commenter noted that the major cost drivers of DPPs are salaries, which are highly variable across the U.S. A commenter acknowledged the DPP model test was conducted in limited geographic areas but believes CMS has enough experience with geographic payment adjustments in performance- based payment structures to apply such adjustments to payments for these services. The commenters urged CMS to consider geographic adjustment of payment for MDPP services now or in the future, emphasizing that the geographic adjustment of payment for MDPP services would be consistent with methodologies used for other services paid under the Medicare program.

Response: We note that the commenters recommending geographic adjustment of payment for MDPP services did not provide specific sources of information for determining geographic cost differences for MDPP services. Moreover, they did not suggest any specific geographic adjustment methodology in the context of the MDPP performance-based methodology that fundamentally differs from the resource-based payment methodologies that apply to most other services paid under the Medicare fee-for-service program.

We will review the suggestions provided by the commenters, as well as our early implementation experience with the MDPP expanded model and other information we receive in the future from stakeholders, as we consider proposing additional payment policies for the MDPP expanded model in the future, as appropriate.

Comment: While not specifically related to geographic adjustment, one commenter requested that CMS consider using authority provided in section 1853(c)(7) of the Act to make adjustments in payment rates to MA plans for benefit changes directed through national coverage determinations or legislative action to recognize the uncertainty in which MA plans operated when developing their CY 2018 bids.

Response: We decline to make an adjustment in payment rates for benefit changes related to MDPP services and believe that we lack authority to do so in this specific circumstance in this final rule. Under section 1853(c)(7) of the Act, adjustments in payment rates to MA plans are available only where a change in benefits or services results from a national coverage determination or a legislative change and the service or benefit required to be provided is projected by the Secretary to result in a significant increase in the costs to Medicare+Choice of providing benefits under contracts entered into under section 1857 of the Act. MDPP services meet neither of these requirements.

First, MDPP services are available under the MDPP expanded model, which has been expanded in duration and scope under section 1115A(c) of the Act. Therefore, while a new service, coverage of MDPP services does not result from a legislative change or a national coverage determination. Second, we recognize that MA plans may negotiate contracts with MDPP suppliers that require the MA plan to pay more than the payments finalized in this final rule (that would pay MDPP suppliers a maximum total performance payment amount of $670 in CY 2018, as described in section III.K.2.d.iii.(2)(a) of this final rule, for furnishing MDPP services to fee-for-service beneficiaries). However, even where an MA plan enters into a contract that pays MDPP suppliers an amount that is substantially higher than the amount that would result from the policies finalized in this final rule, the costs associated with MDPP services objectively fail to rise to the level of a ''significant increase'' in the costs of providing benefits under contracts entered into under section 1857 of the Act. Further, the CY 2017 PFS final rule adopting the set of MDPP services as an additional preventive benefit under Part B (published in the November 15, 2016 **Federal Register**) and guidance to MAOs were both issued prior to the June 5, 2017 bid deadline date for CY 2018, so MAOs had adequate notice to incorporate these costs into bids for CY 2018 coverage.

(9) Updating MDPP Payment Amounts

To account for inflation, we proposed to update MDPP payment amounts annually based on the CPI–U. The CPI–U is a measure of the average change over time in prices paid for a market basket of consumer goods and services, and is a measure of economy-wide inflation. There are no statutory requirements for the update factor for payments for MDPP services so there is no requirement that a productivity adjustment be applied to the MDPP services update factor as there are for certain other Medicare-covered items and services where prices are updated by the CPI–U, such as the Clinical Laboratory Fee Schedule; Durable Medical Equipment, Prosthetics/Orthotics, and Supplies Fee Schedule; Ambulance Fee Schedule; and

Ambulatory Surgical Center payment system.

We considered using other indices such as the Medicare Economic Index (MEI) to update the MDPP payment amounts. The MEI measures price changes in the inputs required to operate a self-employed physician practice. We did not believe that the MEI would be appropriate to update MDPP payment amounts because MDPP suppliers are not similar to self-employed physician practices. We noted that the CPI–U by definition is an economy-wide measure of inflation and, therefore, in the absence of an appropriate specific index for MDPP services, we believed the CPI–U to be the most technically appropriate index available to update payments for MDPP services. We further noted that the CPI–U is used to update Medicare payments for other Medicare-covered items and services, such as ambulance, clinical laboratory, and ambulatory surgical center services.

We proposed to update MDPP performance payments and the bridge payment (a proposed one-time payment to an MDPP supplier for furnishing its first session to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier as discussed in detail in section III.K.2.d.v. of the proposed rule (82 FR 34153 through 34155)) that may be paid to MDPP suppliers in the following manner:

- Beginning in CY 2019 and each year forward, the performance payment and bridge payment amounts would be adjusted by the 12-month percent change in the CPI–U (U.S. city average) for the period ending June 30th of the year preceding the update year. The percent change update would 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 would be published by CMS transmittal.

The proposed methodology to update MDPP performance payments and the bridge payment was included at proposed § 414.84(d). We invited public comments on this proposal.

The following is a summary of the public comments received on the proposal for the methodology to update MDPP performance payments and the bridge payment and our responses:

Comment: Several commenters supported the proposal to update MDPP performance payment and bridge payment amounts annually using the CPI–U.

Response: We appreciate the support of the commenters for the proposed methodology to update MDPP performance payments and the bridge payment annually using the CPI–U.

After considering the public comments received, we are finalizing the proposal, without modification, to update MDPP performance payments and the bridge payment at § 414.84(d).

(10) MDPP Supplier Billing and Payment for MDPP Services

(a) Payment for MDPP Services on an Assignment-Related Basis

We proposed that performance payments and bridge payments to MDPP suppliers for MDPP services would be made only on an assignment-related basis in accordance with § 424.55. As described in Chapter 1, Section 30.3 of the Medicare Claims Processing Manual,[39] CMS identifies a number of supplier and practitioner types who furnish services under the Medicare program and who are required to accept assignment for all Medicare claims for their services. This means that they must accept the Medicare allowed amount as payment in full for their services, regardless of whether the supplier is a participating or non-participating provider in the Medicare program. In these circumstances, the beneficiary's liability is limited to any applicable deductible plus the 20 percent coinsurance if coinsurance applies to the service. CMS currently mandates assignment for claims from multiple types of suppliers and practitioners, including clinical diagnostic laboratory services and physician lab services; physician services to individuals dually entitled to Medicare and Medicaid; and services of physician assistants, nurse practitioners, clinical nurse specialists, nurse midwives, certified registered nurse anesthetists, clinical psychologists, clinical social workers, registered dietitians/nutritionists, anesthesiologist assistants, and mass immunization roster billers. The beneficiary (or the person authorized to request payment on the beneficiary's behalf) is not required to assign the claim to the supplier in order for an assignment to be effective, and when these claims are inadvertently submitted as unassigned, Medicare Administrative Contractors (MACs) process them as assigned.

Consistent with our established requirements for these other types of suppliers, some of whom are similar to MDPP suppliers in that they furnish a limited breadth of Medicare-covered services, we believed that it would be appropriate to require all MDPP suppliers, whether they are participating or not participating in Medicare, to accept assignment. We also believed that making performance payments for MDPP services solely on an assignment-related basis would be the most appropriate methodology, given the proposed performance-based MDPP payment methodology which would be based on the achievement of weight loss and/or attendance performance goals and not based on the MDPP supplier resource expended to furnish individual MDPP services. We further noted that as finalized in the CY 2017 PFS final rule (81 FR 80464), MDPP services are additional preventive services under section 1861(ddd) of the Act and, therefore, consistent with section 1833(a)(1)(W) of the Act, are not subject to the Medicare Part B coinsurance or deductible. Under our proposal, Medicare would pay 100 percent of the Medicare allowed charge for MDPP services furnished to MDPP beneficiaries, and a beneficiary would have no liability for covered MDPP services. MDPP suppliers would be required to accept the Medicare allowed charge as payment in full and would not be able to bill or collect from the beneficiary any amount.

Finally, to minimize the potential administrative burden on beneficiaries related to payment for MDPP services on an assignment-related basis, we proposed that for purposes of claims for services submitted by an MDPP supplier, Medicare would deem such claims to have been assigned by the beneficiary (or the person authorized to request payment on the beneficiary's behalf) and the assignment accepted by the MDPP supplier. This proposed treatment of claims from MDPP suppliers in new § 424.55(d) would be consistent with the current exception in § 424.55(c) regarding payment to a supplier, which specifies that when payment under the Act can only be made on an assignment-related basis or when payment is for services furnished by a participating physician or supplier, the beneficiary (or the person authorized to request payment on the beneficiary's behalf) is not required to assign the claim to the supplier in order for an assignment to be effective.

The proposed assignment-related basis for performance payments and bridge payments made to MDPP suppliers was included at proposed § 414.84(b) and (c). The proposal not to require the beneficiary to assign the claim for MDPP services to the MDPP supplier in order for assignment to be

[39] Available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf.*

effective was included at proposed § 424.55(d). We invited comments on these proposals.

The following is a summary of the public comments received on the proposals for the assignment-related basis for performance payments and bridge payments made to MDPP suppliers and the proposal not to require the beneficiary to assign the claim for MDPP services to the MDPP supplier in order for assignment to be effective and our responses:

Comment: Several commenters supported the proposal to make performance payments and bridge payments to MDPP suppliers on an assignment-related basis. One commenter specifically supported the proposal not to require the beneficiary to assign the claim for MDPP services to the MDPP supplier in order for the supplier to be paid directly by Medicare, claiming that this approach would reduce unnecessary paperwork and administrative burden for both the MDPP beneficiary and the MDPP supplier.

Response: We appreciate the commenters' support for our proposals for the assignment-related basis for performance payments and bridge payments made to MDPP suppliers and the proposal not to require the beneficiary to assign the claim for MDPP services to the MDPP supplier in order for assignment to be effective.

After considering the public comments received, we are finalizing the proposals, without modification, to make performance payments and bridge payments to MDPP suppliers on an assignment-related basis at § 414.84(b) and (c). In additional, we are finalizing the proposal, without modification, not to require the beneficiary to assign the claim for MDPP services to the MDPP supplier in order for assignment to be effective at § 424.55(d).

(b) Requirements for Payment of Bridge Payments and Performance Payments

We proposed that MDPP suppliers may only submit claims for a performance payment or bridge payment for MDPP services when all of the requirements for the payment are met. Claims for services that do not meet these requirements will not be paid. In accordance with § 424.80, we reminded MDPP suppliers that there are exceptions to the prohibition of reassignment of claims by suppliers for certain arrangements provided the applicable requirements are met. We noted that Medicare may pay an agent who furnishes billing and collection services to the supplier if the conditions of § 424.80(b)(5) are met.

Proposed requirements for performance payments and the bridge payment included that the MDPP services were furnished to a beneficiary eligible for MDPP services as specified at § 410.79(c) and that the MDPP supplier complies with all applicable enrollment and program requirements. In addition, we proposed that the MDPP services must be 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, and the MDPP supplier must submit the National Provider Identifier (NPI) of the coach on MDPP claims. We described additional details on how eligible coach information would be processed in section III.K.2.d.iii.(10)(d) of the proposed rule (82 FR 34151 through 34152). All specific additional proposed requirements for the performance payment or bridge payment, as discussed in sections III.K.2.d.iii.(3) through (6) and III.K.2.d.v. of the proposed rule (34141 through 34146 and 34153 through 34155), would also need to be met.

In order to submit a claim for a performance payment under the MDPP expanded model, the billing supplier is required to have documentation in the beneficiary's MDPP record, as specified in proposed § 424.205(g), that all requirements for the payment, including the achievement of the performance goal(s) applicable to the performance payment, have been met. We noted that the billing supplier's MDPP record for the beneficiary may include a copy of the beneficiary's MDPP record from a previous MDPP supplier that has been provided to the billing supplier at the request of the MDPP beneficiary. If an MDPP supplier is submitting a claim for an interval performance payment based on attendance at more than one session, this copy of the MDPP record from the previous MDPP supplier may be used as part of the billing supplier's documentation demonstrating that the attendance or weight loss performance goal for the performance payment was achieved. We noted that as we finalized at § 424.59(b) in the CY 2017 PFS final rule (proposed to be redesignated and amended at § 424.205(g)), MDPP suppliers are required to maintain and handle any personally identifiable information (PII) and protected health information (PHI) in compliance with HIPAA, other applicable state and federal privacy laws, and CMS standards. Therefore, MDPP suppliers must follow these rules, as applicable, when providing any copies of information from a beneficiary's MDPP records to another MDPP supplier.

We proposed that any weight loss measurement taken and recorded by an MDPP supplier for the purposes of performance payments must be taken in-person during an MDPP core session, core maintenance session, or ongoing maintenance session by the MDPP supplier during the MDPP services period. We believed that in-person measurements would be the most feasible method for weight ascertainment at this time for services because the beneficiary would attend regular in-person sessions with the MDPP supplier. Moreover, we believed that self-reported weight loss would not be reliable for the purposes of performance payment in the MDPP expanded model. This proposal also would apply to our proposed policy regarding virtual make-up sessions, described in detail in section III.K.2.c.iv.(3) of the proposed rule (82 FR 34136 through 34137), meaning that weight loss could not be measured or reported during a virtual make-up session for the purpose of the MDPP supplier submitting a claim for a performance payment. We also proposed to require that weight loss be measured in-person at an MDPP session to align with CDC's DPRP standards, which require for in-person sessions that weight be measured in-person at the session.

In addition, we noted that the achievement or maintenance of the required minimum weight loss that determines the performance payment amount for a core maintenance session interval and the maintenance of the required minimum weight loss that determines whether a performance payment for an ongoing maintenance session interval would be made must be determined by an in-person weight measurement at a session furnished during the applicable interval. Thus, for these interval performance payments, achievement of the performance goal for minimum weight loss would not need to be determined based on attendance at a session furnished by the MDPP supplier billing for that performance payment. However, as discussed previously, if achievement of the performance goal for minimum weight loss was measured at a session furnished by a previous MDPP supplier in the interval, the subsequent supplier must have documentation through a copy of the beneficiary's MDPP record from that previous supplier that the weight loss performance goal was met in the interval to bill for the interval performance payment. Finally, the performance payments for the required

minimum and 9 percent weight loss would only be billed by the MDPP supplier furnishing the session at which the weight loss performance goal is met during an in-person session.

Furthermore, we proposed that the beneficiary must achieve the applicable attendance performance goal for core session, core maintenance session interval, or ongoing maintenance session interval performance payments upon attendance at a session furnished by the MDPP supplier billing for that specific performance payment. An MDPP supplier could only bill for a performance payment on the date the beneficiary has achieved all performance goals associated with that performance payment. We noted that in order to bill for an interval performance payment that is based on attendance, the MDPP supplier that furnished the session where the attendance goal is met would bill for the performance payment, even if that supplier did not itself furnish all sessions attended by the MDPP beneficiary during that interval. In these circumstances, as discussed previously, if attendance at a session furnished by a previous MDPP supplier occurred in the interval, the subsequent supplier must have documentation through a copy of the beneficiary's MDPP record from that previous supplier of the session attendance in order to bill for the interval performance payment based on attendance at that session. An MDPP supplier may not bill for an interval performance payment when the MDPP supplier does not furnish the session where the attendance goal is met.

For all interval performance payments, we proposed that the performance payment would be based on the date the MDPP supplier furnished the session where the interval attendance performance goal is met. Thus, for those intervals where the performance payment would be based on MDPP beneficiary session attendance that spans 2 calendar years, the interval performance payment would be the amount applicable to the later calendar year, reflecting the annual update from the prior year as discussed in section III.K.2.d.iii.(9) of the proposed rule (82 FR 34147 through 34148).

The proposed conditions for payment by CMS of performance payments and bridge payments to MDPP suppliers were included at proposed § 414.84(b) and (c). We invited public comments on these proposals.

We received no public comments specific to the proposed conditions for payment of performance payments and bridge payments to MDPP suppliers.

We are finalizing the proposals, without modification, for the conditions for payment of performance payments and bridge payments to MDPP suppliers at § 414.84(b) and (c).

(c) Reporting HCPCS G-Codes on Claims for MDPP Services

We proposed to establish 19 unique Healthcare Common Procedure Coding System (HCPCS) G-codes so that MDPP suppliers may submit claims for payment when all the requirements for billing the codes have been met. Our proposal for the HCPCS G-codes is displayed in Table 40.

We noted that each MDPP supplier would be able to bill one of the 18 payable HCPCS G-codes on the date when all the requirements for billing the code have been met, including the session attendance for specific core and ongoing maintenance session intervals and achievement and/or maintenance of weight loss, as applicable to the specific HCPCS G-code. One of the proposed HCPCS G-codes would be nonpayable and assigned a payment amount of $0 because it would only be reported on a claim that also includes a payable HCPCS G-code for MDPP services as described subsequently.

HCPCS G-codes GXXX1 through GXXX3 and GXXX8 through GXX17 may each be paid only once in a beneficiary's lifetime, and the Medicare claims processing system would ensure that no more than one of each specific performance payment per beneficiary reported with these HCPCS G-codes is made. In addition, because only one performance payment may be made for each core maintenance session interval per beneficiary, the claims processing system would also ensure that no more than one unit of HCPCS code GXXX4 or GXXX6 and no more than one unit of HCPCS code GXXX5 or GXXX7 was paid in a beneficiary's lifetime.

Due to these lifetime limitations on payment for certain HCPCS codes for each beneficiary, in the circumstances where two MDPP suppliers furnished sessions during the MDPP services period and both MDPP suppliers met all requirements for billing the same HCPCS G-code, based on our operational processes, we would pay the first valid claim received and deny the second claim. The first valid claim received for a beneficiary for a given HCPCS G-code with a lifetime limitation would be determined through the CMS' Common Working File (CWF), which processes claims for all MACs.

Based on information from the CDC's national DPP, we expected that circumstances where a beneficiary changes MDPP suppliers during the MDPP services period would be uncommon. In addition, in view of the typical structure of DPPs where core sessions are offered weekly for the first 6 months of the core services period, and then offered monthly, we believed it would be rare for more than one MDPP supplier to meet the requirements for billing for the same once-per-lifetime performance payment. However, as an example an MDPP beneficiary could maintain the required minimum weight loss throughout the first core maintenance session interval and attend 3 sessions furnished by one MDPP supplier in the first 1½ months of the first core maintenance interval, and then change to another supplier and attend 3 more core maintenance sessions furnished by a subsequent MDPP supplier before the end of that interval. While both MDPP suppliers would meet the requirements for billing HCPCS code GXXX6, we would only pay the first claim for the HCPCS G-code that was submitted. The second claim for HCPCS code GXXX6 received by us would be denied. We expected that our operational processes would result in MDPP suppliers submitting claims for HCPCS G-codes as soon as the sessions are furnished that meet all of the requirements for billing for the particular performance payment, and that this practice would generally result in the performance payment being made to the MDPP supplier that furnished the first session where the performance goals were met.

Finally, as discussed in section III.K.2.d.v. of the proposed rule (82 FR 34153 through 34155), we did not propose to limit the number of bridge payments, which would be reported with HCPCS code GXX18, that may be paid for an MDPP beneficiary who changes MDPP suppliers during the MDPP services period.

TABLE 40—PROPOSED HCPCS G-CODES FOR MDPP SERVICES

Proposed HCPCS G-Code for MDPP services *	Proposed payment amount	Description of MDPP service
GXXX1	$25	1st core session attended.
GXXX2	30	4 total core sessions attended.
GXXX3	50	9 total core sessions attended.
GXXX4	10	3 core maintenance sessions attended in months 7–9 (weight loss goal not achieved or maintained).
GXXX5	10	3 core maintenance sessions attended in months 10–12 (weight loss goal not achieved or maintained).
GXXX6	60	3 core maintenance sessions attended in months 7–9 and weight loss goal achieved or maintained.
GXXX7	60	3 core maintenance sessions attended in months 10–12 and weight loss goal achieved or maintained.
GXXX8	160	5 percent weight loss from baseline achieved.
GXXX9	25	9 percent weight loss from baseline achieved.
GXX10	50	3 ongoing maintenance sessions attended in months 13–15 and weight loss goal maintained.
GXX11	50	3 ongoing maintenance sessions attended in months 16–18 and weight loss goal maintained.
GXX12	50	3 ongoing maintenance sessions attended in months 19–21 and weight loss goal maintained.
GXX13	50	3 ongoing maintenance sessions attended in months 22–24 and weight loss goal maintained.
GXX14	50	3 ongoing maintenance sessions attended in months 25–27 and weight loss goal maintained.
GXX15	50	3 ongoing maintenance sessions attended in months 28–30 and weight loss goal maintained.
GXX16	50	3 ongoing maintenance sessions attended in months 31–33 and weight loss goal maintained.
GXX17	50	3 ongoing maintenance sessions attended in months 34–36 and weight loss goal maintained.
GXX18	25	Bridge payment—first session furnished by MDPP supplier to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier.
GXX19	0	MDPP session reported as a line-item on a claim for a payable MDPP services HCPCS G-code for a session furnished by the billing supplier that counts toward achievement of the attendance performance goal for the payable MDPP services HCPCS G-code.

* Illustrative HCPCS G-code numbers were placeholders to allow for comment on the CY 2018 PFS proposed rule. Final HCPCS codes for MDPP services under the MDPP expanded model are included in Table 41 of this final rule.

We also stated that we plan to issue specific billing instructions to MDPP suppliers for those 14 proposed HCPCS G-codes (excluding GXXX1, GXXX8, GXXX9, GXX18, and GXX19) that represent an interval performance payment where attendance at more than 1 session is required for the performance payment to be made. Suppliers would report the applicable HCPCS G-code as a line-item on the claim on the date the session was furnished where the interval attendance goal was met. On the same claim, suppliers would also report 1 line-item of HCPCS code GXXX19 for each other session furnished by the supplier during the interval that was not previously reported on a claim but that counts toward achievement of the attendance performance goal for the applicable HCPCS G-code.

When billing for a HCPCS G-code that represents a cumulative number of MDPP sessions where some sessions already have been reported on a previous claim, only the sessions not previously reported on a claim would be reported by the MDPP supplier. For example, HCPCS code GXXX3 (9 total core sessions attended) would be used to bill for 9 core sessions attended, and the line-item of HCPCS code GXXX3 would represent the 9th core session furnished. Separate line-items of HCPCS code GXX19 would be reported on the same claim only for the 5th through 8th core sessions furnished by the MDPP supplier. Claims for HCPCS codes GXXX1 (1st core session attended) and GXXX2 (4 core sessions attended) would already have been submitted, and those claims would have included line-items for the 1st core session, and for the 2nd, 3rd, and 4th core sessions.

We believed that instructing MDPP suppliers to report a line-item for each session on a single claim submitted for an interval performance payment would simplify the tracking and administrative activities of MDPP suppliers and the reporting of the coach NPI on claims for MDPP services furnished to beneficiaries as discussed in section III.K.2.d.iii.(10)(d) of the proposed rule (82 FR 34151 through 34152). We further believed that there should be no significant administrative burden for MDPP suppliers to include information on all sessions they furnished on interval performance payment claims for two reasons. First, the documentation requirements for MDPP sessions at § 424.205(g), including the beneficiary's eligibility, specific session topics attended, the NPI of the coach who furnished the session attended, the date and place of service of sessions attended, and weight, would require the MDPP supplier to document and retain this information. Therefore, MDPP suppliers would have documentation of the date of each session and the NPI of the furnishing coach for reporting on each line-item on the claim for the interval performance payment. Second, MDPP suppliers would be instructed not to submit separate claims for each session represented in an interval performance payment. All sessions would be reported on the single claim that would be submitted for the interval performance payment.

In the case of an MDPP supplier submitting a claim for an interval performance payment where the billing supplier did not furnish all the sessions attributable to the interval because another supplier had furnished some of the first sessions in the interval, the billing supplier would report on the claim only the sessions it furnished. However, the supplier would need to maintain MDPP records documenting that all requirements, including session attendance and achievement or maintenance of weight loss, if applicable, for billing the HCPCS G-code for the interval for the beneficiary were met. Any sessions covered by the interval performance payment HCPCS G-code but not furnished by the supplier submitting the claim for that interval would not be reported as separate line-items on the claim. However, the billing supplier would need to maintain in the beneficiary's MDPP record a copy of his or her MDPP record from the previous supplier in order to consider sessions furnished by the previous supplier in determining that the performance goal(s) for the interval performance payment were met.

Although the NPIs of the coaches who furnished such sessions that would not be reported as separate line-items would also not be recorded on the claim, the billing supplier would still be required to maintain documentation in the beneficiary's MDPP record of the NPI of each coach who furnished each session through a copy of the beneficiary's MDPP record about those sessions from the previous supplier. Therefore, upon medical review, CMS and its contractors would be able to review and assess the remaining coaches who furnished sessions to Medicare beneficiaries associated with a claim submitted for a given interval performance payment HCPCS G-code, but who do not have an NPI reported on the claim. Because we expected it to be uncommon for suppliers not to furnish all sessions attributable to an interval and due to the administrative burden that could result from a requirement that an MDPP supplier report specific information on sessions on a claim that the particular supplier did not itself furnish, we believed that the program integrity risk associated with the limitation in the completeness of information from administrative claims data under this scenario would be low. However, we would monitor the completeness of reporting line-items on claims for interval performance payments and may consider revising our billing instructions in the future if we determine that we lack information from administrative claims on a significant number of sessions furnished to MDPP beneficiaries.

We invited public comments on the proposals to create 19 HCPCS G-codes for billing for the performance payments and bridge payment.

The following is a summary of the public comments received on the proposals to create 19 HCPCS G-codes for billing for the performance payments and bridge payment and our responses:

Comment: Several commenters observed that the general proposed billing process appeared to be simple based on the use of the CMS–1500 claim form and the proposed 19 unique HCPCS G-codes specific to the MDPP expanded model. However, many commenters expressed concern about the complexity of the proposed coding and billing procedures, as well as the accompanying administrative burden on MDPP suppliers to generate and submit correct claims for MDPP services. Several commenters stated that the proposal would require the entity billing for MDPP services to know whether or not the MDPP beneficiary has achieved his or her performance goals and how far along the beneficiary is in the MDPP services period in order to accurately bill for MDPP services. The commenters claimed that the complexity of the proposals would be unlikely to drive value in the MDPP expanded model and concluded that the extensive billing processes could discourage organizations from participating in the model because those processes would require more time and effort than DPPs have capacity to provide under their current business model. One commenter further added that the administrative requirements of the claims submission processes for submitting 19 HCPCS G-codes for a single beneficiary for MDPP services furnished over time would especially not be cost-effective for small, community-based nonprofit organizations in the context of the proposed performance payment amounts for MDPP services.

A number of commenters recommended that CMS reduce the number of HCPCS G-codes for MDPP services from the 19 new codes proposed. Several commenters urged CMS to provide payment for each MDPP session furnished by streamlining coding to only establish a separate HCPCS G-code for each type of session (core, core maintenance, and ongoing maintenance), coupled with a performance payment when the required minimum weight loss is achieved, in order to substantially simplify coding and billing. One commenter requested that CMS align the MDPP expanded model HCPCS codes and billing requirements with established Medicare diabetes self-management education and training services codes and billing policies. Another commenter reasoned that the more CMS can simplify the coding requirements for the MDPP expanded model and work to align the billing and coding processes with private health plans, the better the chance of broader, more meaningful access to and participation in MDPP services for patients. In contrast, a commenter reported that the claims submission and payment processes have been difficult to date for DPP organizations to implement under current private health plan processes and, therefore, encouraged CMS to streamline its proposed processes.

Several commenters urged CMS to pay separately for the MDPP supplier administrative resources necessary to deliver MDPP services, including the preparation and submission of claims. One commenter noted that community-based organizations may be unfamiliar with Medicare billing requirements and recommended that CMS provide separate payment for an entity that serves as an Integrator between MDPP suppliers, CMS, and other payers.

Response: We acknowledge the large number of new HCPCS G-codes that we proposed to require to provide payment for the multiple types of performance payments and the bridge payment that we are finalizing for the MDPP expanded model. While this is a significant number of codes specific to the MDPP expanded model to be reported by an MDPP supplier on the CMS–1500 claim form when the performance goal(s) for the performance payments or the requirements for the bridge payment are met for MDPP services furnished to an MDPP beneficiary, we agree with those commenters who stated generally that the reporting of HCPCS G-codes for MDPP services on the CMS–1500 claim form should be straightforward. Many types of suppliers paid under the PFS for services currently report CPT and alpha-numeric HCPCS codes that describe those services on the CMS–1500 claim form without substantial problems.

We also understand that entities that enroll in Medicare as MDPP suppliers and have not previously billed Medicare for services will have a learning curve in preparing claims. However, we view this learning as unavoidable with the enrollment as MDPP suppliers of different types of organizations that do not already furnish other types of services to Medicare beneficiaries. We are committed to providing clear guidance to MDPP suppliers on coding and billing for MDPP services to support suppliers' implementation of the most efficient and accurate processes for their respective organizations.

Claim preparation and submission is the responsibility of the MDPP supplier or their billing agent, and Medicare may pay the MDPP supplier or an agent who furnishes billing and collection services to the supplier if the conditions of § 424.80(b)(5) are met. We will not make separate payments to MDPP suppliers for the administrative activities related to claims preparation and submission, nor will we provide separate payments to an entity that serves as an Integrator between CMS, MDPP suppliers, and other payers. MDPP suppliers will bear the cost of these activities.

As several commenters recognized, one of the more significant challenges for MDPP suppliers in billing correctly will be identifying and tracking where the beneficiary is in the MDPP services period, which defines what MDPP services must be offered to the beneficiary, as well as the HCPCS G-codes that can be reported for

performance payments during that timeframe. This may be especially difficult when the MDPP beneficiary switches suppliers during the MDPP services period and the subsequent supplier does not yet have the beneficiary's MDPP records from the previous supplier. Another challenge for MDPP suppliers will be identifying when MDPP beneficiaries have met all the performance goals for the performance payment such that the MDPP supplier may submit a claim for the relevant HCPCS G-code that may be paid. These particular tasks result from the once-per-lifetime limitation on MDPP services and the performance-based payment methodology under the MDPP expanded model. In contrast, under the Medicare fee-for-service payment methodologies, most services are billed individually as they are furnished, without regard to the achievement of performance goals, and most services do not have a once-per-lifetime limitation, especially a limitation that applies to services that may be furnished over many months.

In terms of the alignment of the MDPP expanded model HCPCS G-codes and billing requirements with those currently used for diabetes self-management education and training services, we note that diabetes self-management education and training services are subject to different requirements than MDPP services that are paid based on a performance-based payment methodology specifically established for this expanded model. Therefore, the codes and billing requirements for these different services are not aligned. In terms of alignment with processes used by private payers, the commenters did not provide specific information regarding these processes that we understand, in some cases, are based on invoices and not based on claims. While we appreciate the interest of the commenters in using similar claims processes for all patients in a DPP, regardless of payer, to reduce confusion and administrative burden on the MDPP supplier, this is not feasible given the specific requirements that apply to MDPP services furnished under the MDPP expanded model and the standard CMS claims processing systems upon which the MACs rely to process and pay Medicare claims.

Regarding the requests of some commenters that we reduce the number of HCPCS G-codes to have only a single code for each type of session, we note that our operational processes will edit in the claims processing system to ensure that we make only a maximum of one of each type of performance payment per beneficiary due to the lifetime limitation on MDPP services. Moreover, only the MDPP supplier submitting the claim for a performance payment will know whether or not the beneficiary has achieved or maintained the required minimum weight loss, as the beneficiary's weight is not submitted on administrative claims. Because the majority of the performance payments are in some way related to the achievement or maintenance of the required minimum weight loss, either through identifying whether or not any performance payment should be made or determining the specific performance payment amount to be paid, and the MDPP supplier has documentation of the beneficiary's weight for each session furnished in-person, we believe the MDPP supplier is in the best position to prepare an accurate claim that identifies the specific performance payment that applies to the MDPP services furnished to the beneficiary.

Therefore, each performance payment and the bridge payment require separate payable HCPCS G-codes to be reported on claims to allow editing in the claims processing system for the once-per-lifetime limitation on the performance payment and to apply the policies for the bridge payment. Additionally, a nonpayable HCPCS G-code must be reported as a separate line-item on a claim for a payable HCPCS G-code for each additional session furnished by the billing supplier that counts toward achievement of the attendance performance goal for the payable HCPCS G-code so that we are able to monitor for compliance with the attendance requirement for the performance payment. While we proposed 19 new HCPCS G-codes for the MDPP expanded model, because we are finalizing an ongoing services period maximum duration of 12 months, rather than the 24 months that we proposed, 4 of the proposed HCPCS G-codes for reporting MDPP services in months 25 to 36 of the ongoing services period are not needed. Therefore, we are establishing 15 new HCPCS G-codes, effective April 1, 2018, for the MDPP expanded model. The final HCPCS G-codes and their long descriptors are displayed in Table 41.

Comment: One commenter requested that CMS clarify whether another HCPCS G-code or a specific HCPCS modifier will be established as a way to indicate on claims whether one of the sessions reported was a virtual make-up session in view of the proposal to limit the number of virtual make-up sessions.

Response: We are finalizing limitations on the number of virtual make-up sessions as discussed in section III.K.2.c.iv.(3)(b) of this final rule. So that we can monitor for compliance with these limitations, we are also establishing new HCPCS code modifier VM (Medicare Diabetes Prevention Program (MDPP) Virtual Make-up Session.) to be appended to the HCPCS G-code on each claim line-item that represents a virtual make-up session. Because the HCPCS G-codes for the first core session and weight loss performance payments require that a weight be measured in-person at the session that is reported on the line-item for those HCPCS codes, only 12 of the 15 final HCPCS G-codes for the MDPP expanded model may be reported with HCPCS modifier VM as indicated in Table 41.

Comment: One commenter disagreed with the operational plan that if two MDPP suppliers both meet the requirements for billing a single HCPCS G-code with a one unit lifetime limitation, CMS would only pay the first claim for the HCPCS G-code that was submitted. The commenter stated this is not a viable solution for reconciling the submission of two claims from different MDPP suppliers for the same HPCPCS G-code and may result in confusion and discord among MDPP suppliers.

Response: While we appreciate the commenter's concern about our paying the first claim received for a HCPCS G-code when a different MDPP supplier later submits a claim for the same code, we do not have the straightforward operational capacity to further adjudicate timely the decision about which MDPP supplier should receive the payment for the once-per-lifetime HCPCS G-code if two MDPP suppliers submit a claim for the same HCPCS G-code. Conceptually, we believe it is appropriate that payment be made to the MDPP supplier that furnished the first session that meets all of the requirements for billing for the performance payment reported with that HCPCS code. Our planned operational practice of paying the first claim received would generally result in the performance payment being made to the MDPP supplier that furnished the first session where the performance goals were met because MDPP suppliers would be incentivized to submit claims for HCPCS G-codes as soon as the sessions are furnished that meet all of the requirements for billing for the particular performance payment. Therefore, in general we believe that the appropriate supplier would be paid the performance payment reported with the HCPCS G-code.

We will monitor the frequency of circumstances where we receive two claims from different MDPP suppliers for the same performance payment for the same MDPP beneficiary and, if

indicated, compare the date of the session reported on each paid and unpaid claim where the performance goals for the payment were met. If we see frequent circumstances where the payment was not made to the MDPP supplier that furnished the first session where the performance goals were met, we may consider revisions to this policy so that we are able to specifically reconcile claims for the same performance payment from different MDPP suppliers. However, we remain concerned that any adjudication of these circumstances could require us to hold claims for MDPP services without payment for a period of time and generally delay performance payments to MDPP suppliers, which could result in greater MDPP supplier confusion and burden.

Comment: One commenter requested that CMS confirm that an MDPP supplier can submit a claim for the 5 percent weight loss performance payment on the date that the beneficiary achieves the weight loss goal any time during the 12-month core services period. The commenter explained that one section of the proposed rule suggested that only attendance-based performance payments would be made in the first 6 months of the MDPP services period, whereas another section stated that the 5 percent weight loss performance payment could be made upon achievement of the required minimum weight loss any time during the 12 months of the core services period.

Response: We appreciate the commenter's request for clarification about the time period during the MDPP services period when the 5 percent weight loss performance payment can be billed and paid. The 5 percent weight loss performance payment may be billed by the MDPP supplier on the date it furnishes any session during the 12 months of the core services period when 5 percent weight loss is achieved by the MDPP beneficiary. We note that other than the weight loss performance payments, during the first 6 months of the core services period the core session performance payments are the only other type of performance payments that can be made and they are solely based on the achievement of attendance performance goals.

Comment: One commenter encouraged CMS to develop billing templates for MDPP coaches because coaches are not billing specialists, yet the coaches teach the DPP curriculum.

Response: We define a coach in the MDPP expanded model as an individual who furnishes MDPP services on behalf of an MDPP supplier as an employee, contractor, or volunteer. While we understand that coaches teach the DPP curriculum to MDPP beneficiaries during sessions, we only make performance payments for the beneficiary's achievement of attendance and/or weight loss performance goals or the bridge payment to MDPP suppliers. Thus, MDPP suppliers or their billing agents must prepare and submit claims for Medicare for payments under the MDPP expanded model. Coaches will not submit claims to Medicare and, therefore, will not need to have billing templates.

Comment: One commenter requested that CMS clarify whether, under the circumstances when an MDPP beneficiary completes the full 12-month core services period without achieving or maintaining the required minimum weight loss but requests to continue with ongoing maintenance sessions furnished by the MDPP supplier, the MDPP supplier is permitted to bill the beneficiary for those ongoing maintenance sessions. Similarly, the commenter requested that CMS clarify whether the MDPP supplier can bill the beneficiary for sessions after the beneficiary completes the 36 months of eligibility for MDPP services but remains eligible for the DPP.

Response: We recognize that beneficiaries who are no longer eligible for MDPP services as specified at § 410.79(c)(1) and (2) may still wish to continue participating in DPP sessions. In these cases, MDPP suppliers may decide whether to continue offering such services and whether to bill the individual for such services. In cases where the claim is assigned, section 1879(b) of the Act establishes certain requirements for suppliers that wish to charge beneficiaries for the cost of a non-covered service. This section, however, only addresses the Medicare denial reasons specified in sections 1862(a)(1), 1862(a)(9), and 1879(g) of the Act. Because MDPP services fall under section 1861(ddd) and thus section 1879(b) of the Act does not address the denial reason in the commenter's question, the requirements in section 1879 are not applicable. Therefore, MDPP suppliers that opt to offer services beyond the set of MDPP services for which the beneficiary is eligible may charge the beneficiary for those services, and may do so without requiring the beneficiary to sign an Advanced Beneficiary Notice of Noncoverage (ABN). Although the MDPP supplier standard at § 424.205(d)(11) requires MDPP suppliers to disclose MDPP-related information to beneficiaries at the onset of services, including what is covered and MDPP eligibility criteria, we highly encourage MDPP suppliers to provide notification to a beneficiary when his or her eligibility for MDPP services ends and when continued receipt of DPP services would result in a beneficiary's out-of-pocket expense.

Given the commenter's questions about the circumstances when an MDPP supplier may charge a beneficiary for DPP services furnished when the beneficiary is not eligible for MDPP services, we want to further clarify which DPP services are considered covered as a part of the set of MDPP services and, therefore, charging beneficiaries for these services furnished during the MDPP services period would not be permitted. As defined at § 410.79(a) and (c)(2), the core services period consists of, *at least* 16 core sessions offered at least one week apart during months 1 through 6 of the MDPP services period (emphasis added)'' and two core maintenance session intervals, which mean 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 (emphasis added). Similar, as defined at § 410.79(a) and (c)(2), during the ongoing services period an MDPP supplier offers *at least* 1 ongoing maintenance session to an MDPP beneficiary per month (emphasis added).

These provisions establish the minimum number of sessions an MDPP supplier must offer during these months as a part of the set of MDPP services, as required at § 424.205(d)(10), but do not establish an upper limit on the number of MDPP sessions that can be offered under these time periods. An MDPP supplier may offer sessions beyond what are required under the MDPP expanded model. However, any additional MDPP services offered beyond the minimum required during the core and ongoing services periods would still be subject to the requirements at § 410.79(a) and (c)(2) and, as an additional preventive service, no cost-sharing can be applied to MDPP services. Thus, an MDPP supplier may not charge an MDPP beneficiary for any additional MDPP services furnished beyond the minimum that must be offered during the core services period or during the ongoing services period, provided that the beneficiary is eligible for MDPP services and is in his or her MDPP services period.

After considering the public comments received, we are finalizing the proposals to establish new HCPCS

G-codes for reporting MDPP services under the MDPP expanded model, with modifications. Because we are finalizing the ongoing services period duration of 12 months, rather than the 24 months that we proposed, 4 of the proposed HCPCS G-codes for reporting MDPP services in months 25 to 36 of the ongoing services period are not needed. Therefore, we are adopting 15 new HCPCS G-codes, effective April 1, 2018, for the MDPP expanded model. In addition, the descriptions of the HCPCS G-codes for core maintenance and ongoing maintenance session interval performance payments have been modified to reflect the final attendance performance goal of 2 sessions for each interval, as discussed further in sections III.K.2.d.iii.(4) and (5) of this final rule. The final HCPCS G-codes, long descriptors, indication of whether or not each code may be reported with modifier VM as a virtual make-up session, and their payment amounts are displayed in Table 41.

TABLE 41—FINAL MDPP EXPANDED MODEL HCPCS G-CODES

HCPCS G-code	Long descriptor	May be reported with modifier VM (virtual make-up session)	Final payment amount
G9873	First Medicare Diabetes Prevention Program (MDPP) core session was attended by an MDPP beneficiary under the MDPP Expanded Model (EM). A core session is an MDPP service that: (1) Is furnished by an MDPP supplier during months 1 through 6 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for core sessions.	No	$25
G9874	Four total Medicare Diabetes Prevention Program (MDPP) core sessions were attended by an MDPP beneficiary under the MDPP Expanded Model (EM). A core session is an MDPP service that: (1) Is furnished by an MDPP supplier during months 1 through 6 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for core sessions.	Yes	50
G9875	Nine total Medicare Diabetes Prevention Program (MDPP) core sessions were attended by an MDPP beneficiary under the MDPP Expanded Model (EM). A core session is an MDPP service that: (1) Is furnished by an MDPP supplier during months 1 through 6 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for core sessions.	Yes	90
G9876	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 7–9 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) Is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary did not achieve at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 7–9.	Yes	15
G9877	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 10–12 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) Is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary did not achieve at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 10–12.	Yes	15
G9878	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 7–9 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) Is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary achieved at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 7–9.	Yes	60
G9879	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 10–12 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) Is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary achieved at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 10–12.	Yes	60
G9880	The MDPP beneficiary achieved at least 5% weight loss (WL) from his/her baseline weight in months 1–12 of the MDPP services period under the MDPP Expanded Model (EM). This is a one-time payment available when a beneficiary first achieves at least 5% weight loss from baseline as measured by an in-person weight measurement at a core session or core maintenance session.	No	160
G9881	The MDPP beneficiary achieved at least 9% weight loss (WL) from his/her baseline weight in months 1–24 under the MDPP Expanded Model (EM). This is a one-time payment available when a beneficiary first achieves at least 9% weight loss from baseline as measured by an in-person weight measurement at a core session, core maintenance session, or ongoing maintenance session.	No	25

TABLE 41—FINAL MDPP EXPANDED MODEL HCPCS G-CODES—Continued

HCPCS G-code	Long descriptor	May be reported with modifier VM (virtual make-up session)	Final payment amount
G9882	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 13–15 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) Is furnished by an MDPP supplier during months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 13–15.	Yes	50
G9883	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 16–18 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) Is furnished by an MDPP supplier during months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 16–18.	Yes	50
G9884	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 19–21 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) Is furnished by an MDPP supplier during months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 19–21.	Yes	50
G9885	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 22–24 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) Is furnished by an MDPP supplier during months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 22–24.	Yes	50
G9890	Bridge Payment: A one-time payment for the first Medicare Diabetes Prevention Program (MDPP) core session, core maintenance session, or ongoing maintenance session furnished by an MDPP supplier to an MDPP beneficiary during months 1–24 of the MDPP Expanded Model (EM) who has previously received MDPP services from a different MDPP supplier under the MDPP Expanded Model. A supplier may only receive one bridge payment per MDPP beneficiary.	Yes	25
G9891	MDPP session reported as a line-item on a claim for a payable MDPP Expanded Model (EM) HCPCS code for a session furnished by the billing supplier under the MDPP Expanded Model and counting toward achievement of the attendance performance goal for the payable MDPP Expanded Model HCPCS code. (This code is for reporting purposes only).	Yes	0

In the CY 2018 PFS proposed rule (82 FR 34151), we also invited public comment on matters related to billing instructions for MDPP suppliers that we plan to issue to require the reporting of additional session line-items on claims for MDPP services so that information on the date and coach NPI for each session furnished by the billing supplier would be submitted on claims. However, we noted that we intend to provide additional claims submission instructions in guidance.

The following is a summary of the public comments received on matters related to billing instructions for MDPP suppliers that we plan to issue to require reporting additional session line-items on claims for MDPP services so that information on the date and coach NPI for each session furnished by the billing supplier would be submitted on claims and our responses:

Comment: Several commenters emphasized the need for CMS to provide additional detailed instructions on billing requirements for coding, charting, and charges so that MDPP suppliers are prepared for an audit. One commenter provided specific recommendations for items CMS should include in future billing instructions, regardless of the final HCPCS G-codes established for the MDPP expanded model. These items included: A table with the HCPCS G-codes and their payment amounts; groupings of HCPCS G-codes most likely to be billed together; a sample completed CMS–1500 claim form for various scenarios; and ICD–10–CM diagnosis codes to be reported on claims for MDPP services.

Response: We appreciate the interest of the commenters in ensuring that MDPP suppliers, many of whom may not have previously billed Medicare for services, have sufficient information to accurately and correctly prepare all elements of claims for submission to Medicare in accordance with the final policies of the MDPP expanded model. We share the interest of the commenters and recognize the importance of comprehensive, clear billing instructions to streamline the work of MDPP suppliers that will submit claims and MACs who will process those claims for payment of MDPP services. We will be issuing specific billing instructions for MDPP services in

advance of the April 1, 2018 start date of the MDPP expanded model. We will consider the suggestions of the commenter regarding the contents, as well as information and requests provided to us by other stakeholders, as we develop and refine comprehensive billing instructions for MDPP suppliers. Finally, we note that we expect a learning curve for MDPP suppliers and MACs with respect to claims for MDPP services, and we are prepared to provide further billing instructions or clarify the instructions already provided as the MDPP expanded model begins to be implemented and claims are prepared, submitted, and processed for the first time.

(d) Reporting the Coach National Provider Identifier (NPI) on Claims

In the CY 2017 PFS final rule, we established the policy that coaches will not enroll in Medicare for purposes of furnishing MDPP services, but that they will be required to obtain NPIs. Further details on these policies are described in section III.K.2.e.iii. of the proposed rule (82 FR 34158 through 34166).

As stated in Chapter 26, Section 10.4 of the Medicare Claims Processing Manual,[40] the NPI of the rendering provider is to be reported as Item 24J on the line-item for each service reported on the CMS–1500 claim form. Our proposal in section III.K.2.d.iii.(10)(c) of the proposed rule (82 FR 34149 through 34151) would require that, in the circumstances of a claim for an interval performance payment for MDPP services, each session furnished by the billing supplier be reported as a separate line-item on the claim. In addition, we proposed to require MDPP suppliers to report the NPI of the coach who furnished the session as Item 24J on the line-item for each session reported on claims for performance payments for MDPP services. Under our proposal, the coach who furnished the session would be the rendering provider for purposes of reporting on the CMS–1500 claim form.

Although only MDPP suppliers, not coaches, would be subject to potential Medicare administrative actions related to payments the suppliers may receive, we believed that our proposal to require the NPI of the coach who furnished the session to be reported as the rendering provider for each line-item HCPCS G-code on a claim for MDPP services would provide us with a number of program integrity protections, including the ability to monitor MDPP coach activity to identify suspected fraud or other improper payments and to determine the need for medical review or investigation as appropriate. We would only process claims for payment of MDPP services when all of the coach NPIs reported on the claim are associated with eligible coaches who have been submitted on the coach roster in the MDPP supplier's enrollment application, and when all of the coaches have successfully completed Medicare's screening processes. We would also only process claims for payment of MDPP services furnished by a coach on or after his or her coach eligibility start date, and, if applicable, prior to his or her coach eligibility end date, as the definitions of these terms were included in proposed § 424.205(a).

Without such program integrity protections, we would lack a sufficient method to verify that payment is being made for services furnished by a coach who has met the requirements outlined in section III.K.2.e.iii. of the proposed rule (82 FR 34158 through 34166). This verification would help protect both Medicare beneficiaries and the Medicare Trust Funds. Including coach NPIs on claims could also encourage accuracy in reporting on the achievement of beneficiary attendance and/or weight loss performance goals because both CMS and MDPP suppliers would be able to identify on the claim in question which coaches furnished the sessions attributable to the performance payment. In addition, because the accuracy of information reported on the claim would ultimately be the MDPP supplier's responsibility and the MDPP supplier would attest to the accuracy of each claim submitted, including the relevant coach NPIs on the claim could assist the MDPP supplier when conducting internal monitoring of claim accuracy.

These proposed requirements for reporting the coach NPI as the rendering provider on session line-items included on claims for performance payments and bridge payments to MDPP suppliers were included at proposed § 414.84(b) and (c). We invited public comments on these proposals.

The following is a summary of the public comments received on the proposals for the requirements for reporting the coach NPI as the rendering provider on session line-items included on claims for performance payments and bridge payments to MDPP suppliers and our responses:

Comment: Several commenters supported the proposal to require MDPP suppliers to report the NPI of the coach who furnishes an MDPP session on the claim line-item for that session. One commenter noted that because coaches will not have to individually enroll in Medicare but will be required to obtain an individual NPI, the coach NPI information for each session will be available, making the proposed reporting approach feasible for MDPP suppliers.

Response: We appreciate the commenters' support for our proposed requirements for reporting the coach NPI as the rendering provider on session line-items included on claims submitted by MDPP suppliers for performance payments and bridge payments. After considering the comments received, we are finalizing the proposal, without modification, for reporting the coach NPI as the rendering provider on session line-items included on claims for performance payments and bridge payments to MDPP suppliers at § 414.84(b) and (c).

iv. Comparison of Final Supplier Requirements for Furnishing the Set of MDPP Services and Supplier Payment

As in the DPP model test under section 1115A(b) of the Act, MDPP services are based on a CDC-approved DPP curriculum and, therefore, MDPP suppliers must offer sessions in accordance with that curriculum. We are finalizing a performance-based payment methodology for MDPP services, which ties most payments to outcomes—in this case, weight loss and session attendance—to help incentivize suppliers to be engaged in their beneficiaries' weight loss efforts. Given this methodology, we recognize that there will be an inherent amount of supplier financial risk, and that coverage of sessions and supplier requirements and payment will not always align under the MDPP expanded model final polices. This section clarifies how these elements fit together in the MDPP expanded model under its final policies, as displayed in Table 42.

[40] Available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c26.pdf.*

TABLE 42—FINAL SET OF MDPP SERVICES AND PAYMENT

MDPP services	MDPP beneficiary eligibility for coverage	MDPP supplier must offer	MDPP supplier payment
Core sessions (months 1 to 6 of the MDPP services period).	An eligible beneficiary has Medicare coverage of core sessions in the first 6 months of the MDPP core services period, regardless of attendance or weight loss. * **Note:** To start the MDPP services period, the beneficiary attends his or her first core session, which begins the beneficiary's MDPP services period timeline of a maximum of 24 months.	At least 16 core sessions, furnished no more frequently than once per week, over the first 6 months of the beneficiary's MDPP services period.	• $25 performance payment for beneficiary attendance at the first core session. • $50 interval performance payment after the beneficiary has attended a total of 4 core sessions. • $90 interval performance payment after the beneficiary has attended a total of 9 core sessions. * **Note:** All payments for core sessions are independent of beneficiary weight loss.
Core maintenance sessions (months 7 to 12 of the MDPP services period).	Beneficiary has coverage of core maintenance sessions in months 7 to 12 of the MDPP services period, regardless of attendance or weight loss.	At least 1 core maintenance session per month in months 7 to 12 of the MDPP services period.	• $15 payment if a beneficiary attends 2 sessions within a 3-month core maintenance session interval but does not achieve or maintain the required minimum weight loss at least once within that 3-month core maintenance session interval; *or* • $60 if a beneficiary attends 2 sessions *and* achieves or maintains the required minimum weight loss at least once within that 3-month core maintenance session interval. * **Note:** There are 2 consecutive core maintenance session intervals.
Ongoing maintenance sessions (months 13 to 24 of the MDPP services period).	Beneficiary has coverage of ongoing maintenance sessions in the first ongoing maintenance session interval (months 13 to 15 of the MDPP services period) if: • He or she attended at least 1 session during the final core maintenance session interval (months 9 to 12 of the MDPP services period) and had weight measured. • He or she achieved or maintained the required minimum weight loss at least once during the final core maintenance session interval (months 10 to 12 of the MDPP services period). A beneficiary has coverage of a subsequent ongoing maintenance session interval (for up to 9 months after the end of the first ongoing maintenance session interval) if: • He or she attended at least 2 sessions and maintained the required minimum weight loss from baseline at least once during the previous ongoing maintenance session interval.	At least 1 ongoing maintenance session per month for up to 12 months, if the beneficiary maintains eligibility to have coverage of ongoing maintenance sessions.	• $50 payment if a beneficiary attends 2 sessions and maintains the required minimum weight loss from baseline at least once within a 3-month ongoing maintenance session interval. * **Note**: There are up to four consecutive ongoing maintenance session intervals.

Once an MDPP supplier enrolls in Medicare to furnish MDPP services, it must offer the set of MDPP services in accordance with the MDPP supplier standards (noted in section III.K.2.e.iv.(4) of this final rule and at § 424.205(d)), including that it must offer at least 16 core sessions, furnished no more frequently than once per week, over the first 6 months of the MDPP core services period; at least 1 core maintenance session per month over months 7 to 12 of the MDPP core services period; and at least 1 ongoing maintenance session per month for up to 12 additional months (months 13 through 24 of the MDPP services period), if the beneficiary maintains eligibility for coverage of ongoing maintenance sessions. We recognize that beneficiaries might not attend these sessions. However, they must be made available, in accordance with CDC's DPRP Standards, to beneficiaries as long as they are eligible for coverage of MDPP services. We further note that the set of MDPP services must be furnished in compliance with all applicable federal laws and regulations.

Although a beneficiary is not required to use MDPP services at all, the MDPP services period is initiated by the beneficiary attending his or her first core session, which begins the MDPP services period timeline. To qualify for coverage of ongoing maintenance sessions, a beneficiary also needs to attend at least 1 session during the final core maintenance session interval where in-person weight measurement is performed that demonstrates the achievement or maintenance of the required minimum weight loss.

All of the final performance payments except for the weight loss performance payments require the achievement of an attendance performance goal, and if a beneficiary does not achieve attendance performance goals, an MDPP supplier will not be paid a performance payment that relies on achieving those goals. For example, if a beneficiary does not attend 2 sessions in the first core maintenance session interval, a supplier will not be paid a performance payment for the interval that spans months 7 to 9 of the MDPP core services period. However, a supplier must offer at least 1 core maintenance session per month to the beneficiary to ensure that the beneficiary has the opportunity to attend. Furthermore, although the

weight loss performance payments are based solely on the achievement of the required minimum or 9 percent weight loss, we note that all weight loss measurements must be obtained in-person at a session so that if a beneficiary does not attend a session where weight loss can be measured and compared to baseline, the MDPP supplier will not be paid a performance payment that relies on achieving a weight loss performance goal.

v. Payment Policies When a Beneficiary Changes MDPP Suppliers

In the CY 2017 PFS final rule (81 FR 80470), we confirmed that a beneficiary may change MDPP suppliers at any time. However, we deferred specific policies regarding attribution of beneficiaries who change MDPP suppliers as related to payment to future rulemaking. We subsequently made proposals for payment policies when a beneficiary changes MDPP suppliers during the MDPP services period in the proposed rule (82 FR 34153 through 34155).

At proposed § 414.84(a), we proposed to define ''bridge payment'' as a one-time payment to an MDPP supplier for furnishing its first MDPP services session to an MDPP beneficiary who has previously received one or more MDPP services from a different MDPP supplier. We used this definition in the proposed MDPP payment policies for the circumstances when a beneficiary changes MDPP suppliers for any reason during the MDPP services period after the beneficiary has attended at least the first core session.

In cases where the beneficiary changes MDPP suppliers, there would be a shift in accountability for offering the set of MDPP services for which the beneficiary is eligible for coverage from one MDPP supplier to a subsequent MDPP supplier. Similar to our proposal for a performance payment to an MDPP supplier that furnishes the first core session to an MDPP beneficiary who initiates the MDPP services period as discussed in section III.K.2.d.iii.(3) of the proposed rule (82 FR 34141 through 34143), we proposed that an MDPP supplier would be paid a bridge payment of $25 for furnishing its first session to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier, regardless of whether the MDPP supplier is paid any performance payments for that beneficiary. A subsequent MDPP supplier would be paid this bridge payment after furnishing the first session to a beneficiary and billing the appropriate HCPCS G-code only if the supplier did not furnish the first core session to the MDPP beneficiary.

We believed that making a bridge payment that would be the same amount as the performance payment for the first core session discussed in section III.K.2.d.iii.(3) of the proposed rule (82 FR 34141 through 34143) would be appropriate because we expected the MDPP supplier's resources used to be similar under both of these circumstances. The subsequent supplier would expend resources for furnishing a first session to a beneficiary, including collecting administrative information on the beneficiary who is not already known to the supplier, regardless of whether the beneficiary goes on to receive further MDPP sessions from that supplier.

We proposed that the bridge payment would be paid to the subsequent MDPP supplier any time a beneficiary changes suppliers during the MDPP services period, regardless of when during the core services period or ongoing services period the beneficiary changes MDPP suppliers. The bridge payment was not intended to be a performance payment, which could be paid to the subsequent MDPP supplier in addition to the bridge payment if a beneficiary achieves a performance goal while receiving MDPP services from that the subsequent supplier. Rather, the bridge payment would account for the financial risk a subsequent MDPP supplier takes on by furnishing services to a beneficiary changing MDPP suppliers during the MDPP services period. We believed that when suppliers furnish MDPP services to MDPP beneficiaries in these circumstances, they generally would not have the same opportunity for performance payments that they would have if the beneficiary had been receiving MDPP services from the supplier from the beginning of the MDPP services period because certain performance goals, such as the required minimum weight loss, might already have been achieved by the beneficiary. The proposed bridge payment policy would play an important role in ensuring access to MDPP services and freedom of choice of MDPP suppliers for those beneficiaries who either choose to or must change suppliers during the MDPP services period.

If we were to only make performance payments for MDPP services as proposed in sections III.K.2.d.iii.(3) through (6) of the proposed rule (82 FR 34141 through 34146) and not make a bridge payment to a subsequent supplier when an MDPP beneficiary changes suppliers during the MDPP services period, access problems could result due to the number of scenarios where subsequent MDPP suppliers offering and furnishing MDPP services would be paid no performance payment for the sessions furnished. We provided the following examples to illustrate such scenarios.

- A beneficiary changes from MDPP supplier A to MDPP supplier B after attending core session 4; attends core sessions 5 to 8 with supplier B; and then decides not to attend any more MDPP sessions. Supplier B does not meet the requirements for billing for the performance payment for the 9th core session because only 8 core sessions were attended, despite supplier B offering and furnishing core sessions 5 to 8.
- A beneficiary who has not met the required minimum weight loss performance goal changes from MDPP supplier A to MDPP supplier B after completing the first 3-month core maintenance session interval; attends 2 core maintenance sessions in months 9 through 12 with supplier B; and then fails to attend the 3rd core maintenance session in this interval. Supplier B does not meet the requirements for billing for the performance payment for the second core maintenance session interval despite offering and furnishing core maintenance sessions and the beneficiary eligibility for coverage of MDPP services then ends after month 12, the end of the core services period.

We believed that circumstances like these examples where subsequent MDPP suppliers would receive no payment for sessions furnished to MDPP beneficiaries who change suppliers during the MDPP services period in the absence of the bridge payment policy could lead to those MDPP suppliers preferentially seeking to furnish the remaining MDPP services during the MDPP services period to beneficiaries who have either already achieved the required minimum weight loss, or whom they believe will attend sessions and achieve weight loss, because the required minimum weight loss is tied to eligibility for ongoing maintenance sessions and higher performance payment for core maintenance session intervals.

We noted that we proposed in section III.K.2.e.iv.(4) of the proposed rule (82 FR 34163 through 34164) that MDPP suppliers may not deny access to MDPP services to eligible beneficiaries based on any reason other than the supplier's own capacity limits to furnish MDPP services to additional beneficiaries and on a discretionary basis if a beneficiary significantly disrupts the session for other participants or becomes abusive. However, MDPP suppliers could comply with this access requirement,

while still preferentially seeking to furnish the remaining MDPP services in the MDPP services period to MDPP beneficiaries they believe are most likely to achieve the performance goals. To ensure beneficiary freedom of choice of MDPP supplier, including the choice to change suppliers, we believed that our proposal to make a bridge payment would help mitigate the likelihood of MDPP suppliers acting on such preferences. The subsequent supplier would be paid a bridge payment for a beneficiary who changes suppliers, even if the beneficiary does not achieve performance goals that result in a performance payment being made to the subsequent supplier.

We considered an alternative policy in which the bridge payment would only be made in circumstances where the subsequent supplier would not be paid a performance payment that is based on attendance at the first session furnished by that supplier. For example, under this alternative if a beneficiary attends the first session during the ongoing maintenance session interval for months 13 through 15 at one MDPP supplier and then changes to a subsequent MDPP supplier that furnishes 2 additional ongoing maintenance sessions within that same interval and the beneficiary maintains the required minimum weight loss, the subsequent supplier would *not* be paid the $25 bridge payment but would be paid the ongoing maintenance session interval performance payment for months 13 through 15. The subsequent supplier would only be paid the $25 bridge payment if the beneficiary did not maintain the required minimum weight loss for the performance payment for that ongoing maintenance session interval. We did not propose this alternative because we believed it would be appropriate to make a bridge payment for the first session furnished by the subsequent supplier that expends resources for furnishing a session to a beneficiary not previously known to that supplier, unrelated to whether or not the beneficiary achieves a performance goal that results in a performance payment being paid to the subsequent supplier.

We proposed that an MDPP supplier could be paid either one performance payment for furnishing the first core session or one bridge payment per beneficiary, but not both. We proposed this policy because we believed that the potential to be paid both a performance payment for the first core session and a bridge payment, or multiple bridge payments, for the same beneficiary, could increase the risk of MDPP suppliers encouraging discontinuous care patterns. Such patterns could hinder the achievement of the required minimum weight loss that leads to a reduction in the incidence of type 2 diabetes and could lead to increased Medicare expenditures for MDPP services. Financial incentives resulting from the potential for multiple bridge payments to a single supplier for one beneficiary could lead MDPP suppliers to encourage beneficiaries to repeatedly change among them between sessions during the MDPP services period so that the suppliers may repeatedly bill for bridge payments. We believed that limiting the bridge payment to one per beneficiary per supplier and making it available for payment only if the performance payment for the first core session was not paid to that same supplier helps mitigate this risk. However, we did not propose to limit the number of MDPP suppliers that may be paid a bridge payment for a particular beneficiary because we are not proposing to limit beneficiary freedom of choice for MDPP suppliers. We proposed only to limit the bridge payments that a particular MDPP supplier may be paid for each MDPP beneficiary to one.

Although this proposed limit was intended to provide some protection against MDPP suppliers encouraging certain care patterns for the purposes of their financial gain alone, we understood there may be organizations enrolled in Medicare as the same supplier type but under separate MDPP supplier enrollment records that are part of a larger franchise or umbrella organization with shared financial interests. We noted that there is some program integrity risk that these organizations could coordinate to bill multiple bridge payments that would ultimately increase total MDPP payments to separately enrolled MDPP suppliers to serve the financial interests of the umbrella organization. This scenario could occur if MDPP suppliers systematically encourage beneficiaries to change suppliers for the purpose of being paid the bridge payment.

Although we believed that organizations under a larger umbrella organization may have a greater financial incentive and opportunity to engage in this behavior, we understood that any two or more MDPP suppliers could coordinate in this way, potentially affecting large numbers of MDPP beneficiaries. To mitigate this risk, we proposed to prohibit MDPP suppliers and other individuals or entities performing functions or services related to MDPP services on an MDPP supplier's behalf from unduly coercing an MDPP beneficiary's decision to change or not to change to a different MDPP supplier, including through the use of pressure, intimidation, or bribery as described further in section III.K.2.e.iv.(4) of the proposed rule (82 FR 34163 through 34164). We would monitor MDPP supplier billing patterns to detect how frequently bridge payments are paid and to determine whether patterns exists that may suggest fraudulent activity regarding bridge payment claim submissions across suppliers, conducting audits, medical reviews, and investigations as appropriate.

In the CY 2017 PFS final rule, we finalized at § 410.79(b) that a beneficiary's baseline weight refers to the MDPP beneficiary's body weight recorded during that beneficiary's first core session. This definition applies to determine weight loss throughout the MDPP services period. Additionally, the once-per-lifetime policy finalized at § 410.79(d)(1) applies if a beneficiary changes MDPP suppliers, and the services furnished by the subsequent supplier would begin where the beneficiary left off with the previous supplier. We recognized that these policies could require the beneficiary to request that a copy of his or her MDPP record be provided by the previous supplier to the subsequent supplier so that the subsequent supplier could determine whether the beneficiary achieves or maintains the required minimum weight loss and has information about the MDPP services already furnished. We also finalized at § 424.59(b) (proposed to be redesignated and amended as § 424.205(g)) that an MDPP supplier shall maintain documentation that includes services furnished and body weight measurements. Finally, we finalized at § 424.59(b) (proposed to be redesignated and amended as § 424.205(g)) that MDPP suppliers are required to maintain and handle any beneficiary PII and PHI in compliance with HIPAA, other applicable privacy laws and CMS standards. Any sharing of information from a beneficiary's MDPP record between MDPP suppliers must follow these rules, as applicable.

The proposed bridge payment was included at proposed § 414.84(c). We invited public comments on this proposal and the alternative considered. The following is a summary of the public comments received on the proposals for the bridge payment, and the alternative considered and our responses:

Comment: Many commenters supported the proposal to make a bridge payment to the subsequent MDPP supplier when a beneficiary switches

suppliers after receiving MDPP services from a previous supplier. The commenters stated that beneficiaries should be permitted to change MDPP suppliers during the course of the MDPP services period and, therefore, the bridge payment both supports beneficiary freedom choice to access his or her chosen DPP organization and provides some payment to the subsequent MDPP supplier enrolling the beneficiary in its DPP. The commenters claimed that the bridge payment would make a payment for some of the additional resources used by the MDPP supplier to establish the beneficiary within its DPP, as well as incentivize MDPP suppliers to take on beneficiaries midway through their MDPP services period. In contrast to this perspective, one commenter noted that bridge payments would not support continuity in the MDPP services period and have the potential to encourage fraud or ''cherry-picking'' of beneficiaries because beneficiaries could change MDPP suppliers at will. The commenter expressed concern that providing bridge payments would interfere with the ability of MDPP suppliers to have accurate tracking of progress through the DPP and across MA plans.

One commenter stated that although CMS proposed that only one bridge payment per MDPP supplier per beneficiary would be made, they believe that a performance payment for the first core session and a bridge payment to the same MDPP supplier may be needed under some circumstances, as well as two bridge payments to an MDPP supplier for an MDPP beneficiary under other circumstances. The commenter described the example of a beneficiary who enrolls with an MDPP supplier in Colorado, moves to Florida for the winter where the beneficiary continues MDPP services with another MDPP supplier in that state, and then returns to Colorado and wants to complete the DPP with the first MDPP supplier. The commenter pointed out the under the proposal, the Florida MDPP supplier would receive a bridge payment while the Colorado MDPP supplier would not, despite the need for the Colorado supplier to reengage the beneficiary when the beneficiary returned to Colorado after spending the winter in Florida. Therefore, the commenter urged CMS to allow a performance payment for the first core session and a bridge payment to be made for a single MDPP beneficiary to an MDPP supplier, as well as to allow two bridge payments per beneficiary per supplier to be made.

One commenter who expressed concern about the amount of switching between MDPP suppliers that could occur during a beneficiary's 36-month long MDPP services period urged CMS to limit changing suppliers to no more than two switches per beneficiary during any 1 year of the MDPP services period. Another commenter requested that CMS clarify how it will track how many times beneficiaries switch MDPP suppliers and whether there would be any limit on the number of times a beneficiary could switch MDPP suppliers.

Response: We appreciate the support of many of the commenters for our proposal to make one bridge payment per beneficiary per MDPP supplier during the MDPP services period. As we clarified in the CY 2017 PFS final rule (81 FR 80470), beneficiaries will be able to change MDPP suppliers at any time in order to ensure beneficiary freedom of choice of supplier under the MDPP expanded model.

Given this established policy which allows beneficiaries to change MDPP suppliers at any time during the MDPP services period, our bridge payment proposal was intended to partially account for the financial risk a subsequent MDPP supplier takes on by furnishing services to a beneficiary changing MDPP suppliers during the MDPP services period. We appreciate the concerns of the commenter about the potential for beneficiaries to change MDPP suppliers at will, thereby reducing continuity of care and the ability of MDPP suppliers to track the progress of MDPP beneficiaries in their DPPs. However, we understand from many commenters that beneficiaries switching MDPP suppliers during the MDPP services period may occur for a variety of reasons, including the relatively frequent circumstances where beneficiaries reside seasonally in different areas of the country. Therefore, we continue to believe that providing one bridge payment per beneficiary per MDPP supplier of $25 does not financially incentivize MDPP suppliers to encourage unnecessary switching but, instead, responds to the needs of beneficiaries and MDPP suppliers by reducing potential barriers to switching.

Furthermore, we expect that our different payment policies for core sessions, core maintenance session intervals, and ongoing maintenance session intervals that rely upon attendance at several sessions within a period of time and for weight loss performance payments will encourage the transfer of MDPP beneficiary records from a previous supplier to the subsequent supplier, which should facilitate continuity of care throughout the beneficiary's MDPP services period. For example, in order for a subsequent MDPP supplier to bill for a weight loss performance payment, to bill correctly for a core maintenance session interval performance payment, or to determine a beneficiary's eligibility for coverage and payment of an ongoing maintenance session interval, the subsequent MDPP supplier will need to acquire the MDPP beneficiary record from the previous supplier to have documentation of the beneficiary's baseline weight. In addition, in order to bill for an interval performance payment that requires attendance at multiple sessions and fully reflects the beneficiary's session attendance, the subsequent MDPP supplier will need to acquire the MDPP beneficiary record from the previous supplier to have documentation of sessions furnished by that supplier that count towards achievement of the attendance performance goal for the interval performance payment that will be billed by the subsequent MDPP supplier.

In response to the commenter who presented a scenario where one supplier furnished MDPP services to a beneficiary, the beneficiary then switched to a subsequent supplier that furnished sessions and was paid a bridge payment, and the beneficiary then switched back to the first MDPP supplier, we do not believe it would be appropriate to make a bridge payment to the first supplier in this scenario. We do not believe the financial risk or the supplier resources required for the first supplier to resume accountability for a beneficiary's MDPP services when that supplier already has a relationship with the beneficiary are so substantial that making a bridge payment to the first supplier would be appropriate, given that the first supplier would already have been paid the performance payment for the beneficiary's first core session. In addition, financial incentives resulting from the potential for two (or more) bridge payments to a single supplier for one beneficiary could lead MDPP suppliers to encourage beneficiaries to unnecessarily change among them between sessions during the MDPP services period so that the suppliers may bill for bridge payments. We believe that limiting the bridge payment to one per beneficiary per supplier and making it available for payment only if the performance payment for the first core session was not paid to that same supplier helps mitigate this risk.

We also do not believe it would be appropriate to limit the number of times a beneficiary can switch MDPP suppliers during the MDPP services period in order to preserve beneficiary access to care and freedom of choice.

We further believe that our final methodologies for performance payments and bridge payments do not incentivize beneficiaries to change MDPP suppliers nor MDPP suppliers to encourage beneficiaries to switch suppliers. While beneficiaries have full freedom of choice of MDPP suppliers during the MDPP services period, MDPP beneficiaries have no incentive under the policies of the MDPP expanded model itself to change MDPP suppliers during the MDPP services period. Furthermore, because we are limiting our bridge payment to only one per MDPP beneficiary per MDPP supplier that has not already received a performance payment for the first core session, MDPP suppliers do not have a financial incentive to encourage beneficiaries to unnecessarily change among them between sessions during the MDPP services period so that the suppliers may bill for bridge payments. Finally, as discussed in section III.K.2.d.iii.(10)(c) of this final rule, we are finalizing a HCPCS G-code for the bridge payment that will be submitted on a claim to CMS for the first session furnished by the subsequent supplier to an MDPP beneficiary who has previously received one or more MDPP services from a different MDPP supplier. Therefore, we will be able to obtain information about the number and pattern of beneficiaries switching MDPP suppliers during the MDPP services period from our analysis of administrative claims data.

Comment: Several commenters urged CMS to increase the proposed bridge payment amount of $25 because they believe it underestimates the amount of time and resources an MDPP supplier would need to spend to onboard a beneficiary to a subsequent MDPP supplier. One commenter claimed that successful transition of an individual from one MDPP supplier to another would require individual communication and research on the beneficiary's participation to date, production of new materials, and more administrative time than would be covered by the proposed bridge payment amount. The commenters requested that the bridge payment amount be increased to accurately reflect the time and effort of the subsequent MDPP supplier required for transitioning an MDPP beneficiary to that supplier.

Response: We appreciate the information provided by the commenters about the subsequent MDPP supplier resources that would be required for a successful transition of an MDPP beneficiary from one MDPP supplier to a subsequent MDPP supplier. We understand that the subsequent MDPP supplier will need to gather information about the beneficiary's participation to date in MDPP services, including obtaining the beneficiary's MDPP records from the previous supplier, in order to furnish the appropriate sessions and curriculum to the beneficiary.

However, we continue to believe a bridge payment in the amount of $25 is appropriate for the MDPP expanded model. While we acknowledge based on the commenters' description that the activities and resources required for a subsequent MDPP supplier to enroll an MDPP beneficiary in its DPP are somewhat different from those of the previous MDPP supplier that furnished the MDPP beneficiary's first core session, we continue to believe there is sufficient similarity between furnishing the first core session in the MDPP services period and furnishing the first session to an MDPP beneficiary who has previously received MDPP services from another supplier that the payment amounts should be the same.

We note that as discussed in section III.K.2.d.iii.(3) of this final rule, we are finalizing $25 as the performance payment for the first core session. In addition, as discussed in section III.K.2.d.ii. of this final rule, we are paying for the set of MDPP services through a performance-based payment methodology that makes periodic performance payments to MDPP suppliers during the MDPP services period. The aggregate of all performance payments constitutes the total performance-based payment amount for the set of MDPP services. The subsequent MDPP supplier, like the previous MDPP supplier, will have the opportunity to be paid performance payments based on where the beneficiary is in the MDPP services period when the beneficiary enrolls with the subsequent MDPP supplier and on the performance goals achieved by the beneficiary which receiving MDPP services from the subsequent supplier. The aggregate of the bridge payment and performance payments to the subsequent supplier will constitute the total performance-based payment amount for the MDPP services furnished to the MDPP beneficiary by the subsequent MDPP supplier.

Comment: Several commenters requested that CMS clarify how the performance payments would be made when a beneficiary switches MDPP suppliers during the MDPP services period, expressing concern about the adequacy of payment depending on the timing of the switch. A number of commenters provided the example of a beneficiary switching from supplier A to supplier B during the ongoing services period, after the beneficiary has already met the required minimum weight loss and many of the available performance payments have already been made to supplier A. The commenters noted that supplier B would then be responsible for offering ongoing maintenance sessions throughout the ongoing services period, which would require the use of supplier B's capital for which the remaining performance payments that may be made for MDPP services furnished to the beneficiary by supplier B may not be sufficient.

One commenter requested clarification about a specific scenario where the commenter was concerned that supplier B's payment could be penalized when a beneficiary switches suppliers. In the example presented by the commenter, the beneficiary attends 16 core sessions (months 1 to 6) with supplier A and achieves and maintains the required minimum weight loss. The beneficiary transfers to supplier B closer to her home and, in transferring, misses the first monthly (month 7) core maintenance session, but then attends 3 sessions (months 8 to 10) in a row. The commenter requested that CMS clarify if supplier B would still receive a bridge payment, since the month 7 session was not attended. The commenter further requested that CMS provide information about whether supplier B would be paid for the full second core maintenance session interval if the beneficiary completes 3 sessions in months 11 to 13; whether supplier B should bill only for months 10 to 12; or whether performance payments for core maintenance sessions intervals would not be made to supplier B because the beneficiary did not attend the month 7 session.

Response: With respect to the commenters concerned about MDPP suppliers having sufficient capital to offer ongoing maintenance sessions to beneficiaries who switch suppliers during the ongoing services period after most performance payments have been made, we believe the bridge payment provides appropriate payment for the first ongoing maintenance session furnished to the beneficiary by the subsequent supplier. The subsequent supplier then must offer ongoing maintenance sessions in accordance with the beneficiary's coverage of ongoing maintenance session intervals and will be paid ongoing maintenance session interval performance payments if the beneficiary achieves the performance goals of attendance and maintenance of the required minimum weight loss for the interval.

Because the beneficiary has already achieved the required minimum weight loss and ongoing maintenance sessions must only be offered monthly to the beneficiary, we do not believe that the resources used by the subsequent supplier are so substantial that subsequent suppliers will be unable to offer these sessions to beneficiaries. An MDPP beneficiary who has achieved the required minimum weight loss will already be knowledgeable about the health behavior changes taught in MDPP sessions and will have experienced success incorporating these changes in a meaningful way in his or her own life such that weight loss results. Thus, we expect that subsequent MDPP suppliers offering monthly sessions to these beneficiaries during the ongoing services period will not have to work particularly hard to engage these beneficiaries. In addition, the subsequent MDPP supplier knows they will be paid a bridge payment for the first session furnished and they may also be paid ongoing maintenance session interval performance payments if the beneficiary meets the performance goals for those payments in the future.

In the specific scenario where the beneficiary transfers to subsequent supplier B and misses the month 7 core maintenance session but resumes attending monthly sessions in month 8, supplier B can bill the bridge payment for its first session furnished to the beneficiary, which would be the month 8 core maintenance session. With respect to the beneficiary's month count that defines the core maintenance session interval in the core services period, that does not change based on when the beneficiary attends core maintenance sessions furnished by any MDPP supplier. Therefore, the beneficiary's core maintenance session intervals would always be months 7 to 9 and months 10 to 12 from the date the first core session was furnished to the beneficiary by supplier A.

As finalized in section III.K.2.d.iii.(4) of this final rule, we are adopting a 2-session attendance performance goal for the core maintenance session interval performance payment. Therefore, in the specific scenario described by the commenter where the beneficiary switches suppliers and does not attend any core maintenance session in month 7, but attends core maintenance sessions in months 8 and 9 furnished by supplier B, in addition to the bridge payment to supplier B, supplier B would also bill and be paid for the appropriate HCPCS G-code for the first core maintenance session interval (months 7 to 9) based on whether or not the required minimum weight loss was maintained (in the commenter's scenario, the required minimum weight loss was achieved with supplier A prior to month 7, and 2 core maintenance sessions were furnished by supplier B in months 8 and 9). Similarly, and regardless of the beneficiary's attendance at core maintenance sessions in months 7 to 9, supplier B would bill and be paid for the appropriate HCPCS G-code for the second core maintenance session interval (months 10 to12) if the beneficiary attends at least 2 sessions furnished by supplier B in that 3-month period and the interval performance payment amount would be based on whether or not the required minimum weight loss was maintained.

After considering the public comments received, we are finalizing the proposals, without modification, for the bridge payment at § 414.84(c).

In the proposed rule (82 FR 34155), we also discussed ways to streamline the sharing of information between suppliers about a beneficiary's progress in the MDPP services period when a beneficiary switches suppliers, such as through the development of a model tracker that logs the contact information of a beneficiary's previous supplier and/or coach, and the beneficiary's attendance and weight loss. Beneficiaries could take the tracker with them if they change suppliers during the MDPP services period. Such a tracker would not supplant the previous supplier's beneficiary MDPP record which the subsequent supplier would need to have a copy of in order to consider sessions furnished by the previous supplier in determining whether the subsequent supplier could bill for a performance payment that was based in part on those prior sessions as discussed in section III.K.2.d.iii.(10)(b) of the proposed rule (82 FR 34148 through 34149). If the subsequent supplier did not have the beneficiary's MDPP record from the previous supplier, the subsequent supplier could not use information from the sessions furnished by the previous supplier, such as weight or session attendance, to determine that the performance goals for a performance payment were met so that the subsequent supplier could bill for the performance payment. However, it might help facilitate the process for subsequent suppliers to enroll beneficiaries partway through the MDPP services period while the subsequent supplier is coordinating with the previous supplier to obtain a copy of the beneficiary's MDPP record from that supplier. We invited public comments on additional ways this data sharing could be streamlined between suppliers.

The following is a summary of the public comments received on additional ways information sharing could be streamlined between suppliers regarding beneficiaries switching MDPP suppliers during the MDPP services period and our responses:

Comment: Several commenters claimed that switching among MDPP suppliers may be more common than CMS appeared to have anticipated in the proposed rule discussion about bridge payments. They expressed concern about the operational implications of managing the MDPP services period for Medicare beneficiaries across hundreds of MDPP suppliers when MDPP beneficiaries change suppliers, circumstances that the commenters speculated may lead to disruptions for the beneficiary and added cost for the MDPP supplier.

The commenters requested that CMS provide greater detail on how the handoff between an MDPP beneficiary's current MDPP supplier to a subsequent MDPP supplier should occur when a beneficiary changes suppliers. Specifically, they sought additional written guidance on the required information to be transmitted and the format and method of transmission in order for a proper transition of a beneficiary from one MDPP supplier to the subsequent MDPP supplier to occur, especially given their expectation that transitions may be common for Medicare beneficiaries who live in different locations in the summer and winter months. The commenters urged CMS to provide this guidance to avert potential HIPAA issues when transferring protected health information among MDPP suppliers, especially when many MDPP suppliers will be new to the healthcare environment and lack prior experience with performing HIPAA compliant transfers.

While several commenters described a number of challenges related to the transfer of beneficiary information between MDPP suppliers and requested additional guidance from CMS, one commenter presented an approach to facilitating the transfer of information that would be based on encouraging beneficiaries to switch among MDPP suppliers within a supplier network that uses a shared data-management solution. The commenter reported that there are several DPP organizations all around the country that use a single data platform. They suggested that DPP organizations within a single supplier network could develop a simple process within their current platform that would allow the MDPP services information to be transferred from one supplier to

another within the supplier network. The commenter claimed that this approach would be more secure and less costly than CMS developing a comprehensive database or having individual MDPP suppliers transfer beneficiaries' MDPP records to other MDPP suppliers via fax or mail. However, they acknowledged that this approach could result in other concerns, such as favoring supplier networks, and further noted that there are areas of the country that even these larger supplier networks do not reach, which would result in the need for a backup solution for information transfer.

Response: We appreciate the commenters raising issues related to information transfer when MDPP beneficiaries switch suppliers during the MDPP services period, and in particular for suggesting potential solutions to mitigate the challenges in this regard under the policies of the MDPP expanded model. We recognize that given the maximum 24-month long duration of the MDPP services period, MDPP suppliers should anticipate and prepare for beneficiaries switching between suppliers.

We appreciate that certain networks have independently worked towards use of a single data platform by all DPP organizations in the network that could facilitate the transfer of MDPP services information for beneficiaries who may switch among suppliers in a single network.

While we are not adopting any specific MDPP beneficiary information transfer policies or data systems at this time, we acknowledge the concerns raised by the commenters about subsequent MDPP suppliers having correct and timely information about MDPP beneficiaries enrolling in the subsequent supplier's DPP in the middle of the MDPP services period, given our policy that allows full beneficiary freedom of choice of MDPP supplier. As discussed in more detail in section III.K.2.c.iii of this final rule, we are exploring using existing CMS systems for MDPP suppliers to verify beneficiaries' use of prior MDPP services and plan to provide additional information on this mechanism in future guidance, as appropriate. However, this eligibility check will not supplant the need for MDPP suppliers to maintain documentation as described at § 424.205(g). We note that health care providers often exchange clinical data when their patients seek care from different providers, and we do not view the need for subsequent MDPP suppliers to obtain beneficiary-level MDPP services data from a previous MDPP supplier as a unique circumstance.

We remind subsequent MDPP suppliers that in order to submit a claim for a performance payment under the MDPP expanded model, the billing supplier must have documentation in the beneficiary's MDPP record that all requirements, including the achievement of the performance goal(s) applicable to the performance payment, have been met. The billing supplier's MDPP record for the beneficiary may include a copy of the beneficiary's MDPP record from a previous MDPP supplier that has been provided to the billing supplier at the request of the MDPP beneficiary. If an MDPP supplier is submitting a claim for a performance payment based on the achievement or maintenance of the required minimum weight loss or an interval performance payment based on attendance at more than one session, the copy of the MDPP record from the previous MDPP supplier may be used as part of the billing supplier's documentation demonstrating that the attendance or weight loss performance goal for the performance payment was achieved.

In terms of how MDPP suppliers transfer beneficiary data in a HIPAA-compliant manner, we recommend that MDPP suppliers consult with counsel to determine whether they qualify as a HIPAA-covered entity, and, if so, how to manage and transfer data appropriately based on applicability of HIPAA, other applicable state and federal privacy laws, and CMS standards as required. Resources already exist to help provide guidance on these issues and are available at *https://www.hhs.gov/hipaa/for-professionals/index.html* and *https://www.healthit.gov/providers-professionals/ehr-privacy-security*.

e. Supplier Enrollment and Compliance

i. Preliminary Recognition

The current CDC 2015 Diabetes Prevention Recognition Program (DPRP) Standards do not have standards for preliminary recognition. In the CY 2017 PFS final rule, we indicated that we would align the CDC's DPRP Standards and the set of MDPP services, to the extent possible. It will not be possible for CMS to permit DPP organizations to enroll as MDPP suppliers based on achievement of any new CDC standard through this rulemaking because any updates to the CDC Standards are not expected to go into effect until 2018.

However, our intent is to allow organizations that do not yet have full recognition, but have demonstrated a capacity to furnish DPP services, to enroll in Medicare as of the effective date of the enrollment policies in this rule. We believe this will increase access to MDPP services. For this reason, we proposed, at § 424.205(c), to establish an MDPP interim preliminary recognition standard to permit DPP organizations who meet this standard to enroll in Medicare even if they do not have full CDC recognition. This MDPP interim preliminary recognition standard will be hereafter referred to as ''interim preliminary recognition.'' As we stated in CY 2017 PFS final rule, our intent with this policy is to bridge the gap until such time as any CDC preliminary recognition standards are established following publication of the their DPRP Standards in 2018. Once we have established the transition process with CDC, we would expect DPP organizations that seek to enroll into Medicare to obtain CDC preliminary recognition, but MDPP suppliers who have enrolled in Medicare with interim preliminary recognition would maintain their enrollment eligibility as an MDPP supplier.

(1) MDPP Interim Preliminary Recognition Standard

We proposed, at § 424.205(c)(1)(ii)(B), that DPP organizations with pending CDC recognition that meet the following additional criteria would meet the interim preliminary recognition standard:

- The organization must continue to follow the current 2015 CDC DPRP Standards for data submission and submit a full 12 months of performance data to CDC on at least one completed cohort (see Appendix D, 2015 CDC DPRP Standards, *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf*). For this purpose, a completed cohort is a set of participants that entered into a lifestyle change program that has a fixed first and last session and runs for 12 months. An organization can have multiple cohorts running at the same time:
- The 12-month data submission to CDC includes at least 5 participants who attended at least 3 sessions in the first 6 months, and whose time from first session attended to last session of the lifestyle change program was at least 9 months; and
- Of the participants eligible for evaluation in the first criterion, at least 60 percent attended at least 9 sessions in months 1 through 6 and at least 60 percent attended at least 3 sessions in months 7 through 12.

All data requirements reflect current reporting requirements to progress from pending recognition to full recognition through CDC's DPRP; no new data collection would be required.

To implement the interim preliminary recognition standard, DPP organizations

with pending recognition would submit data following CDC's typical recognition process. For the current standards, this includes data submission every 12 months, during the month of the anniversary of the effective date. The organization's data submission should include: (1) Data for all sessions attended by participants from the approval date to the day before the first anniversary of the effective date, (if the organization has a 2016 effective date; this should include at least 6 months of participant data) *or* data for all sessions attended by participants from the last anniversary of the effective date to the day before the next anniversary of the effective date (if an organization's effective date is before 2016); and (2) one record for each session attended by each participant during the preceding year. CDC would perform a new assessment, interim preliminary recognition, on our behalf. Our interim preliminary recognition will be evaluated by CDC based on those data submissions that use the timetables and submission deadlines that currently apply for CDC recognition. For interim preliminary recognition governed under this regulation, CDC would provide us with its recommendation as to which organizations have met the recognition standards for interim preliminary recognition, but we, using our authority, would make the final decision. CMS would not make any determination for recognition status governed under current or future CDC DPRP recognition processes. We believe that such an approach would minimize burden for DPP organizations, promote consistency in the application of the standards, and allow for a smooth transition if and when CDC adopts preliminary recognition standards. We intend to release additional guidance on the details of this process once the CDC 2018 Standards are released.

(2) MDPP Supplier Enrollment Under the MDPP Interim Preliminary Recognition Standard

Our regulations at § 424.59 (redesignated and amended at § 424.205 in this final rule) specify that a DPP organization with full CDC recognition is eligible for enrollment as an MDPP supplier if it also meets all of the other conditions for enrollment in § 424.59(a) (redesignated and amended at § 424.205(b) in this final rule). We proposed that organizations that meet the MDPP interim preliminary recognition standard, in section III.K.2.e.i.(1) of this final rule, and meet all other enrollment conditions would also be eligible to enroll as an MDPP supplier.

We also proposed that DPP organizations would be eligible to enroll as an MDPP supplier if they meet CDC DPRP Standards for preliminary recognition, once any such standards go into effect (§ 424.205(c)(2)(i)). We anticipate that CDC's preliminary recognition standards will be established on or after January 1, 2018. After the effective date of any updated CDC standards, we proposed that MDPP suppliers who have enrolled in Medicare with MDPP interim preliminary recognition would continue to be eligible for MDPP enrollment (assuming they continue to meet all other requirements for enrollment, described in § 424.205(b)). We intend to ensure that any transition an MDPP supplier may make from interim preliminary recognition to CDC preliminary recognition does not disrupt its status as an MDPP supplier. We will address possible transition issues in future rulemaking or guidance, as appropriate.

We considered an alternative to wait until new CDC DPRP Standards are effective to allow organizations other than those with full recognition to enroll as MDPP suppliers. However, as indicated in the CY 2017 PFS final rule, based on CDC data we believe that waiting until the new DPRP Standards are effective would limit the number of organizations with demonstrated capacity to furnish the set of MDPP services from enrolling in Medicare when enrollment starts and offering MDPP services once they become effective. We invited public comments on this MDPP interim preliminary recognition standard, including performance standards, and the use of this standard as a condition for enrollment in Medicare, and the alternative considered.

The following is a summary of the public comments received on the MDPP interim preliminary recognition standard, including performance standards, and the use of this standard as a condition for enrollment in Medicare proposal and the alternative considered and our responses:

Comment: The majority of commenters supported requiring MDPP organizations to obtain CDC DPRP Recognition, including any preliminary recognition standard CDC finalizes and interim preliminary recognition. Commenters appreciated the provision of more information on the proposed interim preliminary recognition standard and noted the importance of having the interim preliminary recognition process in place to increase the capacity of MDPP.

A commenter requested that a master database of those organizations that meet this new standard be made publicly available well in advance of the effective date of when MDPP services can be delivered and payments made to give suppliers more time to appropriately arrange for the MDPP on behalf of its members.

Response: We appreciate and acknowledge the need for both beneficiaries and clinicians to have access to information on MDPP enrolled suppliers. We note that the CDC currently publishes a registry of recognized DPP organizations online (*https://nccd.cdc.gov/ddt_dprp/registry.aspx*). We intend to make information on MDPP suppliers enrolled for the purposes of the MDPP expanded model publicly available through a Web site and intend to release guidance, as appropriate, on where this information will be located.

Comment: There was agreement among some commenters that DPP organizations that have applied for CDC recognition and have delivered the program for at least 12 months are more likely to demonstrate commitment and results to offer MDPP services. However, several commenters expressed concern about the interim preliminary recognition requirement to submit 12 months of data to CDC because their communities do not collect the data when there is no support or funding for this type of program. They also commented that a majority of partnering programs lack awareness of the process, the criteria, and the period of time it takes programs to become CDC-recognized. Another commenter requested that individuals included in the data set should attend four sessions, and not three, in months 1–6 to better align with scientific literature about CDC's threshold of four or more sessions attended as well as previous and current DPRP standards. For an example, the commenter noted, there is a body of knowledge within organizations and in the scientific literature about CDC's threshold of four or more sessions attended and that it does not make sense to change this threshold, especially when there is lack of data (none was provided by CMS or CDC's DPRP in their proposed 2018 standards) to support the change. Finally, we received a comment recommending that interim preliminary recognition be phased out over time as CDC updates its standards and the program matures.

Response: We acknowledge that it may be difficult for some organizations that need financial support while they are collecting data to obtain CDC DPRP Recognition. We understand from our

coordination with CDC that some organizations obtain financial support from grants through various sources and that there are currently over 100 payers and/or employers offering coverage for the National DPP in selected markets. Despite the time and resources it takes to achieve CDC recognition, we continue to believe the MDPP preliminary recognition standard is an appropriate minimum standard for DPP organizations to obtain prior to enrollment as an MDPP supplier.

To increase awareness of the process, the criteria, and the period of time it takes programs to become CDC-recognized and then implement MDPP, we intend to provide MDPP supplier support through webinars and other types of guidance and education tools. We will continue to coordinate with CDC to provide relevant resources regarding both CDC recognition as it relates to the MDPP expanded model for organizations preparing to become MDPP suppliers.

We disagree that there is a lack of data about the inclusion of individuals who attend 3 sessions (versus 4) as part of the DPRP data submission. CDC DPRP data show no difference in average percent weight loss for those who attend 3 sessions compared to 4, and therefore we believe including participants who have attended at least 3 sessions as compared to 4 will provide data to make an appropriate assessment for the purposes of MDPP preliminary recognition. Furthermore, by allowing organizations to submit data on individuals who have attended 3 sessions (versus 4), we are increasing the number of organizations who are potentially eligible to achieve interim preliminary recognition.

In response to the comments about phasing out interim preliminary recognition as CDC updates its Standards, we reiterate our intent to align data requirements with CDC Standards. The proposed CDC 2018 Standards include the same requirements for CDC preliminary recognition as we proposed for interim preliminary recognition.[41] As described in section III.K.2.e.i.2 of this final rule, after the effective date of these updated CDC Standards, MDPP suppliers who have enrolled in Medicare with interim preliminary recognition would continue to be eligible for MDPP enrollment (assuming they continue to meet all other requirements for enrollment, described in § 424.205(b)). We intend to phase out interim preliminary recognition and ensure that any transition an MDPP supplier may make from interim preliminary recognition to CDC preliminary recognition does not disrupt its status as an MDPP supplier. We will address possible transition issues in future rulemaking or guidance, as appropriate.

Comment: One commenter raised concerns about what would happen to beneficiaries whose MDPP suppliers lost their MDPP supplier status due to loss of CDC DPRP recognition and recommended allowing organizations who move from ''preliminary'' to ''pending'' after 24 months to continue to serve MDPP participants but not be able to enroll any new beneficiaries. If after the 12 months of work to improve outcomes the organization is not successful, then at least the beneficiary would be through the first year of the program and would move to a new supplier for ongoing maintenance.

Response: Last year, we finalized in § 424.59(d) that the loss of CDC DPRP recognition will result in revocation of a supplier's MDPP billing authority. An example of when this might happen is when an organization is unable to meet the requirements for full recognition after having been in MDPP preliminary recognition for 24 months. In this rule, we maintained the policy, but modified the language to take into account the addition of interim preliminary recognition, such that, if an MDPP supplier does not satisfy any of the enrollment requirements (finalized at § 424.59(a) and proposed to be redesignated and amended at § 424.205(b)), which include having preliminary or full recognition, their enrollment would be revoked (proposed at § 424.205(h)(1)(i)(B)).

We disagree that allowing MDPP suppliers whose MDPP billing authority has been revoked should still provide MDPP services to beneficiaries. When their supplier's MDPP billing authority has been revoked beneficiaries may switch to a new MDPP supplier so they can complete their program.

Comment: Regarding interim preliminary recognition and CDC preliminary recognition, a commenter recommended that we should allow organizations to submit for preliminary recognition when the first year of data are collected, on a rolling basis. For an example, with the new standards requiring data submissions every 6 months, the commenter noted that organizations starting their program in the first 5 months of the program would be punished by waiting until they were 18 months into the program, which is when their next data reporting submission would occur. Another commenter noted that while the current interim preliminary recognition standard focuses on the attendance of the DPP cohort, there is no performance metric associated with the criteria.

Response: In response to the comment about timing of the 12-month data submission for preliminary recognition, the commenter is correct that it is possible that an organization may not have a full 12 months' worth of data needed for preliminary recognition at the 12-month data submission point. In this case, organizations could submit the 12 months of data needed for preliminary recognition at the next 6-month data submission interval, or 18 months from their effective date, to achieve preliminary status. The interim preliminary recognition finalized in this rule represents a new category of recognition that does not include a weight loss requirement and provides an intermediate step on the path to full recognition. We believe the time it takes to achieve interim preliminary recognition is reasonable since it has reduced the amount of time it may take an organization initiating the CDC recognition process to enroll as an MDPP supplier from 36 months (full recognition) to 12–18 months (MDPP interim preliminary recognition).

In response to the comment regarding establishing a performance metric for interim preliminary recognition, we proposed standards for interim preliminary recognition (which are the same standards CDC has proposed for preliminary recognition in their 2018 DPRP standards) that rely on attendance based measures, not weight loss. We discussed in the CY 2017 PFS final rule (section III.J.7.b of this final rule) that we believed that full recognitions status, which relies on weight loss measures, would be challenging for many organizations to meet initially and, without broadening the eligibility for an MDPP supplier to enroll, we may limit the number of MDPP suppliers available for beneficiaries to access MDPP services. We continue to believe the standards we are finalizing for interim preliminary recognition will adequately assess DPP organizations' capacity to become MDPP suppliers, and thereby increase the numbers of eligible organizations that beneficiaries can access for MDPP services.

Updates to the CDC Standards are not expected to go into effect until 2018, and we are working closely with CDC on maintaining our alignment between interim preliminary recognition and its proposed standards in the 2018 DPRP Standards.

Comment: Some commenters requested that the Special Diabetes Program for Indians (SDPI) Diabetes

[41] *https://www.gpo.gov/fdsys/pkg/FR-2017-07-14/pdf/2017-14792.pdf.*

Prevention (DP) program be certified as grandfathered in to provide services and receive reimbursement through the MDPP given that it continues to achieve similar results as the National Institutes of Health DPP lifestyle intervention group.

Response: For the purpose of the MDPP services, CDC-recognition is being used for supplier eligibility because the Secretary's determination to expand the DPP model test was based on the CDC-approved program. Consequently, we are not considering other accrediting bodies or standards at this time, nor are we considering grandfathering in programs so they can receive payments for MDPP services without meeting the standards finalized in this rule or finalized in the CY 2017 PFS final rule.

We acknowledge the major contributions of the Special Diabetes Programs for Indians (SDPI) Diabetes Prevention Program (DPP) Demonstration Projects and the many resources—such as the SDPI Diabetes Prevention Toolkit—insights, and lessons learned these projects have contributed on both a local and national level. However, we decline grandfathering in the SDPI programs and making an exception to the MDPP requirements. We do not believe a separate type of recognition can be created for SDPI programs without compromising our intent to rely on the CDC's DPRP. Through the DPRP, CDC is responsible for carrying out a quality assurance function at the national level. Under the CDC's DPRP, we will enroll CDC-recognized organizations that are standardized in delivering the evidence-based behavior change program with quality and fidelity to the original science and subsequent translation studies achieving the outcomes proven to prevent or delay onset of type 2 diabetes. The nine requirements in the DPRP Standards apply equally to all organizations that apply for CDC recognition, regardless of size, experience, capacity, or populations served. We know from CDC that DPRP data collected to date indicate that all types of organizations are successful in achieving full recognition, and that CDC could not meet its obligation to ensure quality of recognized organizations enrolling as MDPP suppliers if each organization was allowed to use a different set of measures.

We recommend that tribal organizations work with CDC to help tribal organizations offering the SDPI lifestyle change program, meet the DPRP Standards set by CDC. We welcome continued consultation with tribes and tribal organizations as required by the CMS Tribal Consultation Policy.[42]

Comment: While unrelated to the specific proposed policy on preliminary recognition and supplier enrollment, we received several comments regarding our previously finalized proposal in the CY 2017 PFS final rule to require Medicare-enrolled suppliers to furnish MDPP services. One commenter expressed uncertainty as to whether the Medicare enrollment requirement in the CY 2017 PFS final rule created a new requirement for all Medicare Advantage providers and suppliers to be enrolled in Medicare by January 1, 2019. This commenter further inquired whether this requirement would apply to coaches and other personnel or suppliers who may provide MDPP services, noting that this requirement would be burdensome if applied to MDPP and should be lifted for MDPP services.

Response: While we did not propose any new policies related to the requirement for any organization seeking to furnish and receive payment for MDPP services to enroll as an MDPP supplier, we are responding to comments regarding enrollment and Medicare Advantage to clarify this issue. Regarding commenter's recommendation to lift the requirement that coaches who provide MDPP services be Medicare-enrolled, we clarify the requirements of coaches who provide MDPP services to beneficiaries. In the CY 2017 PFS final rule, we finalized the requirements for coaches furnishing MDPP services and established that coaches will not enroll in Medicare for purposes of furnishing MDPP services, but that they would be required to obtain NPIs (81 CFR 80479).

Regarding other commenters' recommendations to lift the requirement that suppliers who provide MDPP services be Medicare-enrolled, we decline to adopt the commenters' proposals to eliminate the Medicare enrollment requirement for MDPP supplier-MAOs or for MDPP suppliers with whom MAOs contract to furnish MDPP services. In the CY 2017 PFS final rule, we also finalized the requirement that CDC-recognized organizations that will bill Medicare for MDPP services must enroll in Medicare as MDPP suppliers. MAOs must comply with 42 CFR part 422, subpart E in their relationships with providers; regulations in that subpart generally prohibit employing or contracting with individuals who are excluded from Medicare and require MA organizations to provide basic benefits (that is, Part A and Part B services) only through health care providers that meet the applicable requirements of Title XVIII. We previously issued guidance following the CY 2017 PFS final rule in a November 23, 2016 HPMS guidance memo that we now reiterate. In that HPMS memo, we established that, in order to provide MDPP services, a Medicare health plan such as an MA plan, may choose to contract with an organization that is Medicare-enrolled as an MDPP supplier, or become Medicare-enrolled as an MDPP supplier itself. MA plans that choose to contract with outside Medicare-enrolled MDPP suppliers should follow their normal protocols in accordance with applicable regulations. Medicare health plans that choose to become Medicare-enrolled MDPP suppliers are subject to the supplier enrollment eligibility requirements finalized in this final rule at § 424.205.

Comment: One commenter pointed out that for a Medicare Advantage Organization with an MA plan that is part of an integrated system with pending CDC-recognition, the Medicare-enrollment requirement would interfere with the MAO's ability to contract with providers with which the MAO has existing risk-based relationship that can be aligned with the MAO's incentives with providers.

Response: As stated previously in this section, we finalized the requirement that CDC-recognized organizations that will bill Medicare for MDPP services must first enroll in Medicare as MDPP suppliers. This policy was followed by an HPMS memo that reiterated that, in order to provide MDPP services, a Medicare health plan such as an MA plan, may choose to contract with an organization that is Medicare-enrolled as an MDPP supplier, or become Medicare-enrolled as an MDPP supplier itself. In response to this commenter's concern related to MAOs that operate MA plans as part of an integrated network, where an MA plan is part of such a network and is either not interested in enrolling in Medicare as an MDPP or supplier or has not yet achieved the CDC-recognition required to enroll in Medicare, there is no Medicare prohibition that would prevent an MA plan from contracting with Medicare-enrolled MDPP suppliers under terms that would integrate these suppliers into the existing network or impose risk-based relationships on the newly contracted supplier.

[42] Centers for Medicare & Medicaid Services, ''CMS Tribal Consultation Policy,'' Centers for Medicare & Medicaid Services, 2015, *https://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/AIAN/Downloads/CMSTribalConsultationPolicy2015.pdf.*

Comment: We received several comments expressing concern about a given MA plan's ability to meet network adequacy requirements based on the number of organizations that are currently eligible to enroll in Medicare as MDPP suppliers (which requires CDC recognition). Commenters noted that some geographic locations may not have an MDPP supplier with which an MA plan may contract to provide MDPP services to its enrollees by the proposed effective date of April 1, 2018. Under these circumstances, commenters noted that eligible beneficiaries may not find these travel distances feasible or safe and that it is unlikely that coaches will be able to regularly travel hundreds of miles to a class. One commenter noted that, while there are organizations currently in the process of obtaining CDC recognition, the state of Utah is currently without any CDC-recognized organization that has advanced beyond pending status. This commenter additionally noted that there is currently no way of knowing which organizations will achieve preliminary recognition status in time for an MA plan to establish contracts by the April 1, 2018 start date. We also received comments that specifically recommended that CMS relieve MA plans of the requirement to submit network adequacy information and include MDPP-qualified providers in network adequacy reviews for the same reasons stated above related to the perceived lack of MDPP suppliers to meet these requirements.

Response: In response to concerns expressed by MAOs regarding their ability to meet network adequacy standards for MA plans, we note that when a particular provider-type or facility-type (such as MDPP suppliers) is absent from a service area, an MA plan must provide enrollees with a level of access to Medicare-covered services that is consistent with prevailing community patterns of care under § 422.112(a)(10). As part of its evaluation of network adequacy in connection with this standard, CMS looks to several factors, including the number and distribution of health care providers in both commercial plans and in Original Medicare capable of furnishing the covered services. In some instances, delivery of covered services consistent with community patterns of care can mean that in order to receive a Medicare-covered service, an MA plan enrollee might have to travel to a provider/facility that is geographically distant from his or her plan's service area. The MA plan would not be required to cover travel expenses in this case (but may elect to cover such expenses as a supplemental benefit) as long as the MA plan is referring the enrollee to providers in a manner consistent with community patterns of care. We therefore decline to relieve MA plans of any general network adequacy requirements, or the requirement to provide access to MDPP services.

After considering the public comments, we are finalizing our proposals, without modification, for MDPP preliminary recognition under the MDPP expanded model at § 424.210(c).

ii. Enrollment and Billing Effective Dates

(1) Date MDPP Suppliers May Begin Enrollment

As described in section III.K.2.a. of the CY 2018 proposed rule (82 FR 34131), we proposed to change the start date of the MDPP expanded model to April 1, 2018. All other policies not related to the furnishing or billing of MDPP services would, if finalized, be effective January 1, 2018. Thus, although MDPP suppliers would not be able to begin furnishing MDPP services on January 1, 2018, MDPP supplier enrollment would begin on January 1, 2018, if these proposals are finalized. In the CY 2017 PFS final rule, we established that any organization wishing to furnish MDPP services must enroll as an MDPP supplier, regardless of any existing enrollment in Medicare. As indicated in section J.4. of the CY 2017 PFS final rule, we believe that including an effective date for enrollment that precedes the implementation date for MDPP services is necessary to allow organizations sufficient time to enroll as MDPP suppliers. Thus, MDPP services would only become available after there is sufficient time to enroll MDPP suppliers that will furnish those services.

The following is a summary of the public comments received on the date MDPP suppliers are able to enroll.

Comment: Of the comments we received on this issue, the majority expressed support for the enrollment start date of January 1, 2018. In their agreement, some commenters stipulated that having a 90-day period between when MDPP supplier enrollment began and when enrolled suppliers could begin furnishing MDPP services would provide both a reasonable and necessary timeframe for organizations to enroll and ensure compliance. One commenter in support of this policy urged that CMS maintain this timeline. The same commenter specifically requested that, though implied, CMS clarify that the enrollment period for MDPP suppliers does not begin on January 1, 2018 and end of April 1, 2018. Other commenters in support of this policy urged that CMS provide guidance materials and resources to help prospective MDPP supplier applicants prepare for and ultimately enroll into Medicare. Commenters requested that this information be made available as soon as possible, with one commenter specifically requesting that CMS issue a timeline under which prospective MDPP supplier applicants should expect CMS to release such information.

Response: We clarify that though MDPP supplier enrollment begins on January 1, 2018, enrollment in Medicare occurs on a rolling basis with no current or expected end date when MDPP supplier applications would no longer be accepted. Prospective MDPP supplier applicants should submit their enrollment application on or after January 1, 2018 once they are ready to do so. Given the time it takes to successfully process an enrollment application and potential delays in that process, we encourage prospective MDPP supplier applicants to apply as soon as feasible for the organization.

Comment: One commenter did not believe that any delay was necessary given that organizations were already enrolled and prepared to begin furnishing MDPP services.

Response: We believe the commenter may have misunderstood previously finalized policies in the CY 2017 PFS final rule. We clarify that only entities enrolled as MDPP suppliers may furnish MDPP services to beneficiaries. Thus, regardless of any previous enrollment in Medicare, all entities wishing to furnish these services must enroll as an MDPP supplier on or after January 1, 2018.

After consideration of the comments received on the MDPP supplier enrollment start date, we are finalizing this policy as proposed. MDPP supplier enrollment shall begin on January 1, 2018, when the policies in § 424.205 that enable MDPP supplier enrollment become effective.

(2) Effective Date of MDPP Suppliers' Billing Privileges

Under § 424.502, the definition of enroll/enrollment means ''the process that Medicare uses to establish eligibility to submit claims for Medicare-covered items and services, and the process that Medicare uses to establish eligibility to order or certify Medicare-covered items and services.'' Thus, the purpose of enrollment is to establish billing privileges in Medicare. In accordance with our proposal that MDPP services will be available

beginning on April 1, 2018 (82 FR 34131), we proposed that MDPP suppliers may not have an effective date of billing privileges that precedes the date that MDPP services become available (82 FR 34157 through 34158 and proposed at § 424.205(e)(2)). Given that it typically takes 45–60 days for an enrollment application days to be processed, if an MDPP supplier submitted its application in January, the application may be approved prior to when MDPP services become available on April 1, 2018. For this reason, we specified that, under no circumstances would an MDPP supplier have an effective date for billing privileges for MDPP services prior to April 1, 2018.

We proposed that for MDPP supplier enrollment applications that are submitted and subsequently approved, the effective date for billing privileges would be the date the application was submitted. However, for applications submitted and subsequently approved prior to April 1, 2018, we proposed that the effective date for billing privileges would be April 1, 2018. This is consistent with other suppliers like physicians, non-physician practitioner organizations, ambulance suppliers, and independent diagnostic testing facilities (IDTFs). However, unlike physicians, non-physician practitioner organizations, and ambulance suppliers who may bill for services for a limited period of time—generally for about thirty days—prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries, MDPP suppliers would not be permitted to retrospectively bill for services rendered prior to their effective date for billing privileges. Given that MDPP suppliers do not furnish services with immediate impacts on health like the aforementioned Part B suppliers, we chose to utilize the approach of IDTFs. We proposed that as a condition of enrollment, MDPP suppliers would be required to certify in their enrollment application that they are in compliance and will continue to remain in compliance with all MDPP supplier standards that we described in section III.K.2.e.iv of the proposed rule (82 FR 34159 through 34160). Therefore, an MDPP supplier could begin furnishing services on the date the application was submitted, with the goal of having their application subsequently approved. However, we proposed that payment for those services would depend upon whether the enrollment application is subsequently approved.

We proposed that for any enrollment application that is denied under § 424.530(a)(1) for non-compliance, but then subsequently approved due to the submission of a corrective action plan (CAP), the effective date of enrollment would be the date of the CAP submission. This is also consistent with practices for existing suppliers, and institutes an appropriate safeguard for Medicare beneficiaries and the program at-large by prohibiting services from being furnished from suppliers who are non-compliant. We acknowledged, however, that if a supplier began furnishing services the date it submitted its application, but was then denied enrollment, it would not be paid for any services it furnished prior to the date it submitted the CAP, if approved. However, as described in section III.K.2.e.iv of this final rule (§ 424.205(d)), upon submitting its enrollment application, an MDPP supplier certifies that—to its knowledge—it meets and agrees to continue to meet the following MDPP supplier standards, and all other applicable Medicare requirements. Thus, at the time the MDPP supplier applicant submits its application, it should believe that its enrollment application will be approved. Examples of actions the MDPP supplier could take to improve its certainty and increase the probability that the application will be approved may include reviewing any MDPP supplier supporting documentation to fully understand MDPP supplier enrollment requirements and accompanying CMS guidance or supplier support materials, confirming compliance with the MDPP supplier standards in this rule (including conducting background checks for those who would be screened by CMS during the enrollment process as required under § 424.518(c) and § 424.205(d)(3)), and conducting a thorough review of the enrollment application to ensure the submitted application is accurate.

We also proposed that if an MDPP supplier adds a new administrative location (defined and discussed further section III.K.2.e.iii.(2) of this section of the final rule) that resulted in a new enrollment record or Provider Transaction Access Number (PTAN), the effective date for billing privileges would be the date the MDPP supplier began its MDPP operations at that location. We believe that this is appropriate given that it follows a similar approach for an effective date that applies to when physician organizations, non-physician practitioner organizations, ambulance suppliers, and IDTFs add a new practice location to an existing enrollment record. Though the definition of administrative location differs from that of practice location, it provides a similar function. We sought comments on these proposals.

We received no comments on our proposals on the effective date for billing privileges, and are finalizing these policies as proposed under § 424.205(f).

iii. Enrollment Application

(1) Enrollment Application Type Applicable to MDPP Suppliers

We proposed to require the use of a new, CMS-approved enrollment application specific to MDPP suppliers. We believe that the creation of a new application will be more easily navigated by and reduce the burden on new, non-traditional suppliers because the new enrollment application will only solicit information relevant to the MDPP supplier type. As this new enrollment application is being created specifically for the MDPP expanded model, we have determined that this new enrollment application is exempt from the Paperwork Reduction Act in accordance with section 1115A(d)(3) of the Act. Further, this enrollment application would be considered an ''enrollment application'' for purposes of part 424 subpart P, and therefore, all existing regulations and administrative guidance that govern the CMS–855 enrollment applications would apply to this new form, unless otherwise specified. We also considered an alternative option to amend the current CMS–855B Medicare Enrollment Application for Clinics/Group Practices and Certain Other Suppliers (CMS–855B) for MDPP supplier enrollment, but we determined that the existing length and complexity of the CMS–855B enrollment application and its applicability to other non-MDPP suppliers may add burdens or unnecessary confusion to MDPP suppliers given that many sections of the current CMS–855B enrollment application would not apply to MDPP suppliers. In addition, we would need to add new sections to solicit information specific to MDPP suppliers, which would only further increase the length of the CMS–855B enrollment application. We invited public comments on this proposal.

The following is a summary of the public comments received on the proposal to require the use of a new, CMS-approved enrollment application specific to MDPP suppliers and our responses:

Comment: The majority of comments received on creating a new, MDPP specific enrollment form supported this proposal. However, the emphasis of

these comments expressed a strong desire for simplicity and that CMS make the form available as soon as possible. Commenters stipulated that given that many prospective MDPP suppliers will lack experience with Medicare enrollment, simplicity and plain language would facilitate their ability to enroll with ease. Similarly, commenters expressed that early access to the form would substantially help prospective MDPP applicants prepare for enrollment. In addition to the early access to the form itself, commenters also urged CMS to provide resources and guidance to prospective MDPP suppliers to facilitate their ability to successfully enroll.

Response: We appreciate all of the comments and support regarding our proposal to create a new, MDPP supplier-specific enrollment application based off of the Form CMS–855–B, as well as other commenters who provided suggestions or other considerations. We reemphasize that we proposed to create an MDPP specific enrollment application rather than amend the current Form CMS–855–B specifically to simplify the application to the extent possible and focus the information collected on MDPP supplier-related information. We continue to believe that this approach strikes the appropriate balance between acquiring necessary information from MDPP supplier applicants and doing so in a manner that is clear and as straightforward as possible.

We understand commenters' requests to have expedited access to the enrollment application. Given that many policies related to or specified on the application are being finalized through this rule, we cannot publish the enrollment application prior to the publication of this final rule. However, we agree that having access to the application prior to the enrollment start date will better assist prospective MDPP suppliers preparing to enroll in Medicare, and will plan to release the application as soon as possible following the publication of this final rule. For this reason, we specified in our proposal that we intend for the information collected on the MDPP supplier enrollment application to build off of what is collected on the 855–B for all supplier types, and proposed additional information collection requirements specific to MDPP suppliers in this rule. Until we are able to make the new enrollment application available, we believe that reviewing the existing 855B enrollment form should begin assisting prospective MDPP suppliers in their enrollment preparation. In an effort to disclose information on the enrollment application at our earliest opportunity, we can announce that the MDPP enrollment application will be entitled Form CMS–20134, Medicare Enrollment Application, MDPP Suppliers. Additional information on the enrollment application's availability will be announced publicly via the CMS Web site and other methods as applicable and appropriate.

Comment: Another commenter suggested that once MDPP suppliers successfully enroll, that CMS create a list of all enrolled MDPP suppliers as a method of providing resources to prospective MDPP beneficiaries. The commenter noted that such a resource would be particularly necessary given that not all suppliers with CDC recognition will enroll as an MDPP supplier, and thus, having a separate list of available suppliers would facilitate beneficiary access.

Response: We agree with the commenter's suggestion and will explore the possibility of creating this list and making it available to facilitate access. Further details on these efforts will be released through the CMS Web site as appropriate and when available.

Comment: In addition to supportive comments and suggestions for ways CMS could facilitate prospective applicant's completion of the enrollment application, certain commenters expressed confusion with our proposals, or commented on proposals outside of the scope of this rule. One commenter noted that CMS was requesting comments on whether existing Medicare providers and suppliers that wish to bill for MDPP services would have to inform Medicare of the intention and satisfy all other requirements but would not need to enroll a second time. This commenter did not support this policy, and therefore, did not support the creation of a new enrollment application. Similarly, a handful of commenters expressed concern about this previously finalized policy, and urged CMS to reconsider the requirement to reenroll, particularly for FQHCs and enrolled physicians.

We clarify that we are not considering exemptions for MDPP supplier enrollment. We appreciate commenters who expressed a desire for CMS to reconsider the policies previously finalized in the CY 2017 PFS, but these policies are out of scope of the proposed rule, and we are not reconsidering previously finalized policies at this time. For our rationale on this previous policy decision, please reference section III.J.7.a of the CY 2017 PFS final rule where we addressed these comments.

After considering the public comments, we are finalizing the proposal to create an MDPP supplier specific enrollment application, as proposed.

(2) Information on MDPP Enrollment Application

On the new MDPP enrollment application, we intend to solicit information specific to MDPP suppliers, as well as information consistent with existing reporting requirements applicable to all suppliers who enroll through the CMS–855B enrollment application, while excluding all reporting requirements that do not apply to MDPP suppliers. As a Medicare supplier enrolling under part 424 subpart P, MDPP suppliers are required to provide complete and accurate information on the MDPP enrollment application, or be subject to enrollment denial under § 424.530(a)(4) or revocation under § 424.535(a)(4). This requirement would include all information solicited on the MDPP-specific enrollment application. The MDPP-specific enrollment application is under development and will be available prior to its use. While the application is being developed, we indicate some of the information we intend to include on the MDPP enrollment application, as further described in this section.

As finalized in the CY 2017 PFS final rule, § 424.59(a)(5) requires that MDPP suppliers submit the active and valid NPIs of all coaches who will furnish services on the supplier's behalf, as well as their first name, last name, and SSN (in the proposed rule, § 424.59(a)(5) was proposed to be redesignated and amended at § 424.205(b)(4)). We proposed, at § 424.205(b)(4), to require that MDPP suppliers provide this identifying information of the coaches directly through the enrollment application. This information will be used to complete background checks of the coaches. To accompany the coach identifying information, we proposed to require MDPP suppliers to provide an eligibility start and end date, if applicable, for each coach on the supplier's roster. Coach eligibility start and end dates are described at length in section III.K.2.e.iv.(2). As described in more detail in section III.K.2.e.iv., the background checks would be used to prevent MDPP suppliers from allowing coaches to furnish MDPP services when certain adverse histories may indicate potential to harm Medicare beneficiaries or undermine program integrity. We outline further details on our proposed enforcement of this provision in section III.K.2.e.iv. of this final rule.

To enable us to conduct background checks of coaches, we proposed that MDPP suppliers also submit to CMS the date of birth of all coaches who will furnish MDPP services (§ 424.205(b)(4)). Combined with other identifying information, date of birth plays a critical role in validating an individual's identity. By collecting date of birth, we would be able to more accurately screen coaches, including accurately conducting a background check, and distinguishing them in the Provider Enrollment, Chain and Ownership System (PECOS). In addition, we want to ensure that we have the capability to most accurately identify individuals reported on the form. To mitigate potential confusion or error found when individuals have common names, we are proposing to collect coach's middle initial (if applicable) on the enrollment application (§ 424.205(b)(4)). We believe that this will help to lessen the possibility that CMS or its contractors misattribute the background of one individual for another.

We proposed, at § 424.205(d)(4), that MDPP suppliers would identify their administrative location(s) by reporting these location(s) on their enrollment application. We proposed, at § 424.205(a), to define administrative location as the physical location associated with the supplier's operations, from where coaches are dispatched or based, and where MDPP services may or may not be furnished. We proposed that an MDPP supplier must have at least one such administrative location, and report any additional administrative locations of the supplier, if MDPP services are either furnished at these locations and/or if the location reflects from where coaches are dispatched or based. For example, if an MDPP supplier operated 2 locations, but only 1 of the 2 locations associated with the entity offered MDPP, only the location offering MDPP would be considered an administrative location. If coaches began offering MDPP in community settings (described in the subsequent paragraph and defined at § 424.205(a), but were dispatched and/or based out of the other non-administrative location, then this location would then be considered under the definition of an administrative location, and would need to be reported on the MDPP enrollment application within 90 days of the change. Given that MDPP suppliers are categorized as high risk under § 424.518, these administrative locations may be subject to site visits prior to approval of an enrollment application. Collecting information on the MDPP supplier's administrative location (regardless whether they furnish services in this location) is important because we may utilize this information to verify that the organization is operational per requirements under proposed § 424.205(d)(4) and (6), discussed in detail in section III.K.2.e.iii.(3) of this final rule.

Although we recognize that many suppliers furnish MDPP services outside of their administrative locations in community settings, we proposed to only require enrollment of the administrative locations. In § 424.205(a), we define ''community setting'' as a location where the MDPP supplier furnishes MDPP services outside of their administrative locations. A community setting is a location open to the public, not primarily associated with the supplier. Community settings may include, for example, church basements or multipurpose rooms in recreation centers. When determining whether a location is considered an administrative location or a community setting, MDPP suppliers should consider whether their organizational entity is the primary user of that space and whether coaches are based or dispatched from this location. If so, the location would be considered an administrative location, even if this location dually serves as a community setting. In comparison, community settings are locations not primarily associated with the supplier where many activities occur, including MDPP services.

We sought public comments on these proposals.

The following is a summary of the public comments received on these proposals regarding what information CMS will collect on the MDPP supplier enrollment application and our responses:

Comment: Several commenters expressed disagreement with previously finalized policies out of scope of these proposals, including MDPP suppliers collecting information on MDPP coaches, requiring coaches to obtain NPIs, and tracking and reporting coach NPIs to CMS. One commenter broadly requested that CMS reconsider these policies citing a preference for a less intrusive way for staff to participate. Another suggested that instead of issuing and tracking coaches through NPIs, CMS should allow DPP organizations to self-regulate their coaches using their own management practices. Another commenter expressed a broad concern regarding the burden of the recordkeeping requirements under MDPP, listing the tracking and submission of coach NPIs as one of these burdens.

Response: These comments are out of scope of this final rule. None of the comments received addressed the policies in the proposed rule, which built on previously finalized policies in the CY 2017 PFS final rule. We do not intend to change these policies at this time.

In the absence of public comments on our proposal to collect the date of birth and middle initials, if applicable, of MDPP coaches or our proposal to collect coach identifying information from their roster through the MDPP supplier enrollment application, we are finalizing these policies as proposed.

Comment: Several commenters requested clarity and expressed concern related to differences between an administrative location and community setting.

Response: A location may either meet the definition of an administrative location or a community setting based on whether or not the MDPP supplier is the primary user of that space, including both MDPP services and any other services provided by the supplier. The difference can be easily illustrated by examining two scenarios where MDPP services are furnished in a community center, and the community center can qualify as either an administrative location or a community setting, depending on the circumstance. For example, if the MDPP supplier is also a community-based organization which primarily operates at a community center which offers many services including MDPP, the address of the community center would fall under the definition of an administrative location which, as proposed under § 424.205(a), means a physical location associated with the MDPP supplier's operations. However, if an advocacy organization is enrolled as an MDPP supplier and opts to furnish services in a community center to increase beneficiary access or because the location where their primary business operations occur does not have sufficient space to hold a group meeting, the address of the community center would qualify as a community setting, because, as proposed under § 424.205(a), a community setting means a location where the MDPP supplier furnishes MDPP services outside of their administrative locations, that is open to the public, and not primarily associated with the supplier. To make the distinction between these two definitions more clear, we will amend our proposed definition of an administrative location to include a physical location associated with the MDPP supplier's operations *where it is the primary operator in the space,* from where coaches are dispatched or based,

and where MDPP services may or may not be furnished.

Comment: Specifically, one commenter requested that CMS confirm that MDPP services furnished by an enrolled MDPP supplier can be offered in a setting that is not exclusively used for MDPP services, meaning that the location may be co-located with other non-covered MDPP services.

Response: We confirm the commenters' interpretation that MDPP suppliers may furnish MDPP services in locations where other, non-MDPP services occur.

Comment: Another commenter disagreed with the requirement that MDPP suppliers have at least one administrative location. Though this requirement was proposed in the MDPP supplier standards, the comment stemmed from the stakeholders' understanding of the proposed definition of administrative location, and thus it is discussed in this section of the rule. The commenter stipulated that requiring that MDPP suppliers have at least one administrative location does not align with how some DPP organizations currently deliver and schedule sessions. The commenter noted that DPP organizations may not have an administrative location where coaches remain throughout the day and are scheduled or dispatched from, but rather, that a program coordinator (who may or may not also serve as a lifestyle coach) determines which coach will staff a series of sessions and the corresponding location.

We do not agree with the commenter who noted that our proposed definitions of administrative locations do not align with how DPP organizations currently operate. Though the commenter suggested a program coordinator, not a coach, may dispatch coaches to furnish sessions, this scenario would not disqualify the location from where the coordination dispatched the coach from being an administrative location. We clarify that we take no policy position on who dispatches the coaches, be they another coach, program coordinator, or other personnel working on behalf of the MDPP supplier. Our proposed definition of the administrative location means any physical location associated with the suppliers' primary business operations, regardless of whether coaches furnish MDPP services from that location or not. If the location serves as the supplier's primary operations, but MDPP services are furnished elsewhere, we assume that the supplier or individuals working on its behalf will dispatch coaches from this location, potentially house MDPP related materials at this location, or utilize this location to store records. We purposefully sought to define administrative location to accommodate the non-traditional nature and diversity of settings among current DPP organizations.

After considering the public comments, we are finalizing the requirement to report an MDPP supplier's administrative location(s) and community setting(s) on the enrollment application with minor amendments to the definition of an administrative location to provide greater clarity.

(3) Updating Information on MDPP Enrollment Application

We proposed, at § 424.205(d)(5), that MDPP suppliers must update their enrollment application within 30 days of any changes of ownership, changes to the coach roster, or new final adverse action history of any individual or entity required to report such information on the enrollment application. We proposed that MDPP suppliers report all other changes to information required on the enrollment application within 90 days of the reportable event. Timely reporting and updating of information plays a critical role in our ability to protect Medicare beneficiaries and protect the integrity of the Medicare program and Trust Funds. We believe that these requirements are fair and consistent with existing reporting requirements for other Medicare suppliers.

All suppliers are required to report changes of ownership and new adverse action history within 30 days. Adding the requirement that any changes to the coach roster be reported within 30 days is consistent with IDTFs requirements at § 410.33(g)(2). Although IDTFs differ from MDPP suppliers in many ways, IDTFs must report a roster of supervising physicians who serve functions on the supplier's behalf and must also report changes to this roster within 30 days. Given this similarity with IDTFs, we modeled our approach after this process. However, we note that while MDPP suppliers would be required to submit changes to the coach roster within 30 days, we would encourage them to submit such changes as soon as possible, due to reasoning explained further in section III.K.2.e.iv.(2) of this final rule.

We invited public comments on these proposals. We received no comments on our proposals relating to the timelines under which MDPP suppliers must update their enrollment applications, and thus are finalizing these policies as proposed at § 424.205(d)(5).

(4) Enrollment Application Fee

In the CY 2017 PFS final rule, we finalized that MDPP suppliers would enroll in Medicare. We solicited comments on, but did not propose or finalize, an applicable application fee associated with the MDPP supplier's enrollment. In this final rule, we proposed to amend the definition of ''institutional provider'' as defined under § 424.502, to include MDPP suppliers such that, § 424.514, which governs the application fee, would similarly apply to MDPP suppliers. ''Institutional providers'' that are initially enrolling in Medicare, revalidating their enrollment, or adding a new Medicare practice location are required to submit a fee with their enrollment application. We highlight that while we proposed to include MDPP suppliers as an institutional provider, MDPP suppliers utilize administrative locations, not practice locations, and therefore the fee would not apply when adding a new administrative location to an existing enrollment record. The application fee is adjusted annually, and additional information about how the adjustment is calculated may be found in the November 7, 2016 **Federal Register** notice establishing the calendar year 2017 application fee (81 FR 78159). For calendar year 2017, the application fee is $560. Section 1866(j)(2)(C) of the Act requires the Secretary to impose a fee on each institutional provider of medical or other items or services or supplier. This fee would be used for program integrity efforts including to cover the cost of screening and to carry out the provisions of sections 1866(j) and 1128J of the Act. Given that section 1866(j)(2)(C) of the Act does not require individual practitioners, such as physicians and nurse practitioners, to pay an enrollment application fee, we have previously determined that an ''institutional provider'' includes any provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (not including physician and non-physician practitioner organizations), CMS–855S or associated Internet-based PECOS enrollment application.[43] MDPP suppliers are entities, and not individual practitioners. We believe that they would similarly qualify as a ''provider of medical or other items or services'' used to define institutional providers. Taken together, we believe that the definition of institutional provider would also apply to MDPP

[43] See CMS–6028–FC for further discussion, 76 FR 5862 and 5907 through 5908 (Feb. 2, 2011).

suppliers. Given that the CY 2017 PFS final rule established that MDPP suppliers would be screened under high categorical risk (codified at § 424.59(a)(3), redesignated as § 424.205(b)(3)(i)), the application fee would play an important role in executing particular aspects of the high-risk screening. As we noted in the CY 2017 PFS final rule, any organization that faces financial difficulty related to the application fee may apply for a hardship exception. For more information on the hardship exemption, see *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7350.pdf*. We solicited comments on this proposal.

The following is a summary of the public comment received on the proposal to amend the definition of institutional provider for the purposes of applying an enrollment application fee, as well as our response.

Comment: We only received one comment on this proposal, which supported requiring MDPP suppliers to pay a $560 enrollment application fee.

Response: We clarify that the application fee amounted to $560 in 2017; however, this amount may vary from year-to-year based on adjustments made under the Consumer Price Index for Urban Areas (CPI–U). We encourage prospective MDPP supplier applicants to remain abreast of any changes in that amount. CMS publishes an annual **Federal Register** notice regarding an update of the enrollment application fee.

After considering the public comments, we are finalizing our amendment to the definition of institutional providers to include MDPP suppliers. Though the meaning of the proposal remains the same, now that we have finalized the creation of an MDPP supplier specific form, CMS–2013, we will amend the language at § 424.502 from the proposed which referenced any enrollment application designated for MDPP suppliers to refer to CMS–20134.

iv. MDPP Supplier Standards

We proposed to establish standards that MDPP suppliers must meet and remain in compliance with to be eligible to receive payment under the MDPP expanded model (described in 82 FR 34159 through 34160 and proposed at § 424.205(d)). These supplier standards would build on the conditions for enrollment established under existing § 424.59(a) (which in this final rule is redesignated and amended at § 424.205(b)), as well as any existing Medicare requirements that apply to all suppliers. We proposed that an MDPP supplier wishing to participate in the MDPP expanded model must adhere to current Medicare MDPP supplier requirements as outlined in § 424.59 (redesignated as § 424.205), as well as all other requirements that apply to Medicare providers and suppliers. MDPP suppliers may choose to utilize a third party administrator, billing agent, or other entity to comply with the requirements of § 424.59 (redesignated as § 424.205). Regardless of any use of such entities, any failure to comply with the standards of § 424.205(d) or other relevant Medicare requirements, may result in an enrollment denial under § 424.530(a)(1), revocation of the MDPP supplier for non-compliance under § 424.535(a)(1) or other revocation authority, as appropriate (as in § 424.205(g)). Consistent with existing regulations, we proposed that MDPP suppliers would have appeal rights under part 498.

We stated that we believe that the standards outlined in this section are generally consistent with standards established for other Medicare suppliers while adding safeguards to help ensure compliance with MDPP rules and regulations specific to this expanded model. Because this expanded model would pay MDPP suppliers based on a beneficiary's achievement of performance goals, we stated that we believe that it is prudent to include additional requirements consistent with the Office of Inspector's General's compliance guidance,[44] to promote adherence to applicable statutes, regulations, and program requirements and help reduce fraud, waste, and abuse. In addition to the standards, the MDPP expanded model will be routinely monitored for compliance with supplier standards, consistent with section 1893 of the Act (42 U.S.C. 1395ddd). Although we recognized that these standards may be new for MDPP suppliers and would impose additional requirements on these organizations that they may not otherwise face, both individually and collectively, we stated that these standards play an important role in ensuring the integrity of the Medicare program and the safety of our beneficiaries. Therefore, given the goals of these standards to mitigate fraud, waste, or abuse to the Medicare program and its beneficiaries, we stated that we believe that they are appropriate for governing MDPP suppliers and do not place an undue burden on suppliers. We invited public comments on our approach, as well as any unintended consequences or burdens that we may have not considered.

The following is a summary of the public comments and our responses regarding the proposal to establish standards for MDPP suppliers' general eligibility to furnish services to Medicare beneficiaries and program integrity safeguards that would protect both Medicare beneficiaries and the Medicare program:

Comment: Several commenters provided feedback on the proposal to establish MDPP supplier standards. The majority of these commenters expressed concern that by imposing additional requirements, the standards would pose additional burdens on MDPP suppliers. One commenter stated that the extensive requirements may delay access. Others expressed strong sentiments against CMS' decision to impose MDPP supplier standards. One commenter indicated that these impositions may deter organizations from deciding to enroll as MDPP suppliers even if beneficiaries already served by these organizations could benefit from MDPP services. Rather than establishing MDPP supplier standards to protect against fraud, waste, and abuse, one commenter recommended that CMS conduct random audits and site visits.

Response: We recognize that supplier standards pose additional burdens for MDPP suppliers; however, we believe that these standards play an important role in ensuring against fraud, waste, and abuse in the Medicare program as well as fidelity to the expanded model. Additionally, we have sought to structure these standards such that compliance would be feasible, and at times, even seamless for suppliers to abide by. For example, our proposals regarding MDPP suppliers' operational status were not intended to impose new requirements, but to notify prospective MDPP applicants of the standards by which they will be evaluated. We believe that MDPP suppliers that are operational, as opposed to organizations who wish to appear operational, will not need to make any changes in order to be able to meet these standards. Therefore, we do not agree with the commenter that overall, the supplier standard would pose any additional burden on these suppliers, dissuade legitimate and operational suppliers from choosing to participate, or even significantly delay enrollment. Though we recognize that implementing criteria for eligible coaches could result in an enrollment delay should a coach submitted on a suppliers' enrollment application be determined by CMS to be ineligible, the eligibility criteria narrowly focuses on excluding coaches

[44] *https://oig.hhs.gov/compliance/compliance-guidance/*.

with felony convictions for actions that, if repeated in MDPP, could jeopardize the integrity of the program and/or the safety of its beneficiaries. Therefore, we believe that any delays caused by an ineligible coach are justified.

Comment: A few commenters expressed general support for the standards, noting that they were appropriate, and with few exceptions, generally straightforward to implement. Though MedPAC did not expressly support the proposed supplier standards, they recommended that CMS use all program integrity tools available to monitor MDPP suppliers, including significant oversight from the Office of Inspector General and limitations on supplier enrollment.

Response: We agree with commenters' views of the appropriateness of our proposals, the importance of implementing program integrity tools for this novel supplier type, and that the characterization of MDPP supplier standards as straightforward to implement.

Comment: Instead of establishing MDPP supplier standards to protect against fraud, waste, and abuse, one commenter recommended that CMS conduct random audits and site visits.

Response: We disagree with one commenter's characterization of audits and site visits as an alternative to MDPP supplier standards as the two support one another. Where the MDPP supplier standards establish some of the requirements under which MDPP suppliers must abide, an audit or site visit gives CMS an opportunity to ensure that an MDPP supplier is in compliance with such requirements. Furthermore, given the novelty of the expanded model and this new supplier type created to support its delivery, as well as concerns raised by MedPAC and others, we believe that establishing MDPP supplier standards provides important program integrity safeguards for a range of programmatic objectives.

For example, some of the MDPP supplier standards provide preemptive measures to dissuade organizations that may seek to enroll as an MDPP supplier without planning to actually furnish services, but instead, with the intention of fraudulently billing Medicare for MDPP services not rendered. For example, requiring a working phone number that is listed in association with the supplier and having a physical location with signage associated with the supplier's legal business or doing business as name. These standards have also been implemented with other supplier types to avoid ''shell'' companies from being able to enroll. The supplier standard proposed at § 424.205(d)(1) prevents an organization with a for-cause termination in Medicaid from replicating the same behavior in Medicare that had them terminated in Medicaid. A supplier standard at § 424.205(d)(8) prohibits the MDPP supplier from proactively selecting beneficiaries who they perceive to be more likely to successfully meet the performance goals, which would subsequently generate more funds for the supplier. Another supplier standard at § 424.205(d)(10) ensures that an MDPP supplier offers all services for which an MDPP beneficiary is eligible, which would prevent a supplier that may otherwise seek to cease providing the time investment of offering services to a beneficiary who they believe is unlikely to meet performance goals, and therefore resulting in less reimbursement for the supplier. We have included safeguards to ensure that MDPP suppliers do not engage in this type of discriminatory behavior that could limit access for certain beneficiaries who would benefit from receiving MDPP on the basis of the supplier's own financial benefit.

We believe that establishing these standards also plays an important role in enabling CMS to enforce certain actions and take appropriate administrative action when a supplier fails to comply.

Though MedPAC did not comment on these standards directly, we believe that the both the standards supplier standards and our ability to deny or revoke an MDPP suppliers' enrollment if they fail to comply aligns with their recommendation to utilize all available program integrity tools.

Comment: Many commenters requested that CMS provide technical assistance, subregulatory guidance, and other resources to help ensure MDPP supplier compliance and facilitate the enrollment process, particularly given that many MDPP suppliers may be enrolling in Medicare for the first time. One commenter specifically requested that documents utilize plain and directive language to facilitate understanding and correct implementation of the requirements. One commenter suggested that the MDPP expansion model create a level of technical assistance that occurs with other Innovation Center models, for example, Comprehensive Primary Care Model Plus.

Response: We thank commenters for highlighting the need for guidance and other MDPP supplier support resources. We appreciate the feedback in how we can facilitate MDPP suppliers' understanding of proposed MDPP supplier standards and in doing so, better equip MDPP suppliers to comply with our regulations. We similarly recognize the need to provide resources to support MDPP suppliers' success and are in the process of developing materials. We will also be establishing a Help Desk, which we believe will provide some of the guidance commenters requested. We will explore additional opportunities to assist suppliers, and will provide notification of any materials as they become available either through our Web site or through our MDPP list serv.

After considering the public comments received, we are finalizing our policy to establish MDPP supplier standards at § 424.205(d), as proposed. Note that the specific MDPP supplier standard proposals outlined in the paragraphs of § 424.205(d) are discussed further through this section of the final rule.

(1) Medicaid Terminations

In addition to establishing standards for MDPP suppliers with respect to their delivery of MDPP services, we also proposed standards for MDPP suppliers' general eligibility to furnish services to Medicare beneficiaries. These standards would establish program integrity safeguards that would protect both Medicare beneficiaries and the Medicare program. We proposed that MDPP suppliers must not currently have their billing privileges terminated for-cause from any State Medicaid program or be excluded from any State Medicaid program (§ 424.205(d)(2)). If a supplier's Medicaid billing privileges are currently terminated from or the supplier is excluded from any State Medicaid program, we stated that we do not believe that supplier should be able to furnish Medicare services. We stated that we believe that this is warranted given that a supplier's improper behavior in another federal health care program may be duplicated in Medicare. We stated that we believe that this requirement would mitigate the MDPP expanded model's susceptibility to fraud, waste, and abuse. Consistent with all standards in this section, any MDPP supplier who does not meet this requirement would be subject to a Medicare enrollment denial or revocation. We believe that this standard would serve to ensure continuity of safeguards across federal health care programs, and will help preserve the integrity of the Medicare program and protect beneficiaries by prohibiting suppliers found to be noncompliant in one federal health care program from enrolling in and furnishing services in another.

We sought comments on this proposal.

We received no comments on our proposal prohibiting that MDPP suppliers from being terminated for-cause or being excluded from a State Medicaid agency. Therefore, we are finalizing policies to prevent MDPP suppliers from having previous terminations or exclusions from State Medicaid Agencies as proposed at § 424.205(d)(2).

(2) Ineligible Coaches: Individuals Prohibited From Furnishing MDPP Services to Medicare Beneficiaries

At § 424.205(d)(3), we proposed that the MDPP supplier must report coach information on its enrollment application and the MDPP supplier must only permit MDPP services to be furnished by individual coaches who meet the eligibility criteria. At § 424.205(e)(1), we proposed that MDPP coach eligibility criteria require that a coach must not:

• Currently have his or her Medicare billing privileges revoked and whose reenrollment bar has not yet expired. We believe that this proposed supplier standard would protect beneficiaries from receiving MDPP services from individuals already prohibited from furnishing other Medicare services. If an individual is precluded from maintaining enrollment in Medicare for a non-MDPP service, we believe that it is prudent that they similarly not furnish MDPP services.

• Currently have his or her Medicaid billing privileges terminated for-cause or be excluded from any State Medicaid Agency (§ 424.205(e)(1)(ii)). We believe that this proposed supplier standard is warranted given that an individual's improper behavior in another federal health care program may be duplicated in Medicare. We do not believe that we should permit MDPP suppliers to allow coaches with current for-cause terminations or exclusions in Medicaid to furnish MDPP services to Medicare beneficiaries.

• Currently be excluded from any other federal health care program, as defined in § 1001.2 of this chapter, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act. This includes, but is not limited to, the Office of Inspector General (OIG)'s List of Excluded Individuals and Entities (LEIE). We proposed this supplier standard for similar reasons we proposed not to permit coaches with revocations from Medicare or current exclusions from Medicaid to furnish MDPP services.

• Currently be debarred, suspended, or otherwise excluded from participating in any other federal procurement or non-procurement program or activity in accordance with the Federal Acquisition Streamlining Act implementing regulations and the Department of Health and Human Services non-procurement common rule at 45 CFR part 76. We note that this includes individuals who have an active status on the General Service Administration's System for Award Management list. We may also utilize the Bureau of the Fiscal Service, U.S. Department of the Treasury's Do Not Pay (DNP) List as a resource for determining which individuals fall under this category. The Improper Payments Elimination and Recovery Improvement Act (IPERIA) of 2012 established the DNP to support Federal agencies with their efforts to prevent and detect improper payments by aggregating various data sources for pre-award, pre-payment eligibility verification. Data sources included in this list include Credit Alert System, Death Master File, LEIE, Office of Foreign Assets Control (OFAC), System for Award Management (SAM) Entity Registration Records, and SAM Exclusion Records. We believe that we may utilize the DNP as a method of determining whether a coach is excluded from participating in any other federal procurement or nonprocurement programs. Although coaches will not directly be receiving payment from us for furnishing MDPP services, we do not believe that payment should be made to MDPP suppliers for services furnished by individuals excluded from federal procurement or nonprocurement programs, particularly given that MDPP payments rely on beneficiary's achievement of performance goals that the coaches will document. Although the MDPP supplier is ultimately responsible for attesting to all claims submitted for MDPP services, we do not believe that it would be prudent to permit MDPP suppliers to allow coaches excluded from other federal procurement programs to furnish MDPP services.

• Have, in the previous 10 years, one of the following state or federal felony convictions:

++ Crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion.

++ Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, as defined under § 1001.2, had a guilty plea or adjudicated pretrial diversion.

++ Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in the individual being convicted, as defined under § 1001.2, having a guilty plea or having adjudicated pretrial diversion of criminal neglect or misconduct.

++ Any felonies that for which the individual was convicted, as defined under § 1001.2, had a guilty plea or adjudicated pretrial diversion that would result in mandatory exclusion under section 1128(a) of the Act.

We proposed that CMS will screen each individual identified on the roster of coaches included with the supplier's enrollment application to verify that the individual coach does not meet any of these conditions and that the coach can provide MDPP services on behalf of an MDPP supplier (§ 424.205(e)(2)). We proposed these requirements as a means to ensure the integrity and safety of the Medicare program and the beneficiaries whom we serve. We have selected these types of felony convictions based on the risk we believed they could pose to the Medicare program and our beneficiaries. Additionally, it is consistent with existing criteria that we use to determine felonies that are detrimental to the best interest of the program and its beneficiaries as described in § 424.535(a)(3)(ii). Although we selected these criteria to be consistent with how we evaluate other individuals, we also sought to create a more definite list such that MDPP suppliers would have the ability to conduct background checks on coaches prior to, as well as potentially after enrolling in Medicare, to avoid receiving an enrollment denial or revocation due to failure to meet this standard. Although coaches are not directly enrolled, and therefore, not directly receiving payment, we stated that we believe that it is prudent to prohibit MDPP suppliers from utilizing individuals convicted of certain felonies to furnish services to Medicare beneficiaries. Because coaches will be directly interacting with beneficiaries, recording their attendance and weight loss, we believe that a coach's trustworthiness is vital. Consequentially, we do not believe that such coaches should have a criminal history such as those described in § 424.535(a)(3)(ii).

Coaches that meet any of these criteria would be considered ineligible to furnish MDPP services, and therefore, could not be on an MDPP supplier's roster. Coaches whose information was submitted in an MDPP supplier's enrollment application, screened, and

determined as not meeting any of these criteria would be considered eligible coaches. Although the MDPP supplier is the entity that is enrolled in Medicare and submits claims, coaches furnish MDPP services, directly interacting with the beneficiary and documenting attendance and weight loss. Therefore, we stated that we believe that precluding individual coaches who meet any of the ineligibility criteria from directly furnishing MDPP services to Medicare beneficiaries would both help reduce fraud, waste, and abuse that could occur in the MDPP expanded model, as well as protect beneficiaries from harm.

If after screening, CMS or its contractors determine that a coach is eligible to furnish MDPP services, the coach would be assigned an eligibility start date, similar to a supplier's enrollment effective date. We proposed to define coach eligibility start date as follows: The start date indicated by the MDPP supplier when submitting an eligible coach's information on the MDPP enrollment application (§ 424.205(a)). On the enrollment application, the MDPP supplier will include a date indicating when the coach began furnishing MDPP services. Consistent with § 424.205(d)(5), the MDPP supplier must report changes to the coach roster on its enrollment application, including any new coaches added, within 30 days of such a change. Thus, the start date associated with any new coach information must be within 30 days of the date the MDPP supplier actually reports the change on its application. If the coach has not yet begun furnishing MDPP services, the MDPP supplier should indicate the date the supplier is reporting the information. Though the date reflects either when the coach began furnishing services or when the coach could ultimately be determined as eligible to begin furnishing services, after the enrollment application was submitted, CMS must still determine whether the coach is eligible (§ 424.205(e)(2). If we determine the coach to be eligible, then his or her eligibility start date would be the date the MDPP supplier indicated on its enrollment application. We described in III.K.2.d.(10)(d) of the proposed rule (82 FR 34149 through 34152) that payment can be made for services furnished by this coach on or after his or her eligibility start date.

However, if a coach was determined to be ineligible at the onset, the coach would have its eligibility start and end date on the same date, effectively never being eligible to furnish MDPP services. If the coach later became ineligible, he or she would be assigned an eligibility end date. Consistent with § 414.84, payment for MDPP services is made only if such services 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, to an MDPP beneficiary. This could pose a situation in which an MDPP supplier could submit an updated coach roster that includes a new coach, and allow him or her to begin furnishing services based on the belief that he or she is eligible. Should, after screening, CMS or its contractors determine that the coach is ineligible, the MDPP supplier could be revoked for non-compliance. Though the MDPP supplier would have an opportunity to submit a corrective action plan that removes the ineligible coach from their enrollment application, any claims for services furnished by the ineligible coach would be denied, and the MDPP supplier would not be paid for such services. For this reason, we encourage suppliers to report changes to the coach roster as soon as possible. If the MDPP supplier submits a claim that includes a coach NPI for a coach we have not yet determined to be an eligible coach for furnishing MDPP services as of the date of service, the claim will be rejected, and the supplier will need to refile the claim with the same information once CMS has made the eligibility determination. If at that time, CMS determined the coach to be ineligible, the claim for the service provided by the coach will be denied, as described in section III.K.2.d.iii.(10)(d) of the proposed rule (82 FR 34149 through 34152).

We stated that we believe that the majority of the coach ineligibility criteria described in this section is crafted in such a way that the MDPP supplier could, with reasonable certainty, conduct an independent background check on the coach, to determine whether he or she meets the ineligibility criteria. If the MDPP supplier has any uncertainty about whether the coach meets the ineligibility criteria, they may wish to preclude the coach from furnishing services to Medicare beneficiaries until CMS determines that the coach is eligible. This would avoid a potential situation of a coach furnishing services for which the MDPP supplier could not get paid. If the MDPP supplier believes the coach is eligible and wishes to allow the coach to furnish services prior CMS determining his or her eligibility, then the MDPP supplier would assume the risk not receiving payment for claims for serviced rendered by the ineligible coach.

If a coach no longer provides MDPP services for an MDPP supplier, the supplier must remove that coach from its roster and indicate the date of such event to designate an eligibility end date for that coach. If the MDPP supplier voluntarily terminates its Medicare enrollment or is revoked, CMS will automatically reflect the date of this action as the coach's eligibility end date for that MDPP supplier. We proposed to define coach ineligibility end date as follows, the end date indicated by the MDPP supplier in submitting a change to the supplier's MDPP enrollment application that removed the coach's information, or the date the supplier itself was revoked from or withdrew its Medicare enrollment as an MDPP supplier.

We proposed that CMS or its contractors would determine whether coaches submitted on MDPP rosters satisfy the previously stated criteria by using the identifying information MDPP suppliers submit on their enrollment applications (including any changes that MDPP suppliers would be required to report). This information would be checked against internal and publicly available data sources. We proposed that, upon identification of evidence that a coach met any ineligibility criteria, we may take administrative action to deny or revoke the MDPP supplier's enrollment as appropriate under §§ 424.530(a)(1) and 424.535(a)(1) (proposed at § 424.205(g)(1)(ii)). Consistent with existing enrollment denial and revocation actions, we would notify the prospective or enrolled MDPP supplier via an enrollment denial or revocation notification and include the specific reason for the administrative action. The enrollment denial or revocation notification detailing the findings and the reasoning for the determination would follow requirements under § 488.18. Consistent with similar processes at §§ 424.530(c) and 424.535(e), we proposed that an MDPP supplier could respond to the enrollment denial or revocation by submitting a corrective action plan (CAP) that would include the removal of the coach from its roster within 30 days of receiving the enrollment denial or revocation notification, and therefore, come into compliance and enroll or maintain its enrollment status. If MDPP suppliers believe that the decision was made in error, they could exercise existing appeal rights under part 498.

We also proposed that if we determine that an MDPP supplier has continued to allow an ineligible coach to furnish MDPP services after having submitted a CAP removing the coach from its roster to enroll or maintain

enrollment in Medicare, we would revoke the MDPP supplier without the opportunity for additional corrective action. This authority, outlined in § 424.205(h)(1)(v), would allow us to revoke an MDPP supplier for knowingly using an ''ineligible coach'' to furnish MDPP services. ''Knowingly,'' in this context, means that the supplier received an enrollment denial or revocation notice based on failing to meet supplier standards at § 424.205(d)(3) (related to ineligible coaches), was provided notice by CMS or contractors working on its behalf of this action including the reason(s) for the administrative action, submitted a CAP to remove the coach, but continued to allow the coach to provide MDPP services in violation of the CAP. We proposed to define an ''ineligible coach'' in § 424.205(a) as an individual whom CMS has screened and has determined ineligible to furnish MDPP services on behalf of an MDPP supplier based on the standard specified in § 424.205(e), and we proposed in the same paragraph to define ''eligible coach'' in § 424.205(a) as an individual who CMS has screened and has determined can furnish MDPP services on behalf of an MDPP supplier based on the standard specified in § 424.205(e).

Although any individual may be eligible to become a DPP coach, provided that they meet requirements and trainings as dictated by the CDC's DPRP Standards, an individual can only become an eligible coach for purposes of furnishing MDPP services after having their required identifying information submitted on an MDPP supplier's enrollment application, being screened by CMS or its contractors, and as a result, being determined to be eligible to furnish MDPP services on behalf of an MDPP supplier. If CMS or its contractors deem a coach ineligible, this would apply only to the furnishing of MDPP services and would not preclude the DPP organization from continuing to allow this individual to furnish administrative services or DPP sessions to non-Medicare beneficiaries. However, serving as a coach for Medicare beneficiaries would be prohibited and would be subject the MDPP supplier to this revocation authority.

We proposed this new revocation authority due to the novel program integrity risks that would be posed by MDPP suppliers who knowingly continue to permit ineligible coaches to furnish MDPP services to Medicare beneficiaries. We stated that we believe that this new basis for revocation is necessary because coaches are not enrolled in Medicare, even though they will undergo background checks by CMS or its contractors and must meet specified criteria. Although we considered using existing revocation authorities under § 424.535(a)(1) (related to noncompliance), § 424.535(a)(4) (related to false or misleading information), and § 424.535(a)(9) (related to failure to report), we determined that these authorities were too general for purposes of specifically addressing MDPP coaches who become ineligible to furnish MDPP services. We proposed that this revocation authority would follow similar requirements under § 424.535(c), (g), and (h). We stated that we do not believe that § 424.535(e) (related to reversal of the revocation) should apply in this case, given that the MDPP supplier already had an opportunity to remove the coach from their roster by submitting a CAP, but continued to allow the ineligible coach to furnish MDPP services. The proposals that we would apply from the provisions of § 424.535 stated in this section are as follows:

- The revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the MDPP supplier;
- For the revocation authority, MDPP suppliers are barred from participating in the Medicare program from the date of the revocation until the end of the re-enrollment bar, which begins 30 days after CMS or its contractor mails notice of the revocation and lasts a minimum of 1 year, but not greater than 3 years, depending on the severity of the basis for revocation; and
- A revoked MDPP supplier must, within 60 calendar days after the effective date of revocation, submit all claims for items and services furnished before the date of the revocation letter.

We believe that these proposals would appropriately govern this new revocation authority, given the consistency with existing revocation authorities. Given these consistencies, we stated that we do not believe that these proposals place an undue burden on MDPP suppliers, and any burden established would be warranted given the violation of the supplier standards that jeopardize both the integrity of the Medicare program and the safety of its beneficiaries.

We invited public comments on these proposals.

Comment: Many commenters provided general feedback related to coach requirements. Two commenters criticized coach-related proposals for differing so significantly from CDC's DPRP requirements.

Response: We have sought to align the MDPP expanded model with CDC's DPRP standards in many ways, largely in regards to the set of services itself—the curriculum, the setting in which it is provided, the qualifications of those who offer it. We recognize that the goals of CDC requirements and our requirements overlap, but differ in certain respects. For example, the DPRP requirements primarily serve as quality assurance aimed to ensure that DPP organizations can effectively offer DPP to its participants. Given the focus on the efficacy, CDC requires submission of significant performance data beyond what is required by CMS, for example, participants reported minutes of physical activity. Where CDC's requirements for DPP organizations aims to ensure quality, CMS's requirements aim to protect the integrity of the Medicare program and the beneficiaries it serves through ensuring compliance. We rely on CDC requirements where appropriate for quality purposes, for example, we defer to CDC requirements to determine what credentialing or training coaches must acquire to successfully furnish DPP sessions. However, these requirements do not address potential program integrity concerns such as how to prevent a coach from harming beneficiaries or the Trust Funds. Thus, we have proposed the coach ineligibility criteria to fill this gap. In absence of any alternative approaches to address program integrity concerns that could harm Medicare beneficiaries or the program at large, we are not amending these proposals.

Comment: Although one commenter acknowledged that background tests may take time and delay enrollments, they did not recommend that CMS change this policy as a result of this delay.

Response: We acknowledge that an MDPP supplier may experience a delay in their enrollment should CMS determine that a coach on their enrollment application is ineligible, however, we believe that this delay would be necessary and appropriate to prevent ineligible coaches from furnishing services to Medicare beneficiaries.

Comment: One commenter suggested that the proposal assigns MDPP suppliers responsibility to credential MDPP coaches. When the commenter referenced credentialing requirements, they included oversight and guaranteeing the quality and competency of individual coaches. Given the proposal that having an ineligible coach could cause a denial or revocation of an MDPP supplier's enrollment, this commenter highlighted a need for a standardized credentialing

process for MDPP coaches that would provide oversight to ensure the quality, consistent delivery and fidelity of the MDPP set of services, as well as to appropriate program integrity standards and requirements.

Response: In response to the commenter's concern, we are providing some clarity on our proposals and some distinctions between a coach being eligible as compared to being credentialed, which we believe will address the commenter's concerns raised. The commenter suggested that because CMS holds the MDPP supplier accountable for knowing whether or not their coaches are eligible, then MDPP suppliers are effectively credentialing MDPP coaches. We disagree with this characterization of credentialing, which typically means that, based on an achievement or demonstration of competency, an individual is deemed qualified for a certain activity. We have previously determined that, consistent with CDC DPRP standards, coaches do not require any specific license or credentials that would deem them qualified to furnish DPP. We believe that the CDC is most appropriately suited to specify minimum training requirements for coaches and we do not wish to add any requirements for coaches to fulfill for the purposes of MDPP. Instead, our proposals seek the inverse. Rather than proposing additional requirements, for example a credential, and only allowing individuals with that credential to qualify as an eligible coach, we are allowing all individuals to be eligible to be a coach, with the exception of individuals with certain histories, which are detailed at§ 424.205(e)(1). We proposed these exceptions to protect the safety and integrity of the Medicare program and the beneficiaries we serve. Though the nuance may seem insignificant, we believe it is an important distinction given that requiring credentials has historically limited access for certain benefits, as raised by certain commenters with respect to requiring specific training.

While the commenter is correct in that our proposals will hold suppliers accountable for having ineligible coaches on their roster, and thus MDPP suppliers should independently verify eligibility, we disagree with the commenter's view that MDPP suppliers have this responsibility rather than CMS. Our proposal under § 424.205(e)(2) highlights that CMS ultimately determines coach eligibility through screening. Thus, while the commenter highlighted a need for a standardized, national credentialing body for MDPP suppliers, we view this as a method of quality assurance to determine an individual's capability to successfully meet the requirements of being a coach. As previously stated in a separate comment response, we rely on CDC to implement quality assurance related to MDPP, and they have not created a national credentialing system or suggested that doing so would improve the quality of the program. In contrast, concerns exist that the creation of such a system would create a barrier to entry that could ultimately drive down the number of available coaches. In the absence of the CDC identifying a need for such a system, we believe that CMS conducting screening for MDPP coaches to determine eligibility would sufficiently address program integrity concerns without creating a bottleneck in the supply of coaches. Though not equivalent to creating a national credentialing system our proposals would establish a standard and streamlined system to check for MDPP coach eligibility run by CMS, and not individual suppliers. Therefore, we will not modify our proposals.

Comment: One commenter recommended that given that all coaches are required to have NPIs, CMS should create a new taxonomy code specifically for ''lifestyle change coach.'' The commenter raised concerns that, absent such a policy change, coaches will select a wide variety of taxonomies and that given that MDPP coaches do not require credentialing or licensure, it is possible that none of the existing taxonomies may apply. The commenter suggested that a single taxonomy with accompanying guidance to MDPP coaches could eliminate confusion in the NPI application process and facilitate tracking of coaches.

Response: We thank the commenter for the thoughtful consideration of the most appropriate taxonomy designation for MDPP coaches who obtain an NPI. In the CY 2017 PFS, we previously suggested that Health Educator [174H00000X] may be appropriate for MDPP suppliers. Though we have no current plans to track MDPP coaches through the taxonomy associated with their NPIs at this time, we recognize the commenter's concern and acknowledge that a new taxonomy code specific to MDPP suppliers may be more appropriate than current options, and may also result in a more straightforward process. We will explore the possibility and appropriateness of this suggestion, and will provide updates through guidance and other MDPP supplier support materials, as appropriate.

Comment: One commenter who expressed disagreement with the proposed coach eligibility criteria given that they did not align with CDC DPRP standards later went on to urge CMS to require that coaches be supervised by a licensed medical professionals as an alternative to coach eligibility requirements.

Response: Though supervision by a licensed medical provision has been previously discussed and not finalized in the CY 2017 PFS final rule, and is therefore out of scope as a standalone requirement, using this as an alternative to the coach eligibility requirements differs slightly from our previous consideration of this policy. While we do not believe that CDC's DPRP standards are appropriate for program integrity safeguards and have thus proposed coach ineligibility criteria to avoid any program integrity risks, we do believe that CDC is more appropriately suited to determine credentialing requirements of the individuals furnishing the curriculum it oversees for the DPP. The commenter's proposal that CMS should require licensed medical professionals to supervise coaches does not align with CDC's DPRP standards, and thus, we do not believe it is necessary to add that requirement from a quality standpoint. Furthermore, we do not believe that supervision by a licensed medical professional would address all of the same program integrity risks that are mitigated by the coach eligibility criteria.

Comment: We received a number of comments on policies previously discussed as a part of the CY 2017 PFS final rule. Most commonly, commenters urged CMS to reconsider requiring coaches have a form of credentialing or medical license, or that they be supervised by an individual with either. Two commenters urged against requiring certain coach training requirements that they believed were costly and could potentially limit the number of coaches available to furnish MDPP services. Additionally, we received a comments opposing that coaches obtain national provider identifiers (NPIs).

Response: Each of these topics were previously discussed and final determinations made through the CY 2017 PFS final rule, and therefore, comments are out of scope of the policies proposed in this rule. More information on our previous discussion of these policies can be found in section III.J.7 of the CY 2017 PFS final rule. In response to commenters' concerns regarding the potential barriers of coach training, we clarify that MDPP does not require training beyond current CDC DPRP requirements. Should the commenter have additional questions or

concerns related to DPRP requirements, we encourage them to share this feedback with appropriate contacts at the CDC.

After considering the public comments, we are finalizing all polices related to MDPP coach eligibility as proposed at paragraphs § 424.205(d)(3), (e), and (h)(1)(v).

(3) Ensuring MDPP Suppliers Are Legitimate, Operational Organizations

We proposed a number of requirements that would help ensure that MDPP suppliers are operational, have the resources necessary to furnish MDPP services, and are in compliance with MDPP supplier standards. At § 424.205(d)(4), we proposed that, regardless of whether the MDPP supplier furnishes services solely in community settings, it must maintain at least one administrative location (82 FR 34163). All administrative locations maintained by the MDPP supplier must be on an appropriate site available to the public and must be reported on the CMS-approved enrollment application. We proposed that this administration location may not be a private residence. We proposed that an appropriate site must have signage posted on the exterior of the building, as well as be open for business and have employees, staff, or volunteers present during operational hours. For the purposes of this requirement, such signage may include, for example, the MDPP supplier's legal business name or its ''doing business as'' (DBA) name, as well as hours of operation. This proposal sought to utilize measurable objective indicators to determine that organizations are legitimately operating and able to furnish MDPP services to Medicare beneficiaries. We stated that we believe that, regardless of whether the MDPP supplier furnishes services at its administrative location, establishing a physical location is necessary for associated requirements for furnishing MDPP services, including recordkeeping requirements, training facilities, and storage for any educational materials distributed during sessions.

We proposed, at § 424.205(d)(6), that a MDPP supplier must maintain a primary business telephone number listed under the name of the organization in public view. Public view could signify, for example, that the phone number is listed on a Web site, on flyers and materials. This policy would require that calls must not automatically go to the answering machine or utilize an answering service during posted business hours. The purpose of this requirement is to help verify that the organization is a legitimate organization and not simply posing as an organization and seeking to bill Medicare fraudulently.

We further proposed, at § 424.205(d)(7), that an MDPP supplier must not knowingly sell to or allow another individual or entity to use its billing number, consistent with § 424.535(a)(7). We included this proposal to avoid a situation in which another entity uses an existing MDPP supplier's billing number. We stated that we believe that this policy plays an important role in ensuring that payments are only being made to the intended recipient who has met all of the supplier and compliance standards and that we continue to hold entities responsible for maintaining compliance. Otherwise, we risk making payments to suppliers potentially engaging in fraudulent or potentially harmful behavior.

We stated that we believe that the requirements in this section would not pose an undue burden on MDPP suppliers as they are minimum requirements for any functional, operational organization. By establishing these requirements, we believe that we would ensure that MDPP suppliers that do not meet the baseline requirements for an operational organization would not be permitted to furnish MDPP services to or receive payment for such services. We proposed, at § 424.205(d)(15), that an MDPP supplier must permit CMS or its agents to conduct onsite inspections to ascertain the supplier's compliance with these standards. Although we believe that any operational business that truly furnishes MDPP services would be able to meet these requirements, we invited public comments on any aspects of these standards.

The following is a summary of the public comments received on our proposals for requirements that would help ensure that MDPP suppliers are operational, have the resources necessary to furnish MDPP services, and are in compliance with MDPP supplier standards and our responses:

Comment: Many commenters provided helpful feedback on the applicability, or in some cases, the inability to apply these proposals in certain scenarios. Many commenters expressed concern with the requirement that MDPP suppliers have signage on the exterior of the building. Specially, commenters noted that many organizations lack the ability to post such signage, for example those in historical buildings, those in large, multi-story office buildings, as well as those leasing space who are not permitted to affix signage. One commenter suggested that as alternative to requiring signage, having the supplier's name listed in the building directory, if available, should suffice as an alternative method to meet this policy goal. The same commenter went on to suggest that CMS should leave advertisement decisions for the suppliers to implement rather than stipulate requirements, and that CMS should not impose such stringent requirements under the guise of preventing fraud, waste, and abuse. As an alternative, the supplier suggested that CMS conduct random audit and site visits to determine operational status.

Response: We appreciate the commenters' feedback about the challenges a signage requirement may pose on MDPP suppliers who are operational, but who lack the ability to affix signage on the exterior of the administrative location where they primarily operate. It was not our intention to impose a new requirement on MDPP suppliers or to require signage as a specified form of advertising. Rather, we intended this proposal to indicate to MDPP suppliers what criteria they would be checked against and be held accountable for during a site visit that is aimed at determining operational status. Given that MDPP suppliers enroll upon high categorical risk, a site visit is required as a prerequisite to enrollment. This site visit seeks to ensure both the veracity of what is reported on the applicant's enrollment form and to verify that the organization is operational.

Based on commenters' feedback, we understand that the proposed policy would not serve its intended goal, and therefore, we will amend the proposal to allow multiple methods that an MDPP supplier could use to demonstrate its association with a specific location. We believe that by restructuring the MDPP supplier requirement to require that MDPP suppliers have signage posted on the exterior of the building or suite, in a building directory, or on materials located inside of the building provides sufficient flexibility such that any MDPP supplier who truly is operational would not need to change their current operations in order to meet this supplier standard.

Comment: One commenter disagreed with the proposal that MDPP suppliers must have employees, staff, or volunteers present during operational hours. This commenter did not support this proposal based on inconsistency with previous DPP requirements under the CDC and with how many in-person community programs operationalize their programs. One commenter indicated that current DPP organizations

do not operationalize their in-person programs in a way where employees, staff, or volunteers were present at an administrative location during operational hours.

Response: We do not agree with the commenter that functioning DPP organizations could not meet this requirement. We appreciate the commenter for expressing these concerns and notifying CMS that not all MDPP suppliers operate their business with individuals present during stated operational hours. The commenter did not describe where employees, staff, or volunteers of the MDPP supplier operated during operational hours, if not at the administrative location itself; therefore, we have limited information to better understand how to structure this requirement in way that could determine whether or not a prospective MDPP supplier applicant truly operated its business without requiring current DPP organizations to change their business operations. Though we can conceive of scenarios in which an MDPP supplier has stated operational hours, but furnishes an MDPP session at a community location, and therefore, may not be present at the administrative location during stated operational hours, we do not believe that removing this requirement altogether would be appropriate. Furthermore, we clarify that we are not imposing specific operational requirements on the MDPP supplier. Thus, each MDPP supplier can determine and disclose its operational hours when it plans to physically be at the administrative location. An MDPP supplier who operates many services outside of their administrative location can also disclose when its operational hours are either telephonic or in a location other than its administrative location. We also highlight the significant flexibility we are providing in this supplier standard in that employees, staff or volunteers can fulfill this requirement, and we take no position as to whether these individuals serve as MDPP coaches or in another function for the supplier. The intent of this proposal was to ensure that an MDPP supplier maintains operational hours and truly fulfills these hours. We do not agree with the commenter that functioning DPP organizations could not meet this requirement, thus, we will finalize this policy as proposed.

Comment: A number of commenters disagreed with the requirement that MDPP suppliers maintain a primary business telephone that operates either at an administrative location or directly where services are furnished. In particular, commenters did not agree with the discussion in the preamble of the proposed rule which indicated that the proposed requirement would not allow calls to automatically go to the answering machine or the utilization of an answering service during posted business hours. Many commenters highlighted that it is an unrealistic expectation to never allow a call to go to some form of message system, even during business hours. Though multiple commenters expressed practical concerns with this requirement, one commenter went as far as to suggest that this proposal could potentially dissuade prospective MDPP supplier applicants from their decision to enroll. This commenter recommended establishing a call back standard, for example, that MDPP suppliers must return calls within 1 business day.

Response: We agree with commenters that a requirement that every phone call be answered during operational hours would be burdensome, unrealistic, and extend far beyond the intention behind the proposal. We want to clarify that the proposal at § 424.205(d)(6) only requires that MDPP suppliers have a telephone that operates at an administrative location or the location where MDPP services are being furnished, and that the associated telephone number must be listed with either the legal or doing business as name of the supplier in public view, including on Web sites, flyers, and materials. However, we understand why commenters expressed concern that we were also requiring that phone calls to this number be answered and not automatically go to a machine based on language in the preamble that provided rationale for our proposal.

To clarify, when we noted that the proposal at § 424.205(d)(6), would require that calls must not automatically go to the answering machine or utilize an answering service during posted business hours, we did not intend to add this as a standalone requirement. This sentence was intended to convey that by requiring MDPP suppliers to maintain a primary business telephone that operates either at administrative locations or directly where services are furnished, MDPP suppliers could not, by default use an answering machine or answering service as their primary contact number. We did not mean to suggest that MDPP suppliers may never use an answering machine. Thus, while we expect that MDPP suppliers may allow phone calls to go to an answering machine or service during operational hours, we believe the standard as proposed at § 424.205(d)(6) will achieve the intended goal of providing a mechanism to ensure that MDPP suppliers are operational. We believe that this clarification addresses concerns raised by commenters, and we thus will finalize the policy as proposed.

After considering the public comments, we are finalizing the policy requiring MDPP suppliers to have at least one administrative location at an appropriate site, as proposed at § 424.205(d)(4); however, we are modifying § 424.205(d)(4)(i) to allow for increased flexibility for signage requirements. After clarifying commenters' confusion about telephone requirements, we are finalizing policies as proposed at § 424.205(d)(6). We received no comments on the proposal that MDPP suppliers may not knowingly sell to or allow another individual or entity to use its supplier billing number, and thus are finalizing as proposed at § 424.205(d)(7).

(4) Beneficiary Access

We proposed, at § 424.205(d)(8), that MDPP suppliers may not deny access to MDPP services to eligible beneficiaries based on any reason other than the supplier's own self-determined and published capacity limits to furnish MDPP services to additional people and, on a discretionary basis, if a beneficiary significantly disrupts the session for other participants or becomes abusive (82 FR 34163 through 34164). Given that we do not yet currently have data on optimal class size for MDPP services, we are currently allowing MDPP suppliers to self-determine any upper limitation on class size. Should they establish such a limit and intend to turn beneficiaries away once the capacity limit is reached, the MDPP supplier must have previously made this limit publicly available; for example, denoting the limit in any brochures, Web sites, or other materials that outline their MDPP services. We proposed that MDPP suppliers must maintain a record of the number of eligible Medicare beneficiaries turned away for each of these reasons, as well as the date the beneficiary was informed. We further proposed that if an MDPP supplier denies a Medicare beneficiary access citing disruptive or abusive behavior, details of the occurrence(s), including date(s) of the behavior, any remediation efforts taken by the supplier, and final action (for example, dismissal from an MDPP session or denial from future sessions) must be documented in the beneficiary's MDPP records and adhere to documentation requirements outlined in § 424.205(g). We note that one supplier's decision to dismiss a beneficiary for this purpose would not prevent that beneficiary from switching to another MDPP supplier.

We stated that we will seek to monitor compliance with this requirement, and investigate further if necessary, based on beneficiary complaints, rates of access denials citing capacity limits in comparison to estimated capacity based on claims submitted, as well as monitoring claims for success rates for achieving performance goals that are higher than what would be expected for a typical Medicare population. Illustrative examples of capacity limits could include that the MDPP supplier has met its self-determined and published class size maximum, or that the supplier is providing MDPP sessions in cohorts and does not have a new or upcoming cohort at the time the beneficiary is seeking MDPP services. Furnishing MDPP services in a cohort means that the DPP curriculum is delivered among a single group, or cohort, from start to finish with sessions furnished in a specific order, and not allowing any new individuals to join once the cohort has begun.

Given that our payment structure for MDPP services relies on the achievement of weight loss and attendance goals, there may be incentives for MDPP suppliers to seek to serve only those beneficiaries for which they are more likely to earn performance payments. This, in turn, could result in discriminatory treatment of beneficiaries. Through this supplier standard, we would expressly prohibit MDPP suppliers from conditioning access to MDPP services on the basis of a beneficiary's weight or health status (except as provided in our regulations). We also would prohibit MDPP suppliers from conditioning access to MDPP services on the basis of a beneficiary's achievement of performance goals, except where the beneficiary becomes ineligible for additional sessions as a result of not meeting those goals, as discussed elsewhere in this final rule. We stated that we believe that it is appropriate to prohibit suppliers from denying access to MDPP services except in certain limited circumstances. If a supplier were to deny access to a beneficiary citing lack of capacity, but then furnish MDPP services to a different beneficiary, this may signal a violation of such standards. In addition, and for the same reasons, we proposed to prohibit MDPP suppliers, including any coaches or entities performing functions or furnishing services related to MDPP services on their behalf, from unduly coercing a beneficiary's decision to change or not change to a different or specific MDPP supplier, including through the use of pressure, intimidation, or bribery in § 424.205(d)(9). Information that may result in a beneficiary changing to a different MDPP supplier provided in response to a beneficiary's request for information would not violate this provision.

The CY 2017 PFS final rule, at § 424.79, established the set of services included in the expanded model, but did not stipulate that once a supplier began furnishing such services to a beneficiary, that it must continue to offer them to the beneficiary as a part of the MDPP expanded model. We proposed, at § 424.205(d)(10), that MDPP suppliers must offer and provide beneficiary access to the *entire set* of MDPP services for which beneficiaries are eligible. This includes the requirement that suppliers offer at least 16 in-person core sessions, no more frequently than once per week, over the first 6 months of the core services period and offer at least 6 core maintenance sessions, at least once per month, over months 7 through 12 of the core services period (§ 410.79(c)(2)(i)). For beneficiaries to whom the supplier has begun furnishing MDPP services, and who meet the eligibility requirements for ongoing maintenance sessions described in § 410.79(c)(1)(ii) and (iii), MDPP suppliers are required to offer 24 ongoing maintenance sessions, furnished at least once per month over the course of months 13 through 36 of the MDPP services period, in 3-month consecutive increments. These requirements would also apply to any MDPP supplier which begins furnishing MDPP services to a beneficiary that had begun the MDPP services period with a different MDPP supplier. Should this MDPP supplier begin furnishing services to a beneficiary at any point during the 3-year MDPP services period, it must continue to offer the services for which the beneficiary is eligible but has not yet received. For example, if a beneficiary changed suppliers after the core sessions in month 6, the subsequent supplier would be required to offer core maintenance sessions for months 7 through 12, and ongoing maintenance sessions should the beneficiary remain eligible for these services.

We also solicited public comments on a potential future policy to require a specific class size limit for MDPP sessions. Although we acknowledge that MDPP services may be successfully furnished in group settings, we stated that we believe that it is important to ensure that the group's size is appropriately set such that each beneficiary gains the necessary interaction with the coach furnishing the session to properly learn the curriculum. We considered different mechanisms to ensure this program objective, and requested public comments on considerations to date. The mechanism that currently seems most viable would require a limitation on the number of total attendees in a given session taught by an individual coach. Based on CDC's experience with the DPP program and review of the literature on appropriate class sizes for educational settings, we considered including a class size limitation of 30 participants per coach in a given session (including Medicare beneficiaries). Given that limited data currently exist on this type of requirement among DPP sessions, we solicited public comments on what an appropriate class size limitation would be, including any evidence to support such a proposal.

Furthermore, we solicited public comments on how MDPP suppliers who furnish sessions in no specific sequential order and allow drop ins would balance the requirement of providing beneficiary access with a class size requirement for a given session. For example, if a supplier offers classes multiple times a week and gives beneficiaries flexibility regarding when to participate, we questioned whether a certain class size limitation could force a supplier to turn away a beneficiary seeking to attend a session at a time when attendance is high, and in so doing potentially discourage attendance at MDPP classes. In addition, we are unsure of any implications that would result from establishing a class size restriction for MDPP services while acknowledging that MDPP beneficiaries may participate in DPP sessions with non-Medicare beneficiaries who may not face the same class size limitation. Given these considerations, we solicited public comments on how we could structure a proposal in the future that would achieve the programmatic goals of effectively furnishing the DPP curriculum to Medicare beneficiaries in a manner and setting that contributes to positive behavioral changes and ultimately less progression to type 2 diabetes. In providing comments on this approach, we encouraged the submission of data and evidence to justify what specific class size would be appropriate for MDPP suppliers.

The following provides a summary of and our response to the public comments received on our proposals to prohibit MDPP suppliers from denying access to MDPP beneficiaries with limited exceptions, to require that MDPP suppliers document when they deny a beneficiary access under two of these exceptions, and to prohibit MDPP suppliers or individuals working on its

behalf from unduly coercing a beneficiary's decision to or not to switch to a different MDPP supplier.

Comment: One commenter supported that CMS did not define the capacity limit for MDPP suppliers. The commenter agreed that MDPP suppliers should have the flexibility to determine the optimal class size to effectively deliver MDPP services.

Response: In the absence of data to support a specific class size, we agree with the commenter that providing MDPP suppliers' flexibility to determine capacity limits, such as a supplier's capacity to accommodate or effectively serve a given number of participants per cohort, which is appropriate for its method of delivery is the correct policy decision at this time. We believe that most MDPP suppliers, in absence of a specified limit, will identify a reasonable size class size that enables a sufficient level of beneficiary engagement that results in sustained attendance and weight loss.

Comment: MedPAC, however, contended that the proposal should have specified a class size. Their concerns on class size compounded with other concerns, including but not limited to not requiring eligible individuals to receive referrals from physicians or non-physician practitioners for MDPP services. To illustrate their concerns, they presented a specific scenario of a coach furnishing a large MDPP session in a nursing home without consideration of the clinical inappropriateness of MDPP services and the targeted weight loss for each individual in attendance.

Response: Though we acknowledge MedPAC's concerns that allowing class size flexibility would allow MDPP suppliers to furnish services in large class sizes, we do not wish to impose a specific class size limitation without data to support such a decision. Further, we do not agree that our policy decisions could result in the scenario MedPAC illustrated in their comment. We discuss a response to their concerns about referrals in section III.K.2.c of this final rule.

Furthermore, we believe that even in absence of a specific policy imposed by CMS, MDPP suppliers have incentives to furnish MDPP in smaller class sizes that are more conducive to engaging beneficiaries in behavioral change practices that will lead to weight loss and lowered diabetes risk. We believe that the payment structure rewards MDPP suppliers when MDPP beneficiaries meet weight loss goals. Thus, high levels of beneficiary engagement are to the benefit of both MDPP suppliers and beneficiaries, in order to achieve this weight loss. Based on experience with performance in the DPP indicating that beneficiary engagement plays a critical role with sustained attendance and weight loss, we believe that MDPP suppliers have greater incentives to furnish sessions in smaller settings with high levels of engagement than to furnish sessions with a high volume of participants, but low levels of engagement.

In addition to the importance of both sustained attendance and weight loss for MDPP payment, it also plays a significant role in maintaining CDC recognition. If suppliers conduct large sessions, beneficiary engagement is likely to be lower. Stakeholders have suggested that this may result in decreased attendance and/or failure to lose weight. If a supplier is furnishing MDPP services in extremely large classes where a large proportion of participants either do not attend or lose 5 percent of their body weight, this will negatively impact DPRP performance data that are necessary to maintaining recognition status. Should a supplier lose its recognition status, it will no longer be eligible for enrollment in Medicare.

Taken together, we believe that MDPP suppliers have larger incentives—both financial for MDPP reimbursement and sustainability of recognition status based on DPRP performance requirements—to furnish small sessions rather than large sessions. If some suppliers initially offer larger classes, we believe that lower per beneficiary reimbursement and threat of lost CDC recognition will motivate suppliers to self-correct. Regardless of this belief, we will monitor for activities that would indicate if an MDPP supplier is furnishing services in an overly large group. As a result of this monitoring and/or if we receive evidence to support an appropriate class size limitation, we may reconsider imposing a class size limit at a later date.

Comment: A number of other commenters responded to the request for information on suggested class sizes. In making their recommendations, many commenters noted that beneficiaries require a fairly high level of engagement in order to successfully adopt behavior changes that ultimately result in weight loss and decreased risk of type 2 diabetes. Two commenters recommended a maximum class size of 15, another recommended 20, another a minimum of 5 and maximum of 25, and a final with 30. One commenter recommended that the beneficiary to coach ratio not exceed 1:12–14, though they did not respond to the other challenges we outlined with imposing such a ratio.

Response: We thank the comments for providing this level of detail on their suggested class size and will consider these responses in the future should we decide to reconsider this proposal.

Comment: One commenter with experience offering the National DPP requested an additional exception that would allow MDPP suppliers to deny beneficiaries from joining an existing MDPP cohort that had already met three or four times. The commenter indicated that their experience providing the National DPP showed that the initial classes work to establish a group dynamic, and adding an individual to a recently established group can disrupt that dynamic.

Response: We understand the commenter to be requesting the addition of another exemption under § 424.205(d)(8), which prohibits MDPP suppliers from denying an MDPP beneficiary access to MDPP services during the MDPP services period. We decline to adopt the commenter's recommendation as we stated in the proposal that this would constitute a capacity limit: ''Illustrative examples of capacity limits could include that the MDPP supplier has met its self-determined and published class size maximum, or that the supplier is providing MDPP sessions in cohorts and does not have a new or upcoming cohort at the time the beneficiary is seeking MDPP services.''

Though we specifically utilized the word capacity in order to capture the diversity of MDPP delivery styles, we understand that by framing this requirement as ''lacking capacity'' may have signified that a maximum number of participants had been reached, though in the scenario raised by the commenter, an MDPP supplier may consider furnishing MDPP services through cohorts, and once they have commenced, the capacity can be considered reached for additional MDPP beneficiaries. To more appropriately capture the above listed examples of capacity, we will modify the proposal such that an MDPP supplier may deny access to a beneficiary if the MDPP supplier lacks the self-determined and publicly-posted capacity. Though we discussed the need to publicly post the capacity in our proposal, we would like to emphasize this point by including it in our regulation. Additionally, we are changing the language from ''an additional'' beneficiary to ''a given beneficiary'' in the circumstance where an MDPP supplier establishes a minimum capacity to which to furnish services to beneficiaries, given that

MDPP services are offered in group setting and some MDPP supplier may determine that an optimal capacity for engagement includes both a minimum and maximum number of participants. Other forms of capacity requirements are discussed further in this section in response to other commenters. We would like to clarify that, denying an MDPP beneficiary access to a specific MDPP session due to capacity reasons, even if the MDPP supplier offered the beneficiary access to a different session at a later date would constitute a denial of MDPP services under § 424.205(d)(8)(i)(B) until that beneficiary ultimately received MDPP services from the supplier.

Comment: One commenter requested that CMS allow integrated systems that develop and provide approved MDPP services to serve only their own enrollees.

Response: While the commenter did not point to a specific proposal that would prohibit an integrated system from serving only its own enrollees, we believe that the commenter is referencing the prohibition on denying beneficiaries access to MDPP services under § 424.205(d)(8). Additionally, as the commenter specifically addresses ''enrollees'' we believe the commenter is contemplating Medicare Advantage enrollees in an MA plan who receive services and are provided coverage for those services within an integrated system. Under § 424.205(d)(8), an MDPP supplier must not deny an MDPP beneficiary access to MDPP services during the MDPP services period described in § 410.79(c)(2) of this chapter, including on the basis of the beneficiary's weight, health status, or achievement of performance goals, unless the denial falls under one of three exemptions listed at § 424.205(d)(8)(i)(A)–(C). In the commenter's example, denying access to MDPP beneficiaries other than the MDPP supplier's own enrollees would clearly violate the prohibition established in § 424.205(d)(8), as the MDPP supplier is affirmatively denying access to MDPP services for all non-enrollees. Therefore, to be permissible, the MDPP supplier's denial of non-enrollees must qualify as an exception under § 424.205(d)(8)(i).

The exceptions found at § 424.205(d)(8)(i)(A) (beneficiary no longer meets eligibility criteria for MDPP services) and § 424.205(d)(8)(i)(C) (MDPP beneficiary significantly disrupts the session for other MDPP beneficiaries or becomes abusive) would not apply to the example provided by the commenter. However, § 424.205(d)(8)(i)(B) warrants further discussion. Under this provision, an MDPP supplier may deny an MDPP beneficiary access to MDPP services where the MDPP supplier lacks the self-determined and publicly-posted capacity to furnish MDPP services to a given MDPP beneficiary. A supplier's ''capacity'' to furnish MDPP services encompasses several categories of capabilities that ultimately impact a supplier's capacity to furnish MDPP services to a MDPP beneficiary. For instance, a supplier could lack capacity to furnish MDPP services to a given MDPP beneficiary where the MDPP supplier lacks adequate physical space to accommodate the MDPP beneficiary if the MDPP supplier determines that its enrollment is at capacity for the space. Additionally, a supplier could lack capacity to furnish MDPP services to a given MDPP beneficiary where there are a finite number of coaches to hire to provide MDPP services, which in turn would reasonably limit the number of MDPP cohorts or classes that the MDPP supplier could provide as well as the number of MDPP beneficiaries that the MDPP supplier could accommodate.

Furthermore, an MDPP supplier could lack capacity to furnish MDPP services to a MDPP beneficiary where the MDPP supplier lacks business processes that would be required to furnish services to a MDPP beneficiary. In such a case, the MDPP supplier would need to determine that the burden of implementing the necessary business process rises to the level of a capacity limitation within the meaning of § 424.205(d)(8)(i)(B). It is this type of capacity that we believe to be at issue in the example provided by the commenter as where an MA plan that is part of an integrated system furnishes MDPP services to MA plan enrollees in the role of an MDPP supplier, the MA plan may lack a number of business processes that would be required to furnish MDPP services to non-enrollees and bill Original Medicare on a fee-for-service basis for those services.

Some of these required business processes could not reasonably be determined to rise to the level of a capacity limitation, such as the need for the MDPP supplier to develop processes to request and receive medical information from non-enrollees to determine eligibility for MDPP services. As an integrated system that is both payer and provider, the MDPP supplier would not need such processes as it would be able to pull lab values or recorded weights to determine eligibility for MDPP services from the enrollee's own health records kept by the system. Yet, such processes would be in place for the MA plan of which the MDPP supplier is apart given that the plan would commonly need to request and accept medical information on new enrollees. So, while this is an example of a business process that the MDPP supplier would be required to develop to serve non-enrollees, it likely does not rise to the level of a capacity limitation if it is a business process that the MA plan as a whole already has in place for the MDPP supplier to adopt as well.

However, the need for other business processes could reasonably be determined to rise to the level of a capacity limitation. For instance, MA plans do not bill Original Medicare on a fee-for-service basis for services provided to enrollees, and therefore lack the capacity to perform an operational requirement that would be necessary if the MA plan, as part of an integrated system, were to furnish MDPP services to non-enrollees under their MDPP supplier role. Given the administrative burdens associated with implementing the business processes required to bill fee-for-service Medicare, an MDPP supplier in this instance would be reasonable in determining that the complete lack of such a business process would rise to the level of a capacity limitation. As we believe that commenter's example is permitted under an existing exception to § 424.205(d)(8), we decline to adopt commenter's recommendation to articulate an additional, specific exception for an MDPP supplier that is part of an MA plan operating within an integrated system that wishes to exclusively provide MDPP services to its enrollees. However, we may continue to evaluate this issue for future rulemaking, as appropriate.

Comment: One commenter expressed concern regarding the exception that MDPP suppliers may deny access to MDPP services if a beneficiary is disruptive or abusive. The commenter questioned whether allowing MDPP suppliers to deny access based on behavioral issues would disproportionately affect individuals with serious mental illnesses (SMI) who may be more likely to be disruptive based on their SMI. Given that certain classes of medications used to treat SMI are known to increase the risk of both obesity and diabetes, individuals with SMI who would likely benefit from diabetes risk prevention may be more likely to be denied access based on this exception to the supplier standard. While the commenter did not explicitly suggest removing this exception, but instead, highlighted a potential issue with only offering in-person sessions delivered in a group to individuals with SMI, the commenter suggested that a

virtual model may more appropriately suit the needs of individuals with SMI.

Response: We recognize the concerns raised by the commenter regarding the potential unintended consequences of such a proposal. In proposing the exemption to allow suppliers to deny access to an MDPP beneficiary who significantly disrupts a session for other beneficiaries or becomes abusive, we in no way intended to discriminate against individuals who, because of a condition, medication, or illness may be more prone to disruptive or abusive behavior. In the context of MDPP, disruptive behavior would entail preventing the information from being appropriately conveyed from the coach to other participants. Examples may include repeated interruptions unrelated to the session content, playing music or video content unrelated to MDPP during a session, or raising discussions on topics unrelated to MDPP or its content. Should the beneficiary's communications relate to the MDPP content (for example, a beneficiary asking many clarifying questions about the material), this would not qualify as disruptive behavior in an MDPP group session. Abusive behavior would entail behavior that results in physical, emotional, or psychological harm to those participating in the MDPP session, include an MDPP coach, beneficiary, or other MDPP personnel. For example, any violent behavior or bullying could constitute abusive behavior in this context. Given that MDPP is furnished in group settings where one beneficiary's action can affect others, we believe that allowing MDPP suppliers to remove beneficiaries who engage in these behaviors is particularly appropriate.

Though we do not wish to subject other Medicare beneficiaries to disruptive or abusive behaviors, we agree with the commenter that individuals with those behaviors, either as a result of SMI or otherwise, who are eligible for MDPP services generally should have access to such services. MDPP sessions are furnished by coaches who do not have medical training beyond what the DPRP requires. Should an individual with SMI become abusive, it does not seem appropriate to require that the supplier continue to furnish services to that beneficiary. In such a scenario, the beneficiary may be better suited to be under the care of a professional with specific training to appropriately work with beneficiaries with SMI. Furthermore, given that MDPP coaches furnish sessions in a group setting, we must also consider the needs of all participating beneficiaries. With these considerations in mind, we believe that our original proposal is appropriate.

Comment: We received one comment on our proposal to require documentation when a beneficiary is denied for any reason other than losing eligibility. This commenter disagreed with this proposal, citing that it creates yet another administrative requirement and burden on MDPP suppliers.

Response: While we recognize that this requires additional recordkeeping by suppliers, we believe that it serves an important purpose to dissuade MDPP suppliers from denying access based on any reasons other than those allowed. With such a requirement, CMS would be able to review MDPP suppliers' records related to denial of access to beneficiaries to ensure compliance. Given the performance-based nature of the MDPP payment, we believe some MDPP suppliers may wish to attract beneficiaries they perceive as more likely to achieve attendance and weight loss performance goals and may wish to deny those who they perceive as being less likely. We do not want to encourage cherry picking among suppliers where such behaviors occur, and thus are not altering our proposal.

Furthermore, we would like to take this opportunity to clarify our proposal. Under § 424.205(d)(8)(ii), an MDPP supplier must maintain a record of the number of MDPP beneficiaries for whom it declined access for the reasons outlined in § 424.205(d)(8)(i)(B) and (C), to include the date each such beneficiary was declined access. If a beneficiary is denied under § 424.305(d)(8)(i)(B), stating in the record ''self-determined capacity'' alone as the reason the beneficiary was denied would not sufficiently address the documentation requirements. As stated in the proposal, we intended this documentation to provide insight into the specific capacity reasons a beneficiary was denied to ensure that it aligned with the MDPP supplier's previously published capacity limits.

Comment: We did not receive any comments on proposals at § 424.205(9) which prevented an undue coercion of an MDPP beneficiary's decision to change or not to change to a different MDPP supplier. We similarly received no comments on the proposal at § 424.205(10) requiring that the MDPP supplier furnish all services for which an MDPP beneficiary is eligible.

Response: Given no feedback on these proposals, we are finalizing as proposed.

After considering the public comments, we are finalizing the policies as proposed under § 424.205(d)(8) as proposed except to modify § 424.205(d)(8)(i)(B) to state the MDPP supplier lacks the self-determined and publicly-posted capacity to furnish MDPP services to a given MDPP beneficiary. Given no feedback from commenters, are finalizing § 424.205(d)(9) and § 424.205(d)(10) as proposed, with a modification to § 424.205(d)(10) to align with changes in proposals at § 410.79(c)(2) where ongoing maintenance sessions are only available for eligible beneficiaries for one year, rather than the proposed two.

(5) Disclosure

We proposed, at § 424.205(d)(11), that MDPP suppliers must provide information about the MDPP expanded model to each beneficiary to whom it wishes to begin furnishing MDPP services (82 FR 34164 through 34165). This included detailed information on coverage for the set of MDPP services, the once-per-lifetime limit, on eligibility requirements, and the MDPP supplier standards. We recognized that many aspects of the MDPP expanded model are novel for both beneficiaries and suppliers, and we desire that both parties are well informed. Therefore, we stated that we believe that requiring the supplier to fully disclose information about the MDPP expanded model, coverage, and the MDPP supplier standards will help inform all parties. We intend to provide a specific template for the MDPP supplier to use to disclose this information to the beneficiaries. For this reason, we stated that we do not believe that requiring this type of disclosure places a significant burden on the supplier. Although we believed that this approach will help to address the policy goals of the MDPP expanded model, we invited public comments on this approach, particularly upon the provision of a standard CMS disclosure notification as compared to CMS providing MDPP suppliers with information they could use to their own disclosure notification materials. Along these lines, we highlight that we also intend to publish information on the MDPP expanded model in the 2019 Medicare & You Handbook.

We invited public comments on these proposals.

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

Comment: We received one comment regarding our supplier standard requiring MDPP suppliers to disclose information to beneficiaries about the program. The commenter expressed full agreement with our proposal, and endorsed the potential CMS-created template to ensure consistency of messaging. In particular, this

commenter requested that any such information be provided during the 2018 enrollment period. Additionally, the commenter suggested that MDPP model information be included in the 2019 Medicare & You Handbook.

Response: We appreciate the support for our proposed policy and thank the commenter for expressing specific suggestions regarding how CMS can best equip suppliers to comply with this comment in a manner that is consistent across all MDPP suppliers. We will consider these suggestions as we create any resources to MDPP suppliers, and will release information through guidance as appropriate.

We are clarifying in this final rule that the disclosure requirements we proposed at § 424.205(d)(11) specified that, before the initial core session is furnished, the MDPP supplier must disclose detailed information about the set of MDPP services to each MDPP beneficiary to whom it wishes to begin furnishing MDPP services. At § 424.205(d)(11)(i) and (d)(11)(ii), this requirement then goes on to specify that this disclosure must include eligibility requirements as outlined under § 410.79(c)(1) and the MDPP supplier standards overall. In our proposal, we intended that detailed information about the set of MDPP services included which services, at minimum, were covered in the MDPP set of services. Given that the supplier standard proposed and finalized at § 424.205(d)(10) outlines these services, and MDPP suppliers must disclose their standards to beneficiaries, we believe that under our ordinary proposal, MDPP suppliers have provide MDPP coverage information to beneficiaries. However, to avoid any potential uncertainly, we are amending our proposed supplier standard to explicitly require that the MDPP supplier disclose MDPP coverage information, in addition to information on eligibility and MDPP supplier requirements. Though we believe that this requirement was already implicit in the proposal, we believe that clarifying this point to more overtly stipulate that MDPP suppliers disclose coverage information will only help MDPP suppliers understand and comply with the disclosure requirements. Furthermore, we believe that providing this clarity to ensure that all suppliers are disclosing MDPP coverage information to beneficiaries aligns with the request that CMS make efforts to standardize practices across suppliers. Given the discussion on MDPP suppliers' ability to furnish more than the minimum required sessions during the core services period, but their inability to charge beneficiaries as discussed further in section III.K.2.d.iii.(10)(c) of this rule, we believe that this adjustment to our proposal is warranted to ensure MDPP beneficiaries are as informed as possible.

After considering the public comments, we are finalizing the supplier standard regarding disclosure as proposed at § 424.205(d)(11), with a modification to specifically highlight that detailed information about the set of MDPP services not only includes eligibility and supplier standards, as previously proposed, but also minimum coverage requirements under § 410.79(c)(2).

(6) Beneficiary Complaints

We proposed at § 424.205(d)(12) that MDPP suppliers must answer Medicare beneficiaries' questions about MDPP services and respond to MDPP related complaints within a reasonable timeframe in § 424.205(d)(12) (82 FR 34165). We also proposed that MDPP suppliers implement a complaint resolution protocol and maintain documentation of all beneficiary contact regarding such complaints, including the name and Medicare Beneficiary Identifier of the beneficiary, a summary of the complaint, related correspondences, notes of actions taken, and the names and/or NPIs of individuals who took such action on behalf of the MDPP supplier. We proposed that this information must be kept at a supplier's administrative location and made available to CMS or its contractors upon request. These records would adhere to the same recordkeeping requirements in § 424.205(g), and therefore, would need to be maintained for 10 years. Although other records are typically required to be held only for 7 years (per § 424.516(f)), given that the MDPP expanded model includes beneficiary engagement incentives (described further in section III.K.2.f.v.) which require an extended documentation requirement, we considered it important to align all recordkeeping requirements for the MDPP expanded model. As noted earlier in this section, we proposed at § 424.205(d)(15) that an MDPP supplier must allow CMS or its agents to conduct recordkeeping reviews to ascertain the supplier's compliance with these standards, as well as documentation requirements as outlined in § 424.205(g).

We stated that we believe our proposal that MDPP suppliers must answer, respond to, and document beneficiary complaints and resolutions establishes a tracking mechanism to determine whether or not suppliers are adequately addressing beneficiary concerns. We find this requirement particularly important given that complaint procedures provide a good way to ensure best practices by suppliers. Although we acknowledged that this method requires the MDPP suppliers to self-attest to their response to complaints, we stated that requiring such documentation as a required Medicare standard can help to build accountability to following through with complaint resolution. Additionally, mandating that suppliers take and maintain records of complaints may help to address situations where beneficiaries raise issues with us directly after failing to receive resolution from the supplier.

We stated that we believe that requiring this documentation would provide an additional mechanism for us to ensure that the supplier is fully disclosing information pertinent to the supplier standards, specifically those regarding beneficiary access, and other concerns. As an additional benefit of this policy, if a beneficiary is denied access, the MDPP supplier would be required to demonstrate the reasoning behind this approach, and we could have an opportunity to review if this reasoning complied with the standard under § 424.205(d)(8).

This approach is consistent with supplier standards for other Medicare suppliers, including those for Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers. Given that CMS has imposed similar standards regarding supplier responsibility for addressing beneficiaries' complaints among other supplier types, we stated that we do not believe that requiring a similar such requirement poses an undue burden on MDPP suppliers. Rather, we believed that this approach can facilitate beneficiary satisfaction with the services suppliers furnish by requiring that beneficiary complaints are acknowledged, resolved, and tracked appropriately. We stated that we believe that this approach will help ensure that the supplier is meeting beneficiaries' needs as they relate to the MDPP expanded model. In addition, we stated that we believe that this will help ensure the integrity of the MDPP expanded model.

We invited public comments on these proposals.

We received no comments on our proposals requiring that MDPP suppliers respond to MDPP beneficiaries' questions and concerns within a timely manner or that they complete and maintain a complaint resolution protocol. Similarly, we

received no comments on any of our proposed recordkeeping requirements to document beneficiary complaints. Thus, we are finalizing the MDPP supplier standards related to beneficiary complaints under § 424.205(d)(12) as proposed.

(7) MDPP Expanded Model Evaluation Compliance

In the CY 2017 PFS final rule, we finalized a requirement for MDPP suppliers to maintain and submit to CMS a crosswalk file that documented how the beneficiary identifiers submitted to CMS for billing and the beneficiary identifiers submitted to CDC for session-level performance data linked to the same beneficiary as a documentation retention and provision requirement (formerly § 424.59(b), redesignated and amended at § 424.205(d)(13)) in this final rule) (82 FR 34165 through 34166). CMS will use this crosswalk for evaluation purposes so CMS can review session level data that MDPP suppliers provide to CDC to supplement the claims data we receive directly from MDPP suppliers. We indicated that we would provide additional information on format and frequency of this reporting requirement in future rulemaking or administrative guidance as appropriate. We proposed the maintenance and submission of the crosswalk as an MDPP supplier standard and are providing additional details regarding the format and frequency.

We proposed that the crosswalk file would contain Medicare Health Insurance Claims Numbers or Medicare Beneficiary Identifiers and the unique participant identifier assigned by the organization, for the purposes of CDC performance data reporting, for each beneficiary receiving MDPP services (§ 424.205(d)(13)). Beneficiaries for whom at least one Medicare claim was submitted by an MDPP supplier would be required to be included in the crosswalk. We proposed that the crosswalk be supplied to CMS, or our contractor, beginning 6 months after the organization begins furnishing MDPP services, and quarterly thereafter. The crosswalk would be maintained in a spreadsheet (for example, an Excel file or a CSV file), in a form and manner as specified by CMS. We invited public comments on this approach.

The following is a summary of the public comments received on this approach and our responses.

Comment: We received one comment on our supplier standard related to the crosswalk. The commenter did not request a specific change to the proposal, but expressed concern regarding the administrative burden of having to submit performance data to CDC and the crosswalk to CMS. Their specific concern centered on having two separate data submission requirements to two distinct entities—performance data to CDC and the crosswalk to CMS. They stipulated that these requirements would pose an administrative burden to all MDPP suppliers, though they particularly highlighted smaller suppliers and those new to Medicare.

Response: In the CY 2017 PFS, we proposed and finalized that MDPP suppliers would need to submit a document cross-walking beneficiary identifiers in Medicare with their CDC participant ID submitted on performance data to CDC. In this rule, we did not propose new data submissions, but simply incorporated this finalized requirement into the MDPP supplier standards. Thus, the commenters' concern on the burden of needing to submit both performance data to CDC, as well as the crosswalk to CMS is out of scope with this rule. Should the commenter wish to revisit our rationale for this approach, it may do so in section III.J.4.f of the CY 2017 PFS final rule.

Rather that propose any new requirements in this rule, we sought to provide clarity on the information that MDPP suppliers must submit on the crosswalk and its frequency. In efforts to streamline data submission requirements for the crosswalk across all MDPP suppliers, we are further clarifying the requirement we outlined in the proposed rule (82 FR 34165 through 34166), that data must be submitted 6 months after an MDPP supplier begins furnishing services, and quarterly thereafter. Rather than apply crosswalk submission dates on a per supplier basis, which could conceivably result in different suppliers submitting their crosswalks each month of the year, moving forward, we intend to establish four distinct periods where MDPP supplier crosswalks are accepted. With this change in mind, we are adapting our proposal such that MDPP suppliers will become eligible to submit their crosswalk beginning 6 months after they begin furnishing services and must submit at the closest quarter, and continue submitting on a quarterly basis thereafter. We hope that streamlining the submission periods across all suppliers will decrease confusion among suppliers and work to alleviate some of the burden associated with the crosswalk submission. We will provide details on this submission process through guidance, as appropriate.

Additionally, to enable evaluation of MDPP services for a beneficiary's entire MDPP services period (that is, up to 2 years), we proposed that MDPP suppliers must submit performance data for any beneficiaries who attend ongoing maintenance sessions in a manner and form as specified by CMS (proposed § 424.205(d)(14)). This proposal served to ensure that MDPP suppliers provide session-level data for ongoing maintenance sessions that are consistent with the data they are already providing to CDC for the core MDPP services period. This requirement is necessary given that session-level performance data plays a critical role in the Innovation Center's evaluation of the entirety of the MDPP expanded model. Without such data, the Innovation Center would lack any streamlined method of obtaining session-level data for ongoing maintenance sessions furnished to MDPP beneficiaries. We proposed that this performance data must align with the performance date elements as required by CDC for the DPRP standards. We solicited public comments on this approach.

We received no comments on our proposal requiring MDPP suppliers to submit session-level data, consistent with performance data MDPP suppliers are already providing to CDC, for ongoing maintenance sessions. Thus, without any stakeholder input on this policy, we are finalizing as proposed at § 424.205(d)(14). However, in light of concerns regarding the multiple and distinct data submission requirements MDPP suppliers must submit to CMS and CDC, we clarify that such MDPP suppliers shall submit any performance data for ongoing maintenance sessions, as required under § 424.205(d)(14) to CDC along with the performance data they would already provide per the DPRP standards. We recognize stakeholders concerns raised both in this rule and in our previous policy proposals regarding potential burden associated with multiple and distinct submission requirements, and thus we will plan to align our requirements for data submission under this requirement with the DPRP data submission requirements for the initial core services period. We believe that this alignment with CDC will alleviate some of the potential burden associated with this MDPP supplier standard. We will release additional information through guidance, as appropriate.

We are finalizing our policies as proposed at § 424.205(d)(13) and (14). However, this rule provided an update to the manner and form MDPP suppliers must submit the crosswalk § 424.205(d)(13) that would provide greater consistency across suppliers.

v. MDPP Supplier Revalidation

In the CY 2017 PFS final rule, we specified that newly enrolling MDPP suppliers as high categorical risk in accordance with § 424.518(c), but we did not address the risk level of MDPP suppliers upon revalidation. Section 6401(a) of the Affordable Care Act established that all Medicare suppliers must revalidate their enrollments as a program integrity measure. Upon revalidation, suppliers are screened for their continued enrollment in Medicare. Although MDPP suppliers enroll at the high risk level, we proposed, at § 424.205(b)(3)(ii), that MDPP suppliers would revalidate under a moderate risk level in accordance with § 424.518(b)(2). We believe that this approach is appropriate, given that fingerprint-based criminal history record checks through the Federal Bureau of Investigation's (FBI) Integrated Automated Fingerprint Identification System (IAFIS) requirement for ''high'' categorical risk will have already been completed upon initial enrollment. In addition, we believe that this approach is appropriate, given its consistency with other providers and suppliers who initially enroll under ''high'' categorical risk, but revalidate under ''moderate'' categorical risk, such as DMEPOS suppliers and Home Health Agencies. We also proposed, at § 424.205(b)(6), as a condition of enrollment, that MDPP suppliers must revalidate their enrollment every 3 years, consistent with DMEPOS suppliers who are initially screened under ''high'' categorical risk screening level (82 FR 34166). We welcomed public comments on these proposals.

The following is a summary of the public comments on the proposals to require that MDPP suppliers revalidate every 3 years at moderate categorical risk:

Comment: Generally, commenters supported the proposal that MDPP suppliers' risk categorization decrease from high to moderate upon revalidation. One of the commenters who supported this proposal justified its support because of its alignment with requirements for other high risk suppliers.

Response: We appreciate the support provided for this proposal and are finalizing the requirement that MDPP suppliers pass screening at moderate categorical risk upon revalidation.

Comment: One commenter raised concerns about designating MDPP suppliers as high categorical risk upon initial enrollment, a proposal which we finalized in the CY 2017 PFS final rule, no commenters opposed the current proposal regarding revalidating at moderate risk.

Response: This policy was not proposed in the rule, and therefore, is out of scope. Though we may consider revisiting MDPP supplier risk level upon initial enrollment in the future, we have no current plans to do so at this time. For our rationale for finalizing this policy, please refer to section III.J.7.a of the CY 2017 PFS final rule.

Comment: In response to the proposal that MDPP suppliers revalidate every 3 years, some commenters supported this proposal. Generally, those that expressed support for this policy did so in combination with the proposal that MDPP suppliers revalidate at moderate risk level, meaning that they treated the two proposals as a single policy without acknowledging specific support for the frequency of revalidation. As mentioned previously, one of the commenters in support of the proposal justified their support given its consistency with other high risk suppliers.

Response: We appreciate commenters' support for our proposal. Though we agree with commenters that the proposal for MDPP suppliers to revalidate at moderate categorical risk every 3 years aligns with existing policies for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers, which also initially enroll at high categorical risk, we also acknowledge that Home Health Agencies, which similarly initially enroll at high categorical risk, revalidate at moderate risk level every 5 years.

Comment: A few commenters did not support revalidation every 3 years, given concerns that the frequency of revalidation was high, particularly with respect to the duration of the MDPP services period. While one commenter simply requested that MDPP suppliers revalidate less frequently than every 3 years, another specifically proposed that CMS require MDPP suppliers to revalidate every 5 years. Both commenters stated that requiring MDPP suppliers to revalidate as frequently as every 3 years would pose unnecessary burdens.

Response: Given the novelty of the MDPP supplier type, our expectation that most MDPP suppliers will be non-traditional heath care providers, and general concerns about the potential vulnerabilities of fraud and abuse raised by MedPAC and others, we have sought to design stringent program integrity policies that will enable us to detect, monitor, and ultimately limit the ability for potential fraud, waste, or abuse from organizations which enroll as MDPP suppliers.

While a similar number of commenters expressed support for our original proposal, as well as recommended an alternative proposal that would require less frequent revalidations, we considered this proposal within the context of broader comments regarding the high degree of supplier burden as a result of our cumulative requirements. Though not expressly made in response to this proposal on revalidation, commenters frequently noted that the number of MDPP supplier requirements and burden from those requirements could potentially dissuade prospective MDPP suppliers from deciding to enroll. In light of these concerns and our desire to enable a strong supplier base to meet beneficiary demand for MDPP services, we looked for opportunities where we could alter requirements for MDPP suppliers to alleviate supplier burden without posing vulnerabilities to the integrity of the Medicare program or the safety of our beneficiaries. Ultimately, we determined that decreasing the frequency with which MDPP suppliers revalidate could achieve this balance. As such, we are modifying our proposal such that MDPP suppliers will be required to revalidate every 5 years, instead of the proposed 3 years. That said, we acknowledge MedPAC's concerns against the potential for fraud and abuse, as well as their encouragement to apply all program integrity safeguards possible for this new expanded model and the suppliers who furnish it. Therefore, we will continue to monitor the level of risk posed by MDPP suppliers and will consider revalidating more frequently in the future, if appropriate.

Additionally, given the novelty of this model expansion, we are considering utilizing a provisional period of enhanced oversight authority under section 1866(j)(3) of the Act to monitor for program integrity safeguards. Should we take this approach, CMS would assume the responsibility of conducting any oversight action as a way of avoiding adding any increased burden to MDPP suppliers. We believe that this approach to require that MDPP suppliers revalidate less frequently, and instead, for CMS to assume responsibility for enhanced monitoring demonstrates our commitment to respond to stakeholder comments to both protect the Medicare program and its beneficiaries against fraud, waste, and abuse and also to avoid unnecessary burdens to the suppliers who service our beneficiaries.

After considering the public comments, we are finalizing our proposal at § 424.205(b)(3)(ii) that

MDPP upon revalidation, MDPP suppliers must pass moderate categorical risk. To make MDPP supplier risk levels more clear, we are adding Prospective (newly enrolling) MDPP suppliers to high categorical risk at § 424.518(c)(1)(iii) and revalidating MDPP suppliers to the moderate risk level at § 424.518(b)(1)(xi). Based on feedback from suppliers' broader request for less administrative burden, we are finalizing a modification of our proposal at § 424.204(d)(6) such that MDPP suppliers must revalidate every 5 years.

vi. Documentation Retention and Provisions Requirements

We proposed that the following requirements would apply to records related to a MDPP supplier's compliance with the MDPP expanded model (codified at § 424.59(b), redesignated as amended at § 424.205(g)) (82 FR 34166). We stated that we believe that these proposals would increase supplier recordkeeping accuracy, and clarify documentation retention requirements. Specifically, we proposed that an MDPP supplier must:

- Provide to CMS or its contractors, the OIG, and the Comptroller General or their designee(s) scheduled and unscheduled access to all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the supplier's compliance with MDPP requirements, including the MDPP expanded model requirements for in-kind beneficiary incentive engagements found in § 424.210 in the event that the MDPP supplier chooses to offer such incentives to any MDPP beneficiary.
- Maintain all such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the MDPP beneficiary's receipt of MDPP services furnished by the MDPP supplier or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

++ CMS determines that there is a special need to retain a particular record or group of records for a longer period and notifies the MDPP supplier at least 30 calendar days before the normal disposition rate; or

++ There has been a dispute or allegation of fraud or similar fault, as defined at § 405.902, against the MDPP supplier, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

We stated that we believe these proposals increase the likelihood of operationalizing MDPP program integrity strategies that include audits, evaluations, inspections, or investigations, and that they provide additional clarity on documentation retention for ongoing program integrity. In addition, in the CY 2017 PFS we established supplier requirements for documentation and recordkeeping (codified at § 424.59(b), redesignated and amended at § 424.205(g). In this final rule, we are revising these requirements to improve clarity. We proposed at § 424.205(g)(1) and (g)(2) to require that documentation must be established contemporaneous to the furnished MDPP services, which we believe is important for accuracy. We also proposed that for the initial core session, these records must include the following organizational information:

- The organizational name, CDC DPRP organization number, and organizational NPI;
- Basic beneficiary information including but not limited to beneficiary name, HICN, and age; and
- Evidence that each such beneficiary satisfied the eligibility requirements under § 410.79(c) at the time of service.

For each additional session, we proposed that these records must include:

- Documentation of the type of session, whether a core session, a core maintenance session, an ongoing maintenance session, an in-person make-up session, or a virtual make-up session.
- Identification of which CDC-approved DPRP curriculum was associated with each session.
- The NPI of the coach who furnished the session.
- The date and place of service of the session.
- Each MDPP's beneficiary's weight and date weight taken, in a form and manner as specified by CMS.

We stated that we believe that this information will play an important role in documenting the provision of MDPP services and fidelity to the requirements established for the expanded model. Finally, at § 424.205(g)(4), we proposed that MDPP suppliers must maintain and handle any beneficiary Personally Identifiable Information (PII) and Personal Health Information (PHI) in compliance with HIPAA, other state and federal privacy laws, and CMS standards. We believe these proposals will improve supplier recordkeeping accuracy and lessen the possibility of incomplete records and supplier recordkeeping variations.

We invited public comments on our proposed documentation and maintenance of records requirements, including whether additional or different requirements may provide better program integrity safeguards.

The following is a summary of the public comments received on our proposal for documentation and maintenance of records requirements, including whether additional or different requirements may provide better program integrity safeguards and our responses:

Comment: The majority of commenters who provided feedback on this section did so generally across the recordkeeping requirements overall. For example, a few commenters did not support the documentation requirements proposed in this rule, and instead, urged CMS to reconsider the necessity of the requirements. The commenter did not specify which requirements they believed to be unnecessary. These commenters suggested that requiring MDPP suppliers to maintain significant documentation may pose burdens to MDPP suppliers, particularly smaller organizations. One commenter drew a parallel to the recordkeeping-related burden experienced by suppliers who offer chronic care management. Though no commenter recommended that CMS remove any specific documentation requirements, one commenter suggested that if CMS chose not to minimize burdensome requirements, which included, but was not limited to recordkeeping-related proposals, some form of compensation should be provided to support the necessary infrastructure costs required in recordkeeping.

Response: While we recognize commenters' concerns regarding the level of burden posed by MDPP supplier requirements overall, and in particular documentation requirements, we believe that recordkeeping plays an integral role in CMS' ability to investigate and eventually protect against fraud, waste, or abuse in the program. While CMS does not want to impose unnecessary burdens on MDPP suppliers, we consider our proposed recordkeeping requirements as necessary means for both accountability for MDPP suppliers and ability to verify compliance for CMS. Thus, will not be adopting commenters request for less recordkeeping requirements and will be finalizing the policies as proposed.

Comment: One commenter criticized the proposed documentation requirements stating that they omitted a range of variables that could predict an MDPP beneficiary's likelihood of losing weight over the core services period. The additional variables suggested by the commenter included the number of

weigh-ins per week, the number of steps per day, the percentage of weeks with 5 or more food logs, the number of highly active minutes per week, and the number of coach interactions. The commenter urged CMS to reconsider whether MDPP suppliers should report this data to CMS so that it could be utilized to determine the efficacy of the program.

Response: While CMS appreciates that a commenter suggested additional data be submitted to determine the efficacy of the MDPP expanded model, we do not believe that an evaluation to test the efficacy of the MDPP expanded model would require the additional variables suggested by the commenter. Thus, we are not adopting the suggestion to require MDPP suppliers document additional predictors of weight loss. While we do not see a need to require such documentation, we encourage MDPP suppliers to utilize and record any additional data that they believe will be valuable or will help predict a beneficiaries' success. Collecting this data through the MDPP beneficiaries' services period may assist the MDPP supplier or coach in determining how best to engage beneficiaries and assist them in achieving lasting behavioral change that will decrease their risk of type 2 diabetes. At this time, however, we are not finalizing any documentation requirements beyond what we proposed.

Comment: Several commenters requested that CMS provide guidance, technical assistance, and clarifications with regards to recordkeeping requirements. Two commenters generally requested that CMS provide more guidance on maintaining information on MDPP sessions provided to beneficiaries. One of these commenters had specific questions on when MDPP suppliers could submit certain claims, and requested that CMS provide further guidance with regard to the necessary documentation to support claims payment.

Response: Considering these requirements, coupled with the expectation that many MDPP suppliers will lack previous experience as a Medicare enrolled supplier, we are working to create resources that would facilitate MDPP suppliers' ability to comply with the recordkeeping requirements outlined in this rule. In considering these resources, we also intend to provide guidance on how to appropriately document services to support claims payment, as required under § 424.205(g)(5).

Comment: One commenter raised questions regarding documentation requirements if an MDPP supplier provided more than the minimum amount of sessions required. In a scenario where an MDPP supplier may have provided the total number of MDPP sessions required over the course of the MDPP services period within the first 6 months, the commenter wanted to understand how the supplier should document ''PA minutes'' in the second 6 months, when they believed that participants are less likely to self-report ''PA minutes'' in the second 6 months. Though the commenter did not indicate what PA stood for, given the context of MDPP, we assume this refers to ''physical activity.''

Response: The proposed requirement under § 424.205(g)(2) requires that MDPP suppliers document various aspects of each MDPP session furnished to an MDPP beneficiary, therefore, these documentation requirements would apply to any session delivered to an MDPP beneficiary as a part of the MDPP services period, even if an MDPP supplier furnishes more MDPP sessions than are required under § 410.79(c)(2). We clarify that we are not requiring any documentation of physical activity minutes, though the DPRP standards may require documentation of this variable, and any questions regarding the DPRP standards are beyond the scope of this rule and should be directed to the CDC.

Comment: One commenter requested clarification on whether MDPP suppliers who store records in electronic medical records would sufficiently meet these proposals. Specifically, the commenter requested clarification on whether the use of an electronic medical record which could produce a report would comply with the proposal at § 424.205(g), which required that MDPP suppliers provide to CMS, a contractor acting on CMS' behalf, the Office of the Inspector General, and the Comptroller General or their designee(s) scheduled and unscheduled access to the MDPP supplier's records, including, but not limited to, all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the MDPP supplier's compliance. The commenter preferred the approach of retaining records electronically given it does not rely on generating hard copies and assumes a similar approach to the reporting format required of the DPRP. The commenter also requested whether maintaining the documentation in an electronic medical record would comply with the requirement at § 424.205(g)(6), requiring MDPP suppliers to maintain all records required under § 424.205(g) for a period of 10 years from the last day of the MDPP beneficiary's receipt of MDPP services provided by the MDPP supplier, with limited exceptions.

Response: We do not require documentation or medical records in paper form and encourage the use of a secured electronic medical record system. Without familiarity with the specific electronic medical record system and the reports it may generate, we are not able to confirm whether the commenter's specific approach would satisfy the requirements as outlined under § 424.205(g). In determining whether the system will comply with the requirements, organizations should evaluate whether their system may collect and obtain the required information securely, as required under § 424.205(g)(4) and for the duration as required under § 424.205(g)(6). If so, organizations should evaluate whether the information in this system can be provided to CMS, a contractor acting on CMS' behalf, the Office of the Inspector General, and the Comptroller General or their designee(s), as required. Identifying whether the supplier's current recordkeeping system can meet these requirements may help prospective MDPP suppliers evaluate their readiness to comply with the documentation retention requirements. Additionally, we are exploring possible resources CMS could create to help enable MDPP suppliers to understand how to comply with recordkeeping requirements in this section.

Comment: A commenter requested clarification on how to apply HIPAA requirements to an MDPP supplier when the supplier also provided additional, non-MDPP services as a part of a larger, non-health related business. In this scenario, the commenter suggested that the supplier could designate itself a hybrid covered entity under HIPAA such that HIPAA requirements would only apply to its covered functions. The commenter requested that CMS confirm this understanding.

Response: We proposed the requirement at § 424.205(g)(4) requiring an MDPP supplier to maintain and handle any beneficiary PII and PHI in compliance with HIPAA, other applicable state and federal privacy laws, and CMS standards as a means to protect any PII or PHI the MDPP supplier obtains. The intention of this requirement was to highlight that to protect beneficiary privacy, an array of federal and state privacy laws, including HIPAA, exist, as well as certain CMS standards, and CMS expects that MDPP suppliers would protect beneficiary information as required by these policies. Though in the CY 2017 PFS

final rule, we finalized a similar requirement on HIPAA compliance, we proposed to modify this language to more broadly include applicable federal and state privacy laws as well. We did not intend to apply any new provisions that would not already apply to an MDPP supplier. Instead, though MDPP suppliers are already required to comply with all existing laws, including those related to privacy, we sought to highlight the need to comply with privacy-related laws, given that we anticipate that MDPP suppliers may not necessarily have previous experience in health care. MDPP suppliers will need to consult with their own counsel to determine their obligations and options under the HIPAA regulatory scheme, as well as other applicable privacy laws, such as state laws.

To more clearly state that the requirement at § 424.205(g), we are amending the language to require that MDPP suppliers maintain and handle any beneficiary information related to MDPP, including Personally Identifiable Information (PII) and Protected Health Information (PHI), as appropriate under HIPAA, other applicable state and federal privacy laws, and CMS standards. That said, we would highlight the ''related to MDPP services'' language. We hope that this language more clearly explains that this provisions applies only to beneficiary information related to MDPP, and not information collected by the MDPP supplier for other services they may provide. Any data an MDPP supplier would receive as a function of their non-MDPP related business would not be ''related to MDPP services'' if those non-MDPP business functions are truly separate from the MDPP ones. We believe that this clarification addresses the commenter's concern of how they would handle information related to their non-MDPP activities. Additionally, we hope that shifting the language from ''in compliance with'' to ''as required under'' more clearly signals that we are not imposing any additional requirements to comply with laws or standards that would not otherwise already apply to the MDPP supplier's handling or maintenance of beneficiary information. We proposed a requirement at § 424.205(g)(4) to be more consistent with language at § 424.205(g), and to state that an MDPP supplier must maintain all documentation related to participation in the MDPP in accordance with all applicable Federal and State laws. We recommend that any prospective MDPP supplier applicants consult with counsel to determine whether they qualify as a HIPAA Covered Entity, and, if so, how it will comply with HIPAA as applicable to beneficiary information related to MDPP as opposed to other information collected for non-MDPP related purposes.

After considering the public comments, we are finalizing the proposals under § 424.205(g) with a modification at § 424.205(g) for additional clarity. We are finalizing that under § 424.205(g)(4), MDPP suppliers must maintain and handle any beneficiary information related to MDPP, including PII and PHI, as would be required under HIPAA, other applicable state and federal privacy laws, and CMS standards.

f. Beneficiary Engagement Incentives Under the MDPP Expanded Model

In the proposed rule (82 FR 34166), we stated our belief that the MDPP expanded model would encourage MDPP suppliers to furnish high quality and engaging health behavior change services to MDPP beneficiaries that lead to improved beneficiary health and reductions in Medicare spending. We believe that one mechanism that may be useful to the MDPP suppliers in achieving these goals would be allowing MDPP suppliers to furnish certain in-kind items and services to their MDPP beneficiaries during the core services period and ongoing services period (described at proposed § 410.79(c)(2)). Under such an approach, the costs of these beneficiary engagement incentives would be borne by the MDPP supplier. However, we believe that certain conditions on these incentives would be necessary to ensure that they would be furnished solely for the purpose of achieving the MDPP goal of engaging beneficiaries in making sustainable, healthy behavior changes to reduce their risk of type 2 diabetes.

We proposed to establish the rules governing the furnishing of beneficiary engagement incentives to MDPP beneficiaries under the MDPP expanded model at new § 424.210. As discussed in section III.K.2.a. of the proposed rule (82 FR 34131), we proposed that MDPP services would be available beginning on April 1, 2018.

i. Definitions Specific to Beneficiary Engagement Incentives

We proposed that if an MDPP supplier offers an in-kind beneficiary engagement incentive, the item or service offered as an incentive must be furnished by an MDPP supplier to an MDPP beneficiary during the engagement incentive period. An engagement incentive period would begin when an MDPP supplier furnishes any MDPP service to an MDPP beneficiary. We proposed at § 424.210(a) that the term ''engagement incentive period'' means the period of time during which an MDPP supplier may furnish in-kind beneficiary engagement incentives to a given MDPP beneficiary to whom the MDPP supplier is furnishing MDPP services. The engagement incentive period would end upon the earliest of the following: The beneficiary's MDPP services period ends (as specified in proposed § 410.79(c)(3)) for any reason; the MDPP supplier knows the MDPP beneficiary will no longer be receiving MDPP services from the MDPP supplier; or the MDPP supplier has not had direct contact, either in person, by telephone, or via other telecommunications technology, with the MDPP beneficiary for more than 90 consecutive calendar days during the MDPP services period.

We proposed that items and services may only be furnished as in-kind beneficiary engagement incentives during the engagement incentive period. This was to ensure that the flexibilities that MDPP suppliers would have under these proposed regulations to furnish free items and services to Medicare beneficiaries only apply while the beneficiary is an MDPP beneficiary being offered MDPP services by that MDPP supplier. Once the MDPP beneficiary's engagement incentive period ends with an MDPP supplier, all existing laws and regulations would apply to the furnishing of free items and services to a Medicare beneficiary by the entity that is an MDPP supplier. Limiting the furnishing of beneficiary engagement incentives under the MDPP expanded model to the engagement incentive period with a particular MDPP supplier would serve as a safeguard against the furnishing of free items and services to Medicare beneficiaries to steer them toward particular providers, suppliers, or other services, rather than to engage MDPP beneficiaries in healthy behavior changes that reduce their incidence of type 2 diabetes.

During the course of the MDPP services period, we noted that an MDPP beneficiary may begin and end multiple engagement incentive periods, and, to the extent feasible, the MDPP beneficiary would not be in more than one engagement incentive period at the same time. For example, where, after receiving MDPP services from MDPP supplier A, an MDPP beneficiary notifies MDPP supplier A that he or she has chosen to receive MDPP services from MDPP supplier B and subsequently receives MDPP services from MDPP supplier B, the first engagement incentive period ends when

MDPP supplier A is told by the MDPP beneficiary that he or she will no longer attend MDPP services with MDPP supplier A. A new engagement incentive period begins when the MDPP beneficiary receives his or her first MDPP service from MDPP supplier B. Additionally, where an MDPP beneficiary begins an engagement incentive period with an MDPP supplier and the engagement incentive period has ended because the MDPP supplier has not had direct contact, either in person, by telephone, or via other telecommunications technology, with the MDPP beneficiary for 90 consecutive days during the MDPP services period, should that MDPP beneficiary receive MDPP services from that MDPP supplier on day 100, a new engagement incentive period would begin.

These proposals for the definitions specific to beneficiary engagement incentives were included at proposed § 424.210(a). We invited public comments on these proposed definitions specific to furnishing in-kind beneficiary engagement incentives.

The following is a summary of the public comments received on the proposals for definitions specific to furnishing in-kind beneficiary engagement incentives and our responses:

Comment: One commenter urged CMS to begin the engagement incentive period 30 to 90 days prior to the start of MDPP services to allow for recruitment of beneficiaries into the DPP, rather than beginning the period when an MDPP supplier furnishes any MDPP service to an MDPP eligible beneficiary as CMS proposed.

Response: We continue to believe it is important to limit the furnishing of beneficiary engagement incentives under the MDPP expanded model to the time period when an MDPP beneficiary is receiving MDPP services from a particular MDPP supplier as a safeguard against the furnishing of free items and services to Medicare beneficiaries to steer them toward particular providers, suppliers, or other services, rather than to engage MDPP beneficiaries in healthy behavior changes that reduce their incidence of type 2 diabetes. In addition, as discussed subsequently in this section, an MDPP beneficiary may be made aware of the availability of the item or service at the time the MDPP beneficiary could reasonably benefit from it during the engagement incentive period, in order to safeguard against the advertisement of in-kind patient engagement incentives to beneficiaries based on their perceived ability to achieve the performance goals for attendance and weight loss. Thus, we do not believe it would be appropriate for the engagement incentive period to begin before an MDPP beneficiary receives any MDPP service from a particular MDPP supplier because such an approach would increase the risk of beneficiary steering.

Comment: One commenter stated that the proposal to define the end of the engagement incentive period would be difficult to operationalize, especially if a particular engagement incentive extends for a fixed period of time, such as a month-long gym membership, that would extend beyond the end of the engagement incentive period. The commenter added that the proposed definition also has implications for beneficiaries changing suppliers, such as when a month-long gym membership provided by supplier A to an MDPP beneficiary could overlap the new engagement incentive period that would begin once the beneficiary switches to supplier B for MDPP services.

Response: While we recognize the challenges identified by the commenter in operationalizing the proposed definition of the end of the engagement incentive period, we continue to believe that defining the beginning and end of the engagement incentive period to bound the time period during which a beneficiary can be furnished beneficiary engagement incentives by an MDPP supplier provides an important program safeguard with respect to the flexibilities that allow MDPP suppliers to furnish such items and services. We understand that in some scenarios, a particular beneficiary engagement incentive that was furnished to an MDPP beneficiary could theoretically be used for a period of time after the engagement incentive period ends. However, we do not believe this possibility necessitates changing our definition of engagement incentive period to allow the continued use of the incentive beyond the time when the MDPP supplier is furnishing MDPP services to the MDPP beneficiary. If an engagement incentive period ends for any reason while a beneficiary otherwise could continue to use an incentive, such as a month-long gym membership, we expect the MDPP supplier to notify the beneficiary that the engagement incentive period has ended and that the beneficiary may no longer use the incentive at no cost under the provisions of the MDPP expanded model. We also expect the MDPP supplier to notify any other relevant organization, such as a gym for which a free membership was furnished by the MDPP supplier to the beneficiary during the engagement incentive period, to cancel the beneficiary's ability to use the incentive.

After considering the public comments received, we are finalizing the proposals, without modification, for the definitions specific to furnishing in-kind beneficiary engagement incentives at § 424.210(a).

ii. General Conditions for Beneficiary Engagement Incentives

We proposed, at § 424.210(b), that an MDPP supplier may choose to furnish items or services as in-kind beneficiary engagement incentives to an MDPP beneficiary only during the engagement incentive period, subject to a number of additional conditions as program safeguards. Under this proposal, the in-kind items and services furnished as beneficiary engagement incentives under the MDPP expanded model would not be Medicare-covered items or services, nor would they be any cost-sharing amounts for Medicare-covered items or services.

We proposed that the engagement incentive must be furnished directly by an MDPP supplier or by an agent of the MDPP supplier under the MDPP supplier's direction and control, such as a coach, to an MDPP beneficiary. As established in the § 410.79(b) in the CY 2017 PFS final rule, coach refers to an individual who furnishes MDPP services on behalf of an MDPP supplier as an employee, contractor, or volunteer. We considered whether this policy on beneficiary engagement incentives should extend to entities other than MDPP suppliers and their agents that may refer to or furnish MDPP services during an engagement incentive period. However, given that MDPP suppliers maintain the responsibility to ensure the integrity of MDPP programs and would be best positioned to comply with beneficiary engagement incentive documentation and technology retrieval requirements proposed at § 424.210(e) and (c), respectively, we believed that they would be best suited to furnished beneficiary engagement incentives.

We proposed that the item or service furnished as a beneficiary engagement incentive must be reasonably connected to the CDC-approved curriculum taught by an MDPP supplier to an MDPP beneficiary during a core session, a core maintenance session, or an ongoing maintenance session. For example, under this proposal, an MDPP supplier could furnish beneficiary engagement incentives such as gym memberships to reduce barriers associated with beneficiary achievement of physical activity recommended as part of the CDC-approved curriculum, but they

could not furnish theater tickets, which would bear no reasonable connection to the CDC-approved curriculum. Similarly, MDPP suppliers may offer incentives such as onsite child care when the MDPP beneficiary attends MDPP services or transportation vouchers to the site of MDPP services that may reduce barriers to beneficiary attendance at MDPP services, but they could not furnish attendance awards such as movie tickets or retail gift cards, which would have no reasonable connection to the CDC-approved curriculum. Likewise, this proposal would allow MDPP suppliers to furnish equipment that is reasonably necessary for the curriculum being taught to the beneficiary, such as digital scales to track and document patient weight or pedometers to track physical activity, but not broadly used technology that is more valuable to the beneficiary, such as a smartphone. If an MDPP supplier were to furnish a smartphone at no cost to an MDPP beneficiary, a reasonable inference arises that the technology would not be reasonably connected to the curriculum being taught to the beneficiary. Among other things, this safeguard would preclude incentives that might serve to induce beneficiaries inappropriately to receive other services than MDPP services from the MDPP supplier.

We also proposed that the beneficiary engagement incentive must be a preventive care item or service, or an item or service that advances a clinical goal for an MDPP beneficiary as described in section III.K.2.f.iv. of the proposed rule (82 FR 34169 through 34170) by engaging him or her in better managing his or her own health. This would ensure that a relationship between the incentive and the goals of the MDPP expanded model exists so that the beneficiary engagement incentive is necessary for testing the MDPP expanded model. Under this proposed condition, we noted that beneficiary engagement incentives may not be offered to an MDPP beneficiary as a reward for achievement of a specified outcome, such as losing weight or attending a certain number of sessions, unless the beneficiary engagement incentive meets all the proposed conditions, including that it is reasonably connected to the CDC-approved DPP curriculum furnished to the MDPP beneficiary during a core session, a core maintenance session, or an ongoing maintenance session by the MDPP supplier and that it is a preventive care item or service or it advances a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her own health. Furnishing in-kind patient engagement incentives upon achievement of an outcome may not advance a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her own health unless there are clinical goals that the incentive itself can continue to advance.

We further proposed that the item or service furnished as a beneficiary engagement incentive must not be tied to the receipt of items or services outside the MDPP services, and that the item or service must not be tied to the receipt of items or services from a particular provider, supplier, or coach. These provisions would provide safeguards against the furnishing of in-kind beneficiary engagement incentives to steer beneficiaries toward certain providers, suppliers, or coaches for services outside MDPP services.

We noted that in some circumstances, an item or service may be linked to an MDPP supplier and be offered to the MDPP supplier's MDPP beneficiaries as part of the CDC-approved curriculum that must be furnished during the MDPP services period, rather than being offered to steer the MDPP beneficiary to a particular provider, supplier, or coach. In these situations, we believed that the item or service may be furnished as a beneficiary engagement incentive without violating the requirement that the item or service not be tied to the receipt of the items or services from a particular provider, supplier, or coach. For instance, where an MDPP supplier offers a gym membership as a beneficiary engagement incentive, we understood that the gym membership must be tied to a particular supplier of services so that the beneficiary can use the membership. However, in this case, the gym membership would be linked to the MDPP supplier that, in compliance with the curriculum that must be furnished during the MDPP services period, would be teaching MDPP beneficiaries how to utilize a physical fitness regime to meet the MDPP goal of reducing an MDPP beneficiary's risk of developing diabetes, rather than being furnished to steer the MDPP beneficiary to a particular supplier. Therefore, we believed that gym memberships may be furnished as a beneficiary engagement incentive without violating the requirement that the item or service not be tied to the receipt of items or services from a particular provider, supplier, or coach, as long as the gym membership is reasonably connected to the CDC-approved curriculum and not being furnished to steer the MDPP beneficiary to a particular supplier.

We proposed that, in general, the availability of the items or services furnished as beneficiary engagement incentives must not be advertised or promoted as in-kind beneficiary engagement incentives available to an MDPP beneficiary receiving MDPP services from the MDPP supplier. However, an MDPP beneficiary may be made aware of the availability of the items or services at the time the MDPP beneficiary could reasonably benefit from them during the engagement incentive period. This condition would provide a safeguard against the advertisement of in-kind patient engagement incentives to beneficiaries based on their perceived ability to meet the performance goals of attendance and weight loss as described at proposed § 414.84(a) and associated with the MDPP performance payments proposed at § 414.84(b). The proposed payment structure for MDPP services largely would rely on the achievement of these performance goals. Therefore, advertising patient engagement incentives to encourage participation of MDPP-eligible beneficiaries most likely to meet the attendance and weight loss performance goals could produce financial gain for MDPP suppliers that would not be related to the quality and efficacy of the MDPP supplier's MDPP services.

In addition, prohibiting the advertisement or promotion of in-kind beneficiary engagement incentives available to an MDPP beneficiary receiving MDPP services from the MDPP supplier (except that an MDPP beneficiary may be made aware of the availability of the items or services at the time the MDPP beneficiary could reasonably benefit from them during the engagement incentive period) would provide a safeguard against using the incentive to steer a beneficiary toward a particular MDPP supplier. Beneficiaries would not be made aware of the availability of beneficiary engagement incentives until the MDPP beneficiary was in an engagement incentive period, which would begin when an MDPP supplier furnished its first MDPP service to the beneficiary. At that point in time, the beneficiary would have already selected that MDPP supplier to furnish his or her MDPP services so the incentive could not be used to steer the beneficiary to that MDPP supplier. We noted that we did not intend for beneficiary engagement incentives proposed for the MDPP expanded model to alter an MDPP supplier's market share for an MDPP or non-MDPP item or service.

Finally, we proposed that the cost of the items or services offered as in-kind

beneficiary engagement incentives must not be shifted to another federal health care program, as defined at section 1128B(f) of the Act. This requirement would affirm that the cost of any beneficiary engagement incentive offered by an MDPP supplier is the sole responsibility of the MDPP supplier, and the furnishing of a beneficiary engagement incentive, for instance, must not result in increased payments to the MDPP supplier by federal health care programs for other items or services.

These proposals for the general conditions for in-kind beneficiary engagement incentives were included at proposed § 424.210(b). We invited public comments on these proposed general conditions for furnishing beneficiary engagement incentives. In addition, we invited public comments on additional or alternative program integrity safeguards.

The following is a summary of the public comments received on the proposals for the general conditions for in-kind beneficiary engagement incentives and our responses:

Comment: Many commenters supported the proposal to allow MDPP suppliers to furnish beneficiary engagement incentives that support beneficiaries in their pursuit of the clinical goals of the MDPP. The commenters stated that items or services that are not traditionally covered by Medicare may significantly improve beneficiary access and use of MDPP services and even further enhance the savings potential of the MDPP expanded model, and that the findings from such incentive use may be studied by CMS to inform the agency's consideration of engagement incentives in other parts of the Medicare program. Several commenters noted in further support of CMS' proposal that MA plans already provide beneficiaries with non-covered items and services, which the commenters stated have helped those plans lower chronic disease costs among their plan enrollees. The commenters reasoned that this MA plan cost experience in furnishing non-covered items and services to plan enrollees was consistent with the goal of the MDPP expanded model to reduce Medicare expenditures for MDPP beneficiaries with prediabetes.

Response: We appreciate the support from many commenters for our proposal to allow MDPP suppliers to furnish in-kind beneficiary engagement incentives that we believe may be useful in augmenting the effects of high quality health behavior change services furnished to MDPP beneficiaries that lead to improved beneficiary health and reductions in Medicare spending. We agree that these incentives have the potential to increase beneficiary engagement in MDPP services and health behavior change that lead to achievement and maintenance of the required minimum weight loss which is associated with a reduction in the incidence of type 2 diabetes.

Comment: In the context of their view that the proposed performance payments to MDPP suppliers for MDPP services were low, several commenters speculated that it would be unlikely that MDPP suppliers would have sufficient funds to furnish beneficiary engagement incentive in-kind since they would be functioning at a financial deficit. The commenters stated that not all supplier organizations would have the resources available to furnish such incentives that could engage more beneficiaries and result in greater rates of attendance and weight loss, thereby placing these lower-resource suppliers at a distinct disadvantage for maintaining full CDC recognition of their DPPs, which would in turn affect the availability of the program for Medicare beneficiaries, as well as other eligible participants.

To address their concerns about MDPP suppliers having funds to furnish beneficiary engagement incentives, several commenters recommended that CMS alter the proposal that the costs of the beneficiary engagement incentives be borne by the MDPP supplier. The commenters urged CMS to pay MDPP suppliers for furnishing beneficiary engagement incentives such as transportation, child care for grandchildren, and other incentives that support session attendance, especially for MDPP suppliers serving high-risk populations. One commenter observed that CMS currently allows payment to be made for transportation to medical appointments in some Medicaid populations. Another commenter advocated for direct payment by CMS to MDPP suppliers for tools such as digital scales and fitness trackers, noting they are useful to DPP participants, whether enrolled in virtual or in-person programs.

Finally, one commenter stated that consumer engagement in services and programs occurs in a well-designed, evidence-based program that offers easily accessible services that consumers need. The commenter urged CMS to shift its focus away from the detailed proposed conditions for beneficiary engagement incentives that could be furnished by MDPP suppliers to engage MDPP beneficiaries to instead focus on establishing the right MDPP services, making appropriate MDPP services payments, and minimizing the administrative burden associated with becoming an MDPP supplier.

Response: MDPP suppliers are not required to furnish beneficiary engagement incentives, although we proposed a framework for in-kind beneficiary engagement incentives to allow MDPP suppliers the flexibility to furnish these incentives under certain conditions to ensure that they would be furnished solely for the purpose of achieving the MDPP goal of engaging beneficiaries in making sustainable, health behavior changes to reduce their risk of type 2 diabetes. As part of each DPP organization's decision-making about offering in-kind beneficiary engagement incentives under the MDPP expanded model, we expect that each MDPP supplier will consider the potential additional value of these incentives to MDPP beneficiaries and its operations. Relevant considerations may include whether greater beneficiary engagement may lead to a greater likelihood that beneficiaries will achieve the performance goals and, therefore, higher Medicare performance payments to the supplier, in the context of the resource costs of the incentives that would be borne by the MDPP supplier.

We understand that some MDPP suppliers may not have funds available that allow them to furnish beneficiary engagement incentives to MDPP beneficiaries, especially early in the supplier's experience furnishing MDPP services. However, once an MDPP supplier begins to receive performance payments from CMS for MDPP beneficiary achievement of performance goals, the supplier may have more information about the potential for beneficiary engagement incentives to reduce barriers to MDPP beneficiary achievement of performance goals, as well as additional funds that may be used for these incentives. For those MDPP suppliers with funds that may potentially be used to furnish in-kind incentives, this experience may allow the MDPP supplier to make a more informed decision on furnishing beneficiary engagement incentives versus other MDPP supplier investments that have the potential to improve beneficiaries' achievement of performance goals under the MDPP expanded model.

While we acknowledge the suggestions of some commenters that CMS pay directly for certain beneficiary engagement incentives, we do not believe it would be appropriate in the context of the performance-based payment methodology for MDPP services discussed in section III.K.2.d. of this final rule for CMS to pay MDPP

suppliers individually for specific incentives furnished to beneficiaries. Instead, we believe that MDPP suppliers are best positioned to determine the potential value of beneficiary engagement incentives toward achievement of performance goals by the MDPP beneficiaries they are serving and, in the context of the performance-based payment methodology for MDPP services, MDPP suppliers should appropriately bear the cost of the beneficiary engagement incentives they choose to furnish.

Comment: One commenter requested additional clarification of the meaning of ''furnished directly'' in the proposed condition, ''The item or service must be furnished directly to an MDPP beneficiary by an MDPP supplier or by an agent of the MDPP supplier, such as a coach, under the MDPP supplier's direction and control.'' The commenter asked CMS to specify how MDPP suppliers could contract with other entities to provide items that cannot be furnished by the MDPP supplier, such as gym memberships or transportation services.

Response: The commenter's request for clarification was made in the context of MDPP suppliers considering establishing contractual relationships with other entities to provide items as beneficiary engagement incentives that the MDPP supplier is unable to furnish. For purposes of this proposed condition, we consider that an entity under contract with an MDPP supplier to furnish items or services specified by the MDPP supplier for an MDPP beneficiary as beneficiary engagement incentives would be an agent of the MDPP supplier. The proposed condition permits beneficiary engagement incentives to be furnished directly to an MDPP beneficiary by an agent of the MDPP supplier, as long as the agent is under the MDPP supplier's direction and control when furnishing the incentive. Thus, we believe that this condition does not limit MDPP suppliers' ability to contract with entities to provide items as beneficiary engagement incentives, as long as the contractual relationship complies with all applicable laws and regulations, including those specific to beneficiary engagement incentives under the MDPP expanded model.

Comment: One commenter who expressed appreciation for the proposed program safeguard that the item or service must be reasonably connected to the CDC-approved DPP curriculum furnished to the MDPP beneficiary during a core session, a core maintenance session, or ongoing maintenance session furnished by the MDPP supplier also identified the potential for confusion resulting from the phrase ''reasonably connected to the CDC-approved DPP curriculum.'' The commenter urged CMS to review beneficiary engagement incentives suggested by MDPP suppliers and provide additional guidance on the types of incentives that are ''reasonably connected to the CDC-approved DPP curriculum'' and those that would not meet this condition.

Response: We appreciate the commenter's support for this proposal. However, because only the MDPP supplier knows the specific CDC-approved DPP curriculum that is furnished to an MDPP beneficiary during a particular session and in view of the large number of types of potential beneficiary engagement incentives, we are not able to further clarify the types of beneficiary engagement incentives that would be reasonably connected to the DPP curriculum furnished to a particular MDPP beneficiary during a session. We note that as finalized at § 424.205(g)(2)(ii), the MDPP supplier must maintain documentation of each MDPP session furnished to an MDPP beneficiary that identifies which CDC-approved DPRP curriculum was associated with that session. Thus, the MDPP supplier will have available the information necessary to make a determination about whether a specific beneficiary engagement incentive being considered for an MDPP beneficiary meets this condition.

If the MDPP supplier determines that the incentive being considered is reasonably connected to the DPP curriculum furnished to a beneficiary during a session, the MDPP supplier must also make a determination about whether the incentive meets the other requirements for beneficiary engagement incentives under the MDPP expanded model before deciding whether or not to furnish the item or service to the beneficiary as a beneficiary engagement incentive. Through information from claims for MDPP services and the MDPP supplier documentation required under the MDPP expanded model, we plan to monitor beneficiary engagement incentives furnished to MDPP beneficiaries by MDPP suppliers for compliance with the final conditions for the incentives, including that incentives furnished to MDPP beneficiaries are reasonably connected to the DPP curriculum furnished to those beneficiaries during sessions.

Comment: One commenter questioned how a beneficiary engagement incentive could meet the proposed condition that it be reasonably connected to the CDC-approved DPP curriculum and also be a preventive care item or service, which the commenter noted is another condition that each beneficiary engagement incentive must also meet. The commenter stated that not all items would meet both criteria and provided the example of a digital scale that would be connected to the DPP curriculum but is not itself a preventive care item or service.

Response: We believe the commenter may have misunderstood our proposal related to the condition for beneficiary engagement incentives that includes reference to a preventive care item or service. We proposed that the item or service must be a preventive care item or service *or* an item or service that advances a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her own health. The proposed clinical goals of the MDPP expanded model are attendance at core sessions, core maintenance sessions, or ongoing maintenance sessions; weight loss; long-term dietary change; and adherence to long-term health behavior changes. While we agree with the commenter that a digital scale is not a preventive care item or service, it is an item that may advance the clinical goal of weight loss for an MDPP beneficiary. Therefore, we believe it is possible for a digital scale and other items and services furnished as beneficiary engagement incentives to both be reasonably connected to the CDC-approved DPP curriculum furnished to an MDPP beneficiary during a core session, core maintenance session, or ongoing maintenance session by the MDPP supplier *and* be an item or service that advances a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her health.

Comment: Several commenters expressed concern about the potential for MDPP suppliers to shift the cost of beneficiary engagement incentives to MDPP beneficiaries. The commenters requested that CMS solicit additional public input on this topic, noting that it may be difficult for MDPP suppliers to amass the resources needed to provide such incentives without cost-shifting before the supplier receives payment for MDPP services based on claims that are submitted to Medicare. The commenters urged CMS to clarify that MDPP suppliers are prohibited from requiring MDPP beneficiaries to shoulder any of the costs of beneficiary engagement incentives and that incentive structures that financially penalize beneficiaries for lack of adherence to health behavior changes taught in the DPP curriculum or

failure to achieve a performance goal are not permitted.

Response: We appreciate the interest of the commenters in ensuring that the costs of beneficiary engagement incentives furnished to MDPP beneficiaries by MDPP suppliers are borne by the suppliers, as we proposed, and not shifted to beneficiaries. We note that our proposal for beneficiary engagement incentives specifies that these are items and services that may be furnished in-kind by MDPP suppliers and, therefore, MDPP suppliers would bear the costs of the incentives.

In response to the concerns about MDPP suppliers lacking sufficient resources to furnish beneficiary engagement incentives early on in the MDPP services period before receiving performance payments, we note that there is no requirement that MDPP suppliers furnish beneficiary engagement incentives. Thus, MDPP suppliers could wait until they have amassed enough payments to bear the costs of the incentives or forgo furnishing incentives to MDPP beneficiaries altogether.

We proposed at § 424.210(b)(7) that the cost of the item or service furnished as a beneficiary engagement incentive must not be shifted to another Federal health care program, as defined at section 1128B(f) of the Act, but did not explicitly prohibit cost-shifting to MDPP beneficiaries. Shifting the cost of beneficiary engagement incentives to MDPP beneficiaries would not be permitted under our proposal, and we agree with the commenters that MDPP beneficiaries should not bear any of these costs. Therefore, in view of the concerns of the commenters over the potential for MDPP suppliers to shift the costs of beneficiary engagement incentives to MDPP beneficiaries and our interest in safeguarding against such a shift, we believe it would be appropriate to add an additional condition in new § 424.210(b)(8) to specify that the cost of the item or service furnished as a beneficiary engagement incentive must not be shifted to an MDPP beneficiary. For example, under this condition the beneficiary engagement incentive structure used by an MDPP supplier may not financially penalize an MDPP beneficiary through a cost to the beneficiary for lack of adherence to health behavior changes taught in the DPP curriculum or failure to achieve performance goals.

As we stated in the proposed rule (82 FR 34168) in the context of our proposal that the beneficiary engagement incentive must be a preventive care item or service, or an item or service that advances a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her own health, beneficiary engagement incentives may not be offered to an MDPP beneficiary as a reward for achievement of a specified outcome, such as losing weight or attending a certain number of sessions, unless the beneficiary engagement incentive meets all the proposed conditions, including that it is reasonably connected to the CDC-approved DPP curriculum furnished to the MDPP beneficiary during a core session, a core maintenance session, or an ongoing maintenance session by the MDPP supplier. Similarly, beneficiary engagement incentive structures that financially penalize beneficiaries for lack of adherence to health behavior changes taught in the DPP curriculum or failure to achieve a performance goal would not meet the requirements for beneficiary engagement incentives under the MDPP expanded model, including that the item or service be a preventive care item or service or an item or service that advances a clinical goal for an MDPP beneficiary by engaging him or her in betting managing his or her own health. Such an approach would shift all or part of the cost of the beneficiary engagement incentive to the MDPP beneficiary, which is explicitly not permitted under the new condition we are finalizing at § 424.210(b)(8).

Comment: A few commenters requested that CMS closely monitor the use and impact of beneficiary engagement incentives to ensure they are not being used as a reward for reaching certain MDPP goals or in any way that may be discriminatory. Other commenters recommended that CMS provide more information on how it will enforce the regulations regarding beneficiary engagement incentives.

Response: We plan to monitor beneficiary engagement incentives furnished to MDPP beneficiaries by MDPP suppliers under the MDPP expanded model for compliance with the final conditions for the incentives. Should issues of non-compliance with the conditions or other concerns arise, CMS will utilize established enforcement mechanisms to address these issues.

Comment: Many commenters strongly supported the proposal to disconnect furnishing beneficiary engagement incentives from the achievement of outcomes under the MDPP expanded model.

Response: We appreciate the commenters' support for separating the provision of beneficiary engagement incentives by MDPP suppliers to MDPP beneficiaries from the beneficiary's achievement of outcomes. However, we note that we did not propose to completely disconnect furnishing beneficiary engagement incentives from the achievement of specific outcomes in all cases. Instead, we proposed that beneficiary engagement incentives may not be offered to an MDPP beneficiary as a reward for achievement of a specified outcome, such as losing weight or attending a certain number of sessions, unless the beneficiary engagement incentive meets all the proposed conditions, including that it is reasonably connected to the CDC-approved DPP curriculum furnished to the MDPP beneficiary during a core session, a core maintenance session, or an ongoing maintenance session by the MDPP supplier. That is, if a beneficiary engagement incentive meets all of the proposed conditions for such incentives and is offered to the MDPP beneficiary as a reward for the achievement of a specified outcome, we would consider that beneficiary engagement incentive to be permitted under the MDPP expanded model. We continue to believe that our proposed policy is appropriate because it ensures that the beneficiary engagement incentive itself is a preventive care item or service or an item or service that advances a clinical goal by engaging a beneficiary in better managing his or her own health, including under those circumstances where the incentive is offered by the MDPP supplier as a reward for the achievement of an outcome.

Comment: One commenter observed that CMS did not propose to limit the aggregate retail value of items and services furnished as beneficiary engagement incentives that are not items of technology, which the commenter noted could invite competition among MDPP suppliers for beneficiaries based on the value of the incentives and not based on quality or clinical outcomes of the MDPP services furnished by the MDPP supplier.

Response: As the commenter stated, we did not propose a maximum aggregate retail value limit for beneficiary engagement incentives other than items and services involving technology that are furnished to an MDPP beneficiary by an MDPP supplier. We do not believe the risk of misuse of non-technology items and services furnished as beneficiary engagement incentives warrants the greater administrative burden on MDPP suppliers that would result from limiting the aggregate retail value of these items and services. Such an aggregate limit would require documentation of all beneficiary engagement incentives of any retail

value, thereby significantly increasing the MDPP supplier administrative burden beyond that required by our proposal for documentation of only those incentives with a retail value of greater than $25. In contrast, we believe that items and services involving technology, which we address in detail subsequently in this section, have a higher risk of misuse so we proposed enhanced safeguards for those types of incentives, including a maximum aggregate retail value limit of $1,000 per beneficiary from a single MDPP supplier during the MDPP services period.

In addition, we proposed a number of other conditions for beneficiary engagement incentives discussed throughout this section that provide program safeguards, including protection against competition among MDPP suppliers for beneficiaries based on the value of incentives and not based on the quality or clinical outcomes of MDPP services.

Comment: One commenter stated that smaller MDPP suppliers that furnish MDPP services with equally effective outcomes as larger MDPP suppliers may not be able to sustain their programs if Medicare beneficiaries are lured to receive MDPP services at the larger suppliers by the beneficiary engagement incentives offered by these bigger organizations. While the commenter acknowledged CMS' intent to disallow advertisement of available incentives, the commenter reasoned that in the community individuals talk to one another, and thus, word would spread within the community. The commenter urged CMS to further clarify the difference between MDPP suppliers furnishing a specific non-covered item or service as a beneficiary engagement incentive and CMS' intent that use of specific incentives would not ''steer'' particular beneficiaries away from or to the supplier furnishing the incentive.

Response: We proposed that the availability of the item or service must not be advertised or promoted as an in-kind beneficiary engagement incentive available to an MDPP beneficiary receiving MDPP services from the MDPP supplier except that an MDPP beneficiary may be made aware of the availability of the item or service at the time the MDPP beneficiary could reasonably benefit from it during the engagement incentive period. While we understand that individuals within communities speak to one another so that a person may become aware of beneficiary engagement incentives furnished by certain MDPP suppliers before the individual becomes an MDPP beneficiary, we believe this condition still provides a reasonable safeguard against MDPP suppliers acting directly to recruit beneficiaries for MDPP services based on the availability of a beneficiary engagement incentive. Beneficiaries would not be made aware by the MDPP supplier of the availability of beneficiary engagement incentives until the MDPP beneficiary was in an engagement incentive period, which would begin when the MDPP supplier furnished its first MDPP service to the beneficiary. At that point in time, the beneficiary would have already selected that MDPP supplier to furnish his or her MDPP services so the incentive could not be used to steer the beneficiary to that MDPP supplier.

Comment: One commenter generally supported the concept of not advertising beneficiary engagement incentives to deter MDPP suppliers from encouraging Medicare beneficiary participation in their DPP only for purposes of gaining the incentives. However, the commenter further reasoned that the MDPP supplier's having the ability to advertise some incentives (including transportation and childcare) that remove barriers to session attendance could enable more Medicare beneficiaries to participate in MDPP services. The commenter concluded that transportation and childcare are not incentives but instead services that reduce barriers and should be in another category with different rules tied to them.

Response: Regarding the commenter's recommendation that we apply different rules to certain beneficiary engagement incentives, such as transportation or childcare, that advance the clinical goal of attendance at MDPP services rather than the clinical goal of weight loss, long-term dietary change, or adherence to long-term health behavior changes, we disagree that we should treat these types of incentives differently by allowing them to be advertised to Medicare beneficiaries. If advertised to beneficiaries by an MDPP supplier prior to the start of the beneficiary's engagement incentive period, incentives such as transportation or childcare could steer beneficiaries toward that particular MDPP supplier. We believe that in-kind items and services furnished by MDPP suppliers to MDPP beneficiaries to reduce barriers to session attendance are similar to other beneficiary engagement incentives that advance different clinical goals of the MDPP expanded model because they assist the beneficiary in better managing his or her own health. An MDPP supplier may make a beneficiary aware of a beneficiary engagement incentive at the time the MDPP beneficiary could reasonably benefit from it during the engagement incentive period, and we believe this condition provides sufficient flexibility for MDPP suppliers to be able to remove attendance barriers when beneficiaries participate in MDPP services.

Comment: Several commenters requested that CMS clarify whether certain items and services would be permitted to be furnished as beneficiary engagement incentives to MDPP beneficiaries by MDPP suppliers under the proposal. One commenter reported that some managed care organizations and DPP organizations have experienced success providing retail gift cards to socially at-risk populations. The commenter further explained that individuals may use the retail gift cards at their discretion to buy healthy food, scales, pedometers, work-out shoes and clothes, thereby reducing the burden on DPP organizations, as not all direct service suppliers have the capacity to buy equipment in sufficient quantities or to buy different types of items that anticipate each beneficiary's need. Another commenter urged CMS to permit supermarket gift cards to be furnished as a beneficiary engagement incentive, reasoning that these would allow some beneficiaries to purchase more produce and healthy foods.

Response: We disagree with the commenters' suggestion that we globally permit retail gift cards to be considered as a form of beneficiary engagement incentive under the MDPP expanded model. Because we are testing the model to determine if MDPP services improve the quality and reduce the cost of health care for Medicare beneficiaries, we continue to believe that it is important to maintain the requirements of a reasonable connection between the item or service furnished as a beneficiary engagement incentive and the CDC-approved DPP curriculum furnished to the MDPP beneficiary during MDPP services and that the item or service must be a preventive care item or service or an item or service that advances a meaningful clinical goal for the MDPP beneficiary. These conditions both protect against MDPP suppliers' incentives to influence the beneficiary's choice of MDPP supplier and other types of care and ensure that the MDPP expanded model is implemented in accordance with consistent standards across MDPP suppliers in order to allow for evaluation of the model.

Therefore, regarding the potential for retail gift cards, including supermarket gift cards, to be furnished by MDPP suppliers as beneficiary engagement incentives, we encourage MDPP suppliers considering furnishing these items to assess whether the specific gift

cards meet all the requirements for beneficiary engagement incentives, including that they are reasonably connected to the CDC-approved curriculum and advance a clinical goal for the MDPP beneficiary. Whether these requirements are met may be related to the particular retailer at which the beneficiary could purchase items with the gift card. To the extent the retailer sells a large variety of items and a substantial percentage of those items would not meet the requirements for beneficiary engagement incentives if furnished directly to the MDPP beneficiary by the MDPP supplier, we would consider a gift card furnished by an MDPP supplier to that retailer *not* to meet the beneficiary engagement incentive conditions under the MDPP expanded model.

Comment: One commenter stated that incentives targeted to food access and physical activity access support the goals of the MDPP expanded model and requested that CMS clarify that MDPP suppliers would be permitted to offer these items as beneficiary engagement incentives.

Response: Beneficiary engagement incentives targeted to food access or physical activity access would be permitted to be offered as beneficiary engagement incentives only if the specific item or service meets all of the requirements for beneficiary engagement incentives finalized for the MDPP expanded model. These types of potential incentives need to be assessed by the MDPP supplier that is considering offering them with respect to their connection to the CDC-approved DPP curriculum furnished to the MDPP beneficiary at sessions and their potential to advance the MDPP expanded model clinical goals for the MDPP beneficiary, as well as with regard to the other conditions for beneficiary engagement incentives.

Comment: One commenter recommended that CMS clarify that certain items or services would not be beneficiary engagement incentives, and therefore, would not be subject to the conditions for these incentives. The items and services the commenter requested be excluded from the requirements for beneficiary engagement incentives were: assistance in enrolling in public benefits; assistance connecting to emergency food services (for example, food pantries); and provision of meals during the MDPP session.

Response: To the extent that MDPP suppliers want to assist MDPP beneficiaries in enrolling in public benefits, connect MDPP beneficiaries to emergency food services, or provide meals during MDPP sessions at the MDPP supplier's expense. The MDPP supplier must determine whether furnishing the item or service meets the requirements of all applicable laws and regulations. The conditions for beneficiary engagement incentives under the MDPP expanded model are intended to provide MDPP suppliers with additional flexibilities to furnish in-kind items and services, rather than further limiting an MDPP supplier's provision of items and services beyond existing laws and regulations.

Comment: One commenter, who supported the proposal to allow beneficiary engagement incentives to be furnished to increase beneficiary engagement toward achieving the goals of MDPP services, sought confirmation from CMS that if a beneficiary engagement incentive is furnished to an MDPP beneficiary covered under an MA plan, this action would not violate the guidance in the Medicare Managed Care Manual, Chapters 3 and 4, for MA program rules.

Response: We appreciate the commenter's support for our proposal to allow MDPP suppliers to furnish beneficiary engagement incentives to MDPP beneficiaries under certain conditions, as well as their request for clarification about the relationship between these provisions and MA program rules. We are clarifying that the beneficiary engagement incentive regulations at § 424.210 strictly apply to MDPP services furnished under the MDPP expanded model, including when furnished or covered by an MA plan. Because the beneficiary engagement incentive regulations are more specific than the Medicare Advantage Rewards and Incentives Program regulations at § 422.134 (outlined in Chapter 4 of the Medicare Managed Care Manual) and the corresponding Rewards and Incentives Program marketing guidelines (outlined in Chapter 3 of the Medicare Managed Care Manual), the MDPP regulations will apply to MDPP services furnished under the MDPP expanded model.

After considering the public comments received, we are finalizing the proposals for the general conditions for in-kind beneficiary engagement incentives at § 424.210(b), with modifications. We are adding another condition for beneficiary engagement incentives at § 424.210(b)(8) that specifies that the cost of the item or service must not be shifted to an MDPP beneficiary.

iii. Technology Furnished to an MDPP Beneficiary

In some cases, items or services involving technology may be useful as beneficiary engagement incentives because they can advance a clinical goal of the MDPP expanded model by engaging an MDPP beneficiary in managing his or her health. However, in the proposed rule (82 FR 34169) we stated our belief that specific enhanced safeguards are necessary for these items and services to prevent abuse.

First, we proposed that items or services involving technology furnished by an MDPP supplier to its MDPP beneficiary may not, in the aggregate, exceed $1,000 in retail value for any one MDPP beneficiary. We believed that this proposed limit would be appropriate, in conjunction with our proposed enhanced requirements for items of technology with a retail value greater than $100 as discussed subsequently. The proposed $1,000 limitation would allow sufficient MDPP supplier flexibility to furnish items or services involving technology as beneficiary engagement incentives to improve the likelihood of the beneficiary's achievement and maintenance of the required minimum weight loss.

For example, under this proposal, an MDPP beneficiary who begins receiving MDPP services from an MDPP supplier and who, after receiving MDPP services from that MDPP supplier, is furnished items or services of technology with a total retail value of $1,000 may not receive additional items or services of technology from that MDPP supplier. Therefore, an MDPP beneficiary may receive from an MDPP supplier a tablet valued at $700 that is preloaded with weight loss and fitness tracking apps that would support the beneficiary's weight loss goals under the MDPP expanded model and also receive from the same MDPP supplier a fitness tracking watch valued at $200 that uploads and monitors fitness data to the tablet, but he or she could not then receive additional items of technology from the MDPP supplier with an aggregate retail value greater than $100 as this would exceed the $1,000 limit.

In addition, we proposed that if the same MDPP beneficiary chooses to receive MDPP services from another MDPP supplier, the subsequent supplier would be under no obligation to determine the value of any items or services of technology furnished to the MDPP beneficiary by other MDPP suppliers, and may furnish items or services of technology to the MDPP beneficiary so long as those items or services furnished by the subsequent

supplier are the minimum necessary to advance a clinical goal for the MDPP beneficiary, are furnished during the engagement incentive period, and do not, in aggregate, exceed $1,000 in retail value.

We further proposed that items or services involving technology furnished to an MDPP beneficiary must be the minimum necessary to advance a clinical goal for MDPP beneficiaries as discussed in section III.K.2.f.iv. of the proposed rule (82 FR 34169 through 34170).

We proposed enhanced requirements for items of technology exceeding $100 in retail value as an additional safeguard against misuse of these items as beneficiary engagement incentives. In the proposed rule (82 FR 34169), we stated our belief that it would be inappropriate for MDPP suppliers to furnish items of technology with a retail value of over $100 for beneficiaries' permanent use because the high value of these items could unduly influence the beneficiary to continue to receive MDPP services from that supplier, or to receive items or services from the supplier other than MDPP services. Therefore, we proposed that items of technology with a retail value of over $100 would remain the property of the MDPP supplier and be retrieved from the MDPP beneficiary at the end of the engagement incentive period. We did not believe that this requirement would substantially increase the administrative burden on MDPP suppliers because a central facilitator of the success of an MDPP beneficiary in meeting MDPP performance goals is the MDPP supplier's ability to maintain contact with the MDPP beneficiary and engage him or her in MDPP services. We noted that items of technology with a retail value of $100 or less could be furnished as beneficiary engagement incentives and would remain the property of the beneficiary. In the case of these items of a technology with a lower retail value, we believed that the administrative burden of retrieving these items would outweigh the program integrity benefits of retrieval.

We further proposed that the MDPP supplier must document all technology retrieval attempts, including the ultimate date of retrieval. However, because we understood that MDPP suppliers may not always be able to retrieve these items, such as when a beneficiary dies or moves to another geographic area, documented, diligent, good faith attempts to retrieve items of technology would be deemed to meet the retrieval requirement.

Our proposals for enhanced requirements for technology furnished to MDPP beneficiaries as beneficiary engagement incentives under the MDPP expanded model were included at proposed § 424.210(c). We invited public comments on our proposed requirements for beneficiary engagement incentives that involve technology and welcomed comments on additional or alternative program integrity safeguards for this type of beneficiary engagement incentive, including whether the proposed financial thresholds were reasonable, necessary, and appropriate.

The following is a summary of the public comments received on the proposals for the requirements for beneficiary engagement incentives that involve technology and our responses:

Comment: Several commenters encouraged CMS to provide more information on the evidence base for the $100 maximum retail value threshold for items involving technology that can remain the property of the beneficiary and the $1,000 aggregate limit on the retail value of items and services involving technology that can be furnished as beneficiary engagement incentives by one MDPP supplier to an MDPP beneficiary, including whether there are a similar beneficiary engagement incentive amount thresholds used elsewhere in Medicare or another program.

Response: We appreciate the interest of the commenters in additional information on the proposed $100 maximum retail value threshold for items involving technology that can remain the property of the beneficiary and the proposed $1,000 aggregate limit on the retail value of items and services involving technology that are furnished as beneficiary engagement incentives. We note that we finalized through notice and comment rulemaking these same thresholds for other Innovation Center payment models, including the Comprehensive Care for Joint Replacement Model (80 FR 73436). We refer readers to that discussion for further information on our reasoning for finalizing the thresholds for that model, which is similar to our rationale for these thresholds under the MDPP expanded model.

For example, we believe that the $100 retail value retrieval threshold for items involving technology would allow some types of electronic tablets that could be furnished to an MDPP beneficiary for activity and dietary monitoring during an engagement incentive period to remain the property of the beneficiary for permanent use following the end of that period. In addition, we believe the $1,000 aggregate limit on the retail value of items and services involving technology that may be furnished by one MDPP supplier to an MDPP beneficiary is sufficiently high to allow MDPP suppliers the flexibility to furnish a wide range of items and services involving technology that advance the goals of the MDPP expanded model, without significantly risking suppliers furnishing more broadly used technology that is more valuable to the beneficiary than reasonably necessary for the DPP curriculum being taught.

Comment: In the context of a commenter's request that CMS not limit the MDPP services period to once-per-lifetime per beneficiary, the commenter asked that CMS clarify whether the $1,000 technology incentive limit could ''reset'' if the MDPP beneficiary resumes MDPP services with an MDPP supplier after a long absence.

Response: As we stated in the proposed rule (82 FR 34169), the $1,000 aggregate retail value limit for items and services involving technology that may be furnished to any one MDPP beneficiary by any one MDPP supplier would not otherwise be affected by the engagement incentive period. In addition, we finalized the once-per-lifetime MDPP services period in the CY 2017 PFS final rule (81 FR 80470). Therefore, if an MDPP beneficiary begins and ends multiple engagement incentive periods with the same MDPP supplier spread apart after an absence that would be limited in the context of the maximum 24-month duration of the MDPP services period finalized in section III.K.2.b.i. of this final rule, we see no reason to allow the $1,000 aggregate retail value limit for items and services involving technology to ''reset'' at the beginning of a new engagement incentive period with the same MDPP supplier within the MDPP services period due to the risk that a high value technology incentive could be used to steer a beneficiary back to that MDPP supplier if we allowed the limit to ''reset.''

Comment: Because CMS proposed that the cost of beneficiary engagement incentives be borne by MDPP suppliers as in-kind incentives and that CMS would not pay for these incentives, several commenters urged CMS not to set any retail value dollar threshold for items involving technology that can remain the property of a beneficiary. The commenters stated that MDPP suppliers should not be required to retrieve any items from MDPP beneficiaries after the engagement incentive period ends, especially since CMS did not offer guidance on what should happen with these recovered items, such as refurbishing them for

future use that could risk PII being stored and transmitted. The commenters claimed that the proposed technology retrieval requirements and resulting returned equipment would have limited value to the ongoing work and effort of MDPP suppliers, especially because technology quickly becomes obsolete. They noted that in addition to contacting beneficiaries who may have discontinued their participation in MDPP services with the MDPP supplier that furnished the technology, MDPP suppliers would have to develop costly, administratively burdensome processes for maintenance, documentation, and tracking of inventory, which most likely would require a system different from their existing MDPP documentation systems. The commenters concluded that the proposed technology retrieval requirements would have the unintended consequence of a high level of effort invested by MDPP suppliers with marginal returns, so they recommended that CMS not finalize this proposal.

One commenter who urged CMS not to adopt a retail value dollar threshold for items that can remain the property of the beneficiary provided a list of potential beneficiary engagement incentives, including pedometers, water bottles, memberships at health clubs and exercise facilities, blood sugar monitors, slow cookers, and stretch bands, and claimed that it would not currently be the practice of DPP organizations to collect these items after the end of the program because reusing them is not practical and storing them would serve no purpose.

Response: We do not believe it would be appropriate to eliminate the retrieval threshold for items involving technology altogether, even for those items involving technology that may provide additional health benefits to beneficiaries after the engagement incentive period ends and/or lead to reduced expenditures on health care in the future. It would be inappropriate for MDPP suppliers to furnish items involving technology with a retail value of over $100 for beneficiaries' permanent use because the high value of such items could unduly influence the beneficiary to continue to receive MDPP services from the MDPP supplier. We do not believe the potential longer-term benefits of continued use or the administrative burden of retrieving items involving technology with a retail value in excess of $100 outweigh the program integrity benefits of retrieval.

In response to the commenter who disagreed with the retrieval of items involving technology of any retail value and provided a list of potential beneficiary engagement incentives where the commenter concluded that these items would generally not be reused and their storage would serve no purpose upon retrieval, we emphasize that the threshold of $100 maximum retail value for items that can remain in the MDPP beneficiary's permanent possession applies only to items involving technology, not to other types of beneficiary engagement incentives. We do not believe that the list of potential incentives provided by the commenter generally included items involving technology with a retail value of greater than $100 to which retrieval would apply.

Finally, we note that items involving technology with a retail value of greater than $100 that are furnished as beneficiary engagement incentives under the MDPP expanded model would always be the property of the MDPP supplier, and it would be up to the MDPP supplier to make all decisions about the item's treatment upon return and further use. To the extent the item of technology returned to the MDPP supplier includes PII, MDPP suppliers are required to maintain and handle any PII and PHI in compliance with HIPAA, as applicable, other applicable state and federal privacy laws, and CMS standards.

Comment: Several commenters urged CMS to increase the $100 threshold for the maximum retail value of items involving technology that can remain the property of the beneficiary to a $200 threshold in order for MDPP suppliers to furnish items involving technology for beneficiary permanent use, such as wearable trackers and other beneficiary engagement incentives that often cost more than $100 per item. The commenters reasoned that the permanent use of these items involving technology could help beneficiaries sustain weight loss and healthy behaviors after MDPP services ended and, therefore, could be important for the maximum long-term reduction in the incidence of type 2 diabetes to be achieved.

Response: While we understand the administrative burden on MDPP suppliers that tracking and retrieval requires, we believe that a higher retrieval threshold, such as $200, is not warranted. As stated previously, it would be inappropriate for MDPP suppliers to furnish items involving technology with a retail value of over $100 for beneficiaries' permanent use because the high value of these items could unduly influence the beneficiary to continue to receive MDPP services from the MDPP supplier. We do not believe the potential longer-term benefits of continued use or the administrative burden of retrieving items involving technology with a retail value in excess of $100 outweigh the program integrity benefits of retrieval. We further note that wearable trackers with a retail value of less than $100 are widely available, so we do not believe that maintaining the retrieval threshold at $100 poses a significant risk that MDPP suppliers will be unable to furnish wearable trackers, the specific example cited by the commenters, to MDPP beneficiaries for their permanent use.

Comment: Several commenters requested that CMS address what the commenters observed may be an inconsistency between two separate discussions in the proposed rule. The commenters pointed out that in one location CMS stated, ''This proposal would allow MDPP suppliers to furnish equipment that is reasonably necessary for the curriculum being taught to the beneficiary, such as digital scales to track and document patient weight or pedometers to track physical activity, but not broadly used technology that is more valuable to the beneficiary, such as a smartphone.'' The commenters further observed that in the specific proposal regarding the maximum retail value for items and services involving technology furnished by an MDPP supplier to an MDPP beneficiary, CMS stated, ''An MDPP beneficiary may receive from an MDPP supplier a tablet valued at $700 that is preloaded with weight loss and fitness tracking apps that would support the beneficiary's weight loss goals under the MDPP expanded model and also receive from the same MDPP supplier a fitness tracking watch valued at $200 that uploads and monitors fitness data to the tablet . . .'' The commenters requested that CMS clarify its apparent distinction between smartphones and other forms of mobile technologies with apps.

Response: We appreciate the request for clarification about the discussions in the proposed rule that included examples of smartphones and tablets, two types of mobile technologies. We proposed that items or services involving technology must be the minimum necessary to advance a clinical goal for an MDPP beneficiary. We continue to believe this requirement is appropriate as a program safeguard against items involving technology being furnished to steer beneficiaries toward particular MDPP suppliers or other services, coupled with the additional requirement that items involving technology with a retail value greater than $100 must remain the property of the MDPP supplier and,

therefore, cannot remain in the permanent possession of the beneficiary. As to whether individual items of equipment, including mobile technologies with apps such as tablets or smartphones, meet the requirements for beneficiary engagement incentives that are items and services involving technology, we believe that the principal uses of the items must be considered in making such a determination. As we stated in the proposed rule (82 FR 34168), we do not believe that a smartphone, which is broadly used technology with uses that generally extend far beyond the DPP curriculum and clinical goals of the MDPP expanded model, would be reasonably necessary for the DPP curriculum being taught to the MDPP beneficiary, and we further do not believe that a smartphone would be the minimum technology necessary to advance a clinical goal for the MDPP beneficiary.

In the proposed rule (82 FR 34169), we included an example of an MDPP beneficiary who receives from an MDPP supplier a tablet valued at $700 that is preloaded with weight loss and fitness tracking apps that would support the beneficiary's weight loss goals under the MDPP expanded model. It was our expectation that the principal use for such a tablet would be related to the DPP curriculum being taught to the MDPP beneficiary and the advancement of the MDPP expanded model's clinical goals for that beneficiary. To the extent the tablet is also populated with apps whose uses extend far beyond the DPP curriculum and clinical goals of the MDPP expanded model, consistent with our discussion of a smartphone, we do not believe such a tablet would be reasonably necessary for the DPP curriculum being taught to the MDPP beneficiary, and we further do not believe it would be the minimum technology necessary to advance a clinical goal for the MDPP beneficiary.

Comment: One commenter reported that a major barrier to a beneficiary's attendance at MDPP services may be unstable access to a consistent phone number, and further speculated that while providing a smartphone might not solve this issue, assisting the beneficiary in signing up for a publicly available free cell phone could be a major tool for improved attendance. The commenter expressed concern that this assistance could be discouraged by the smartphone example included in the proposed rule.

Response: Given that one of the clinical goals of the MDPP expanded model is MDPP beneficiary session attendance, if an MDPP supplier believes erratic access to a consistent phone number creates a barrier to MDPP session attendance for a particular MDPP beneficiary, it is possible that furnishing a basic cell phone or assisting a beneficiary in signing up for a publicly available free cell phone would meet the requirements for beneficiary engagement incentives under the MDPP expanded model. However, we do not believe that a smartphone, which is broadly used technology with uses that generally extend far beyond the DPP curriculum and clinical goals of the MDPP expanded model, would be reasonably necessary for the DPP curriculum being taught to the MDPP beneficiary, and we further do not believe it would be the minimum technology necessary to advance a clinical goal for an MDPP beneficiary.

After considering the public comments received, we are finalizing the proposals, without modification, for enhanced requirements for items and services involving technology furnished to MDPP beneficiaries as beneficiary engagement incentives under the MDPP expanded model at § 424.210(c).

iv. Clinical Goals of the MDPP Expanded Model

As established at § 410.79(b) in the CY 2017 PFS final rule, MDPP services furnished to MDPP beneficiaries must follow a CDC-approved curriculum, which outlines required and recommended topics for structured health behavior change sessions offered as MDPP services with the goal of preventing diabetes through long-lasting health behavior change. MDPP suppliers seeking recognition under the CDC's DPRP must furnish either the CDC-preferred curriculum, based on the current evidence base, or may develop their own curriculum. MDPP suppliers that wish to develop their own curriculum must submit it to the CDC for approval. This requirement ensures that all curricula furnished to MDPP beneficiaries meet the DPRP's curriculum content requirements and are based on evidence from efficacy and effectiveness trials consistent with the current evidence base. To be consistent with the current evidence base, all curricula offered by MDPP suppliers must furnish MDPP services focused on the overarching goal of preventing type 2 diabetes in persons at high risk for diabetes because they have prediabetes. This requires MDPP suppliers to emphasize the need to make lasting health behavior changes, rather than simply completing a one-time set of MDPP services that result in the required minimum weight loss during the MDPP services period. MDPP services must also emphasize long-term improvements in nutrition and physical activity that contribute to beneficiaries sustaining weight loss. Therefore, in the proposed rule (82 FR 34170) we stated our belief that in-kind patient engagement incentives may appropriately be furnished to support and motivate MDPP beneficiaries in achieving dietary and health behavior change and to teach MDPP beneficiaries to problem-solve strategies to overcome challenges to maintaining weight loss and healthy behaviors, as well as to assist MDPP beneficiaries in meeting the attendance and weight loss performance goals of the MDPP expanded model.

Therefore, we proposed that the following would be the clinical goals of the MDPP expanded model, which may be advanced through beneficiary engagement incentives:

- Beneficiary attendance at MDPP core sessions, core maintenance sessions, or ongoing maintenance sessions during the MDPP services period.
- Beneficiary weight loss.
- Long-term dietary change for the beneficiary.
- Beneficiary adherence to long-term health behavior changes.

We noted that under this proposal, the MDPP supplier may not furnish multiple free meals or meal replacement services to an MDPP beneficiary over a substantial portion of the engagement incentive period because such a practice would not advance a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her own health.

When a beneficiary engagement incentive does not qualify as a preventive care item or service, our proposals for the clinical goals of the MDPP expanded model that a beneficiary engagement incentive must be intended to advance were included at proposed § 424.210(d). We invited public comments on our proposed clinical goals of the MDPP expanded model, as well as whether the advancement of additional or different clinical goals through beneficiary engagement incentives may better advance the overarching goals of the MDPP expanded model, while maintaining appropriate program integrity safeguards.

We received no public comments on the proposals for the clinical goals of the MDPP expanded model.

We are finalizing the proposals, without modification, for the clinical goals of the MDPP expanded model that a beneficiary incentive must be intended to advance at § 424.210(d).

v. Documentation of Beneficiary Engagement Incentives

As a program safeguard against misuse of beneficiary engagement incentives under the MDPP expanded model, we proposed that, in addition to the documentation requirements for MDPP suppliers at proposed § 424.205(g), MDPP suppliers must maintain documentation of items and services furnished as beneficiary engagement incentives that individually exceed $25 in retail value. We recognized that an MDPP beneficiary could receive many incentives that are each of low dollar value but in the aggregate constitute an excessively high value to the beneficiary. Therefore, we believed that it would be important to incorporate a documentation threshold at a modest level for all beneficiary incentives in order to monitor compliance with the proposed conditions for furnishing these items and services. Moreover, we believed that the proposed $25 retail value threshold would strike an appropriate balance between beneficiary and program protections and MDPP supplier administrative burden.

In addition, we proposed to require that the documentation must be established contemporaneously with the furnishing of the items and services and must include at least the date the incentive was furnished; the identity of the beneficiary to whom the item or service was furnished; the agent of the supplier that furnished the item or service, if applicable; a description of the item or service; the retail value of the beneficiary engagement incentive; and documentation establishing that the item or service was furnished to the MDPP beneficiary during the engagement incentive period.

In addition to the requirements in the previous paragraph, we further proposed that the documentation regarding items or services furnished to the MDPP beneficiary for use on an ongoing basis during the engagement incentive period, including items of technology exceeding $100 in retail value, must also include contemporaneous documentation establishing that the MDPP beneficiary is in the engagement incentive period throughout the time period that the MDPP beneficiary possesses or has access to the item or service furnished by the MDPP supplier. For example, if an MDPP supplier furnishes a gym membership to an MDPP beneficiary, the MDPP supplier would need to maintain contemporaneous documentation establishing that the MDPP beneficiary is in the engagement incentive period throughout the time period that the MDPP beneficiary has access to the gym via the membership furnished by the MDPP supplier.

In addition to the above requirements, we further proposed that the documentation regarding items of technology exceeding $100 in retail value that MSPP suppliers would be required to retrieve from the MDPP beneficiary must also include contemporaneous documentation of any attempts to retrieve the item of technology furnished by the MDPP supplier from the MDPP beneficiary as required at proposed § 424.210(c)(3)(ii). We reiterated that under our proposal documented, diligent, good faith attempts to retrieve items of technology would be deemed to meet the retrieval requirement. Finally, we proposed that the MDPP supplier must retain and provide access to the required documentation in accordance with proposed § 424.205(g).

Our proposals for the documentation requirements for beneficiary engagement incentives under the MDPP expanded model were included at proposed § 424.210(e). We invited public comments on our proposed documentation requirements, including whether additional or different documentation requirements may provide better program integrity safeguards.

The following is a summary of the public comments received on the proposals for the documentation requirements for beneficiary engagement incentives under the MDPP expanded model and our responses:

Comment: Several commenters urged CMS to require MDPP suppliers to document all beneficiary engagement incentives furnished to MDPP beneficiaries, not just those items and services with a retail value greater than $25, to further the goal of data collection about the incentives used.

In contrast, other commenters stated that the proposal to require documentation of beneficiary engagement incentives that are in-kind with a retail value of greater than $25 would lead to an undue reporting burden for MDPP suppliers because of the large number of these incentives that could be furnished to an MDPP beneficiary. The commenters further stated the documentation burden would be particularly onerous for small suppliers with limited infrastructure and staffing. Multiple commenters claimed that while the administrative burden posed by the proposed documentation and tracking requirements would be large, the documentation would be of limited value to the ongoing work and effort of MDPP suppliers. The commenters urged CMS to not require documentation of beneficiary engagement incentives of any retail value.

Response: We appreciate the diversity of perspectives of the commenters on our proposed documentation requirements for beneficiary engagement incentives in the MDPP expanded model. We proposed to require MDPP suppliers to document certain information about beneficiary engagement incentives with a retail value of greater than $25 to allow us to monitor compliance with the proposed conditions for furnishing these items and services, while striking an appropriate balance between beneficiary and program protections and MDPP supplier administrative burden. We recognized that an MDPP beneficiary could receive many incentives that are each of low dollar value but in the aggregate constitute an excessively high value to the beneficiary. While we did not propose to limit the aggregate value of non-technology items and services that may be furnished as beneficiary engagement incentives to an MDPP beneficiary by an MDPP supplier, documentation of items with a retail value greater than $25 would allow us to monitor compliance with the conditions for these incentives, which safeguard against misuse of beneficiary engagement incentives in the MDPP expanded model.

We do not believe it would be appropriate to require documentation of all beneficiary engagement incentives of any retail value for purposes of data collection about incentives as recommended by some commenters, in view of the greater administrative burden this would place upon MDPP suppliers. We also do not believe that requiring no documentation of beneficiary engagement incentives of any retail value would be appropriate because we would be unable to monitor for compliance with the conditions for furnishing these items or services.

Given the substantial flexibilities we will be affording MDPP suppliers to furnish beneficiary engagement incentives under the MDPP expanded model, we believe that requiring documentation of items and services with a retail value of greater than $25 is a reasonable responsibility for MDPP suppliers to assume. Our rationale for establishing documentation requirements for beneficiary engagement incentives is based on establishing program safeguards against misuse of beneficiary engagement incentives under the MDPP expanded model and not based primarily on the

value of documentation of beneficiary engagement incentives to the ongoing work and effort of MDPP suppliers. The documentation threshold of $25 reflects our interest in balancing the additional administrative burden on MDPP suppliers resulting from the documentation requirements for beneficiary engagement incentives with the beneficiary and program protections that will result. Finally, while under the MDPP expanded model MDPP suppliers are not required to maintain documentation for beneficiary engagement incentives with a retail value of less than or equal to $25, we encourage MDPP suppliers to maintain such documentation for other purposes as they see fit.

Comment: One commenter observed that the proposed documentation requirements for beneficiary engagement incentives included many of the same variables as those required for claims submission, such as the date the incentive was furnished and the identity of the beneficiary to whom the item or service was furnished. The commenter claimed that documentation of beneficiary engagement incentives furnished to MDPP beneficiaries could more easily be achieved by adding a 'non-covered' (or otherwise) HCPCS service code(s) or code modifier(s) to the proposed coding and billing structure for MDPP services. Under the commenter's recommended approach, such a code or code modifier included on a claim would reflect that a beneficiary engagement incentive had been furnished by the MDPP supplier during the period of time where sessions were furnished that were reported on the claim for a performance payment. The commenter reasoned that this approach to documentation would: (1) Reduce the administrative burden on the DPP supplier; (2) promote the use of automation in health care administration; (3) promote program integrity safeguards through the Medicare claims system; (4) mitigate the risk of incentives as an inducement for MDPP supplier selection; and (5) support the comprehensive evaluation of the use of incentives under the MDPP expanded model.

Response: While we appreciate the potential benefits, including the availability of comprehensive information on incentives, of adopting the commenter's suggestion that we establish new HCPCS codes and/or modifiers that could be reported on claims in order to identify when beneficiary engagement incentives were furnished, we disagree with the commenter that this approach would reduce the administrative burden on the MDPP supplier or provide a sufficient program safeguard by mitigating the risk of incentives being furnished as an inducement for MDPP supplier selection.

In order to monitor for compliance with the conditions for these incentives, we need information on the date the incentive was furnished; the identity of the beneficiary to whom the item or service was furnished; the agent of the supplier that furnished the item or service, if applicable; a description of the item or service; the retail value of the beneficiary engagement incentive; and documentation establishing that the item or service was furnished to the MDPP beneficiary during the engagement incentive period. The complexity of the coding that would be required to allow all of this information to be reported on administrative claims would be great, and we believe such a reporting methodology for beneficiary engagement incentives would lead to significantly greater administrative burden on MDPP suppliers than our proposed documentation approach. Therefore, we do not believe it would be feasible for MDPP suppliers to report on administrative claims all of the information about beneficiary engagement incentives that is necessary for us to monitor compliance with the conditions for these incentives that have been adopted to protect beneficiaries and the program from their misuse.

Comment: Several commenters urged CMS to collect data on beneficiary engagement incentives from MDPP suppliers to study the effects of the various engagement incentives furnished to MDPP beneficiaries, including the amount and type of incentive; whether beneficiaries receiving the incentives actually maintained participation in MDPP services; and whether identified beneficiary engagement incentives contributed to beneficiaries meeting the weight loss performance goal or achieving other positive outcomes under the MDPP expanded model. The commenters stated that these data are needed to inform both effective incentive designs that could be offered to MDPP beneficiaries and best practices for future use.

Response: We appreciate the interest of the commenters in expanding the evidence-base on the use of beneficiary engagement incentives in payment models, both the MDPP expanded model and other innovative payment models. As discussed previously in this section, we are not requiring documentation of all beneficiary engagement incentives of any retail value in view of the greater administrative burden this would place upon MDPP suppliers. We also do not currently have a mechanism for collecting data from MDPP suppliers on beneficiary engagement incentives. While we agree with the commenters that this information could be useful in informing future incentive designs, MDPP suppliers are already expected to submit a significant amount of information to CMS on claims and under the requirement to submit a crosswalk (finalized in this final rule at § 424.205(d)(13)) under the MDPP expanded model that will inform the evaluation of the model overall, including the totality of its design features which include the voluntary provision of beneficiary engagement incentives. Therefore, we believe that requiring MDPP suppliers to submit detailed information on the type and amount of all incentives that are furnished to MDPP beneficiaries would place an undue documentation and reporting burden on suppliers. Instead, we expect that MDPP suppliers choosing to offer in-kind beneficiary engagement incentives, where the costs of these incentives are borne by the supplier, will be reviewing their experiences in their own DPP and making adjustments to their incentive practices based on their analysis of the MDPP performance of the population they are serving.

After considering the public comments received, we are finalizing the proposals, without modification, for the documentation requirements for beneficiary engagement incentives under the MDPP expanded model at § 424.210(e). Table 43 summarizes the final documentation requirements for beneficiary engagement incentives under the MDPP expanded model.

TABLE 43—FINAL BENEFICIARY ENGAGEMENT INCENTIVE DOCUMENTATION REQUIREMENTS

Beneficiary engagement incentive	Documentation requirement
Item or service with retail value greater than $25.	• Contemporaneous documentation that includes at least: ▪ The date the incentive was furnished. ▪ The identity of the MDPP beneficiary to whom the item or service was furnished. ▪ Documentation establishing that the item or service was furnished to the MDPP beneficiary during the engagement incentive period. ▪ The agent of the supplier that furnished the item or service, if applicable. ▪ A description of the item or service. ▪ The retail value of the item or service. • Documentation regarding items or services that are furnished to the MDPP beneficiary for use on an ongoing basis during the engagement incentive period, including items involving technology exceeding $100 in retail value, must also include contemporaneous documentation establishing that the MDPP beneficiary is in the engagement incentive period throughout the time period that the MDPP beneficiary possesses or has access to the item or service furnished by the MDPP supplier. • The documentation regarding items involving technology exceeding $100 in retail value must also include contemporaneous documentation of any attempt to retrieve the technology.* • The MDPP supplier must retain and provide access to the documentation.

* = Items involving technology with a retail value greater than $100 remain the property of the MDPP supplier and must be retrieved from the MDPP beneficiary at the end of the engagement incentive period.

vi. Compliance With Fraud and Abuse Laws

Certain arrangements between MDPP suppliers and beneficiaries may implicate the civil monetary penalty (CMP) law (sections 1128A(a)(5), (b)(1) and (b)(2) of the Act), or the Federal Anti-kickback statute (section 1128B(b)(1) and (2) of the Act). In many cases, arrangements that implicate these laws can be structured to comply with them by using existing safe harbors and exceptions. Section 1115A(d)(1) of the Act authorizes the Secretary to waive certain specified fraud and abuse laws as may be necessary solely for purposes of testing of models under section 1115A(b) of the Act. A waiver is not needed for an arrangement that does not implicate the fraud and abuse laws or that implicates the fraud and abuse laws, but either fits within an existing exception or safe harbor, as applicable, or does not otherwise violate the law. Accordingly, under section 1115A(d)(1) of the Act, the Secretary will consider whether waivers of certain fraud and abuse laws are necessary for the MDPP expanded model. Such waivers, if any, would be promulgated separately from this proposed regulation by OIG (as to sections 1128A and 1128B of the Act), to which the respective authorities have been delegated.

Because of the close nexus between the final regulations governing the structure and operations of the MDPP expanded model and the development of any fraud and abuse waivers necessary to carry out the provisions of the model, CMS and OIG may, when considering the need for or scope of any waivers, consider comments submitted in response to the proposed rule and the provisions of the final rule. No waivers of any fraud and abuse authorities are being issued in this final rule.

3. Virtual DPP and the MDPP Expanded Model

The CDC's DPRP Standards allow evidence-based DPP curricula to be furnished through a variety of modes, including through remote technologies. Similar to the description noted in section III.K.2.c.iv.3 of this final rule with respect to virtual make-up sessions, virtual DPP refers to any modality, or method of furnishing MDPP services, that is not in person. This includes, but is not limited to:

(1) Furnishing services online where the behavior change program is furnished 100 percent online, with participants accessing course resources and lifestyle coach via a computer, laptop, tablet, smart phone, or other device with internet access. This modality requires an internet connection to participate in all aspects of the DPP;

(2) Furnishing services online with other means of support by a coach (for example, telecommunications, video conferencing). This modality requires an internet connection for some aspects of the DPP, but not all; and

(3) Distance learning, where a coach is present in one location and participants are calling, video-conferencing, or otherwise using telecommunications technology to access the coach from another location. This modality does not require any internet connection for any of the aspects of the DPP.

These types of delivery modes are hereafter referred to as ''virtual,'' and DPP furnished *exclusively* through these modes with no in-person delivery is hereafter referred to as ''virtual DPP.''

We acknowledge that the public comments in response to the MDPP expanded model in the CY 2017 PFS proposed rule supported the inclusion of virtual DPP in the MDPP expanded model. Many commenters stated that this proposal would increase access to MDPP services, referenced emerging evidence that suggests virtual DPP may be as effective as DPP furnished in a community setting, and stated that virtual delivery may be preferable to some beneficiaries. In the CY 2017 PFS final rule, we deferred policies pertinent to virtual DPP to future rulemaking.

Although in the CY 2018 PFS proposed rule, we proposed to allow a limited number of virtual make-up sessions in the MDPP expanded model (82 FR 34136 through 34137), we did not propose to include virtual DPP services (that is, DPP furnished *exclusively* through remote technologies with no in-person delivery), (82 FR 34171 through 34172). We considered including virtual DPP services in the MDPP expanded model; however, the DPP model test that was used to make the statutorily required determination for expansion did not include virtual DPP services. Instead, we noted that we are considering a separate model under CMS's Innovation Center authority to test and evaluate virtual DPP services. Consistent with our regular practice for Innovation Center models, we would release details on any model test for virtual DPP services separately.

We noted that some DPP organizations currently offer DPP services through a combination of in-person and virtual delivery. We are finalizing to only allow this combination of delivery subject to the requirements on virtual make-up

sessions, discussed in section III.K.2.c.iv.3 of this final rule. The combined-delivery DPP services that are currently offered are intended to offer a participant DPP services through both online and in-person methods. The MDPP expanded model, in contrast, is intended to offer participants in-person DPP services primarily, but allows a limited number of virtual make-up sessions on an individual basis. As discussed in section III.K.2.c.iv.3 of this final rule, there is substantial research on the effectiveness of DPP furnished virtually, and emerging evidence on DPP delivered virtually suggests that virtual delivery can show similarly successful participant weight loss and health benefits to DPP delivered in other settings, including among Medicare-age participants. However, since the DPP model test only included in-person delivery, we are finalizing a limit on the number of virtually-delivered make-up sessions to the limits discussed in section III.K.2.c.iv.3 of this final rule.

An organization may furnish separate DPPs where some participants receive only in-person DPP services, others receive only virtual DPP services, and others receive a combination program where some sessions are offered in person and others virtually. If an organization that offers multiple distinct DPPs through different delivery modes enrolls as an MDPP supplier, we proposed that only DPP services furnished in person will be paid in the MDPP expanded model, with the exception of virtual make-up sessions as discussed in section III.K.2.c.iv.3 of this final rule.

The following is a summary of the public comments received on virtual DPP services and our responses:

Comment: We received many comments on virtual DPP services. The majority of commenters supported the use of virtual DPP services, either in the MDPP expanded model or in a separate virtual model test. These commenters noted that virtual options will expand access to DPP for individuals in rural areas, who are homebound, or who lack transportation options, and that including virtual DPP services would increase beneficiary choice of service provision and flexibility of program location. Commenters noted that virtual DPP has proven successful and has a strong evidence base, and some commenters noted that including virtual DPP in the expanded model would improve the effectiveness of MDPP services. Some commenters provided recommendations for a virtual DPP model test. Many commenters requested that CMS allow Medicare Advantage plans to offer virtual DPP services and requested clarity about the provision of virtual DPP services for MA plans. Only 2 commenters supported only including virtual DPP as a limited number of make-up sessions or deferring virtual DPP policies.

Response: We appreciate the comments received related to virtual DPP; however, we note that we did not propose any policies related to exclusively virtual services. We will, however, be clarifying issues regarding virtual DPP services and MA plan members in future guidance. The development of new voluntary Innovation Center payment and service delivery models is not typically performed through notice and comment rulemaking, but we intend to utilize the comments received, as appropriate, to inform the development of any virtual model test that occurs as part of broader CMS efforts to promote expanded access to remote and telehealth services.

Comment: We received several comments requesting that CMS permit MA plans to provide both in-person and fully virtual MDPP services to enrollees as part of the MDPP Expanded Model. These MAOs noted that virtual services would provide more access to MDPP services for MA plan enrollees and would ensure the MA enrollees have a choice in how to access MDPP services.

Response: We believe that the reasons stated in this section regarding the exclusion of fully virtual MDPP services from the expanded model apply equally to the Medicare Advantage setting, and therefore, MA plans will not be able to provide fully virtual MDPP services to enrollees as a means to satisfy the requirement that an MA plan provide basic benefit MDPP services to its enrollees. However, we note that MA plans may continue to offer coverage of fully virtual MDPP-like services to enrollees as a supplemental benefit.

4. Evaluation

We intend to evaluate the MDPP expanded model using a combination of encounter and claims data to analyze the long-term utilization of services by beneficiaries who have received the MDPP services. As discussed in the CY 2017 PFS final rule, we will continue to assess whether the MDPP expanded model is expected to improve the quality of care without increasing spending, reduce spending without reducing the quality of care, or improve the quality of care and reduce spending, and we will terminate or modify the MDPP expanded model if the expanded model is not expected to meet these criteria.

Among other possible questions we might explore, our analysis will specifically look at long-term utilization and expenditures that might suggest subsequent treatment of diabetes. We intend to use beneficiary-level encounter data and program data furnished by CDC and will match these data to Medicare claims using the crosswalk finalized at § 424.59(b)(3) of the CY 2017 PFS final rule (redesignated and amended at § 424.205(d)(13)). As with other Innovation Center model evaluation reports (which are currently published online at *https://innovation.cms.gov/Data-and-Reports/index.html*), we intend to publish the MDPP expanded model evaluation annual reports publicly on a CMS Web site. We refer readers to the supplier requirements discussed under section III.K.2.e.iv.(7) of this final rule regarding supplier compliance with this requirement, as well as specifications on the timing and format of the crosswalk. Although CMS did not propose specific evaluation criteria in this rule, and therefore, did not seek comment on the evaluation approach, CMS acknowledges the comments received. Some commenters requested that CMS test and evaluate the impact of changes to lifetime limits, diabetes diagnosis, incentives, and the ongoing maintenance session framework. A few commenters requested CMS evaluate the effects of the various incentives furnished to MDPP beneficiaries, including the amount and type of incentive and whether beneficiaries receiving the incentives actually maintained participation. Other commenters suggested that CMS evaluate the total cost of care for MDPP services based on various personnel types (for example, community health workers, RDNs, CDEs, other qualified health care professionals) as well as study the effectiveness of various methods of delivery of the MDPP services based on personnel. Some commenters recommended analyses stratified by income and race as a means to ensure that the program is reaching all eligible Medicare beneficiaries and that these programs are able to achieve good outcomes for these populations. A few commenters suggested incorporating risk-adjustment for social factors or other methods to appropriately account for social risk factors in future years. One commenter requested that CMS continue to support further innovation and evaluation of these services through additional model tests and other pilots within Medicare and other populations who could benefit, specifically including children covered by Medicaid and the Children's Health Insurance Program. One

commenter requested a continuous feedback loop among all entities involved in the MDPP on evaluation findings.

Response: CMS appreciates all of the recommendations commenters provided. These comments will be considered in informing the evaluation design.

L. Physician Self-Referral Law: Annual Update to the List of CPT/HCPCS Codes

1. General

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain designated health services (DHS) to an entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless an exception applies. Section 1877 of the Act also prohibits the DHS entity from submitting claims to Medicare or billing the beneficiary or any other entity for Medicare DHS that are furnished as a result of a prohibited referral.

Section 1877(h)(6) of the Act and § 411.351 of our regulations specify that the following services are DHS:

- Clinical laboratory services.
- Physical therapy services.
- Occupational therapy services.
- Outpatient speech-language pathology services.
- Radiology services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

2. Annual Update to the Code List

a. Background

In § 411.351, we specify that the entire scope of four DHS categories is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS Level II publications. The DHS categories defined and updated in this manner are:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.

The Code List also identifies those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibition:

- EPO and other dialysis-related drugs furnished in or by an ESRD facility (§ 411.355(g)).
- Preventive screening tests, immunizations, or vaccines (§ 411.355(h)).

The definition of DHS at § 411.351 excludes services for which payment is made by Medicare as part of a composite rate (unless the services are specifically identified as DHS and are themselves payable through a composite rate, such as home health and inpatient and outpatient hospital services). With respect to ESRD services, *for purposes of the physician self-referral law,* we interpret the ''composite rate'' as the per-treatment payment amount under the ESRD prospective payment system (PPS). The methodology used to calculate the ESRD PPS per-treatment payment amount incorporates the cost of drugs paid under the ESRD PPS using the transitional drug add-on payment adjustment (TDAPA). (See *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R1889OTN.pdf.*) Thus, TDAPA drugs incorporated into the per-treatment payment amount are not DHS for purposes of the physician self-referral law. Because TDAPA drugs are included in the ESRD PPS ''composite rate'' and not considered ''designated health services,'' they need not be included on the list of CPT/HCPCS codes that are eligible for use with the exception at § 411.355(g). We refer readers to the CY 2018 End-Stage Renal Disease Prospective Payment System final rule for more information.

Additionally, ESRD-related oral-only drugs, which are drugs or biologicals with no injectable equivalents or other forms of administration other than an oral form, were scheduled to be paid under ESRD PPS beginning January 1, 2014 (75 FR 49044). However, there have been several delays of the implementation of payment of these drugs under ESRD PPS. Most recently, on December 19, 2014, section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295) was enacted and delayed the inclusion of these oral-only drugs under the ESRD PPS until 2025. Until that time, such drugs furnished in or by an ESRD facility are not paid as part of a composite rate and thus, are DHS.

We revised the description of the CPT/HCPCS codes related to the exceptions at §§ 411.355(g) and (h) to reflect more accurately the purpose for including these codes on the Code List. The revisions are intended to clarify that these sections of the Code List are not lists of CPT/HCPCS codes to which the physician self-referral law simply does not apply; rather, rather they are comprehensive lists of designated health services to which the exceptions at § 411.355(g) and (h) may apply. The exception at § 411.355(g) protects certain designated health services that are dialysis-related outpatient prescription drugs furnished in or by an ESRD facility and that satisfy the requirements of the exception. The exception at § 411.355(h) protects certain designated health services that are furnished as preventive screening tests, immunizations, or vaccines and that satisfy the requirements of the exception. As noted at § 411.355(g)(1) and (h)(4), the exceptions may be utilized only for designated health services included in the applicable sections of the Code List. The revised section descriptions reflect the language of § 411.355(g)(1) and (h)(4). These Code List sections represent the entire universe of CPT/HCPCS codes eligible for the exceptions at § 411.355(g) and (h), and the exceptions may not be utilized to protect referrals and claims submission for any other designated health service or category of designated health services.

The Code List was last updated in Tables 45 and 46 of the CY 2017 PFS final rule (81 FR 80534).

b. Response to Comments

We received no comments relating to the Code List that became effective January 1, 2017.

c. Revisions Effective for CY 2018

The updated, comprehensive Code List effective January 1, 2018, is available on our Web site at *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html.*

Additions and deletions to the Code List conform it to the most recent publications of CPT and HCPCS Level II and to changes in Medicare coverage policy and payment status.

Tables 44 and 45 identify the additions and deletions, respectively, to the comprehensive Code List that become effective January 1, 2018. Tables 44 and 45 also identify the additions and deletions to the list of codes used to identify the items and services that may qualify for the exception in § 411.355(g) (regarding dialysis-related outpatient prescription drugs furnished in or by an ESRD facility) and in § 411.355(h) (regarding preventive screening tests, immunizations, and vaccines).

TABLE 44—ADDITIONS TO THE PHYSICIAN SELF-REFERRAL LIST OF CPT [1] HCPCS CODES

Clinical Laboratory Services	
{No additions}	
Physical Therapy, Occupational Therapy, and Outpatient Speech-Language Pathology Services	
97763	Orthc/prostc mgmt sbsq enc.
G0515	Cognitive skills development.
Radiology and Certain Other Imaging Services	
71045	X-ray exam chest 1 view.
71046	X-ray exam chest 2 views.
71047	X-ray exam chest 3 views.
71048	X-ray exam chest 4+ views.
74018	X-ray exam abdomen 1 view.
74019	X-ray exam abdomen 2 views.
74021	X-ray exam abdomen 3+ views.
Radiation Therapy Services and Supplies	
Drugs Used by Patients Undergoing Dialysis	
{No additions}.	
Preventive Screening Tests, Immunizations and Vaccines	
90756	CCIIV4 vacc abx free im.
90682	RIV4 vacc recombinant dna im.

[1] CPT codes and descriptions only are copyright 2017 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

TABLE 45—DELETIONS FROM THE PHYSICIAN SELF-REFERRAL LIST OF CPT [1] HCPCS CODES

Clinical Laboratory Services	
{No deletions}	
Physical Therapy, Occupational Therapy, and Outpatient Speech-Language Pathology Services	
97532	Cognitive skills development.
97762	C/O for orthotic/prosth use.
Radiology and Certain Other Imaging Services	
71010	Chest x-ray.
71015	Chest x-ray.
71020	Chest x-ray.
71021	Chest x-ray.
71022	Chest x-ray.
71023	Chest x-ray and fluoroscopy.
71030	Chest x-ray.
71034	Chest x-ray and fluoroscopy.
71035	Chest x-ray.
74000	X-ray exam of abdomen.
74010	X-ray exam of abdomen.
74020	X-ray exam of abdomen.
78190	Platelet survival kinetics.
G0202	Scr mammo bi incl cad.
G0204	Dx mammo incl cad bi.
G0206	Dx mammo incl cad uni.
Radiation Therapy Services and Supplies	
77422	Neutron beam tx simple.
Drugs Used by Patients Undergoing Dialysis	
{No deletions}	

TABLE 45—DELETIONS FROM THE PHYSICIAN SELF-REFERRAL LIST OF CPT [1] HCPCS CODES—Continued

Preventive Screening Tests, Immunizations and Vaccines	
G0202	Scr mammo bi incl cad.

[1] CPT codes and descriptions only are copyright 2017 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. chapter 35), we are required to publish a 30-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.

We solicited comments in the notice of proposed rulemaking that published in the **Federal Register** on July 21, 2017 (82 FR 33950). For the purpose of transparency, we are republishing the discussion of the information collection requirements along with responses to the public comments that we received.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 46 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 46—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead costs ($/hr)	Adjusted hourly wage ($/hr)
Family and General Practitioner	29–1062	96.54	96.54	193.08

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Information Collection Requirements (ICRs)

1. ICRs Regarding the Medicare Diabetes Prevention Program (MDPP) Expanded Model

In §§ 410.79, 414.84, 424.200, 424.205, 424.210, 424.502, 424.516, 424.518 and 424.55 of this final rule, we finalize policies necessary to implement the Medicare Diabetes Prevention Program (MDPP) Expanded Model, which is aimed at preventing the onset of type 2 diabetes among Medicare beneficiaries with an indication of prediabetes. 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. Specifically, this section provides that the provisions of the PRA does not apply to the testing and evaluation of Innovation Center models or to the expansion of such models.

2. ICRs Regarding Appropriate Use Criteria for Advanced Diagnostic Imaging Services (§ 414.94)

We proposed to revise § 414.94(i)(3) by reiterating the availability of a significant hardship exception for

ordering professionals who demonstrate a significant hardship consistent with the criteria listed under § 495.102(d)(4)(i), (d)(4)(iii), (d)(4)(iv)(A) or (d)(4)(iv)(B). As discussed in section III.E. of this final rule, we are not finalizing our proposals to revise § 414.94(i)(3). Consistent with a final rule that published on November 14, 2016 (81 FR 79865 through 79866) the hardship exception process involves the completion of an application which imposes no burden beyond the provision of identifying information and attesting to the applicable information. In this regard, the application is not ''information'' as defined under 5 CFR 1320.3(h), and therefore, is exempt from requirements of the PRA.

Consistent with section 1834(q)(4)(A) of the Act (as amended by section 218(b) of the PAMA), § 414.94(j) proposed to require that ordering professionals consult specified applicable AUC through a qualified clinical decision support mechanism (CDSM) for applicable imaging services ordered on or after January 1, 2019. We proposed a one-time burden associated with a possible 6-month voluntary consulting period beginning sometime in 2018, as well as a mandatory annual burden beginning January 1, 2019. In response to public comments requesting more time to prepare before requiring AUC consultation and claims reporting, we have finalized an effective date of January 1, 2020, for the consulting requirement under this program. The voluntary consulting period will begin as early as July 2018 and last through 2019, thus extending the 6-month period proposed to 18 months.

General practitioners make up a large group of practitioners who order applicable imaging services and would be required to consult AUC under this program so we use ''family and general practitioner'' from the BLS occupation title (see Wages, above) to calculate the following cost estimates. As noted in our response to comments, we conducted an initial analysis of recalculations based on volume weighted averages specific to different specialties using the BLS May 2016 National Occupational Employment and Wage Estimates, which would include both higher paid physicians and lower paid non-physician practitioners as advanced diagnostic imaging services are ordered by a variety of medical professionals. For these estimates and using Medicare claims data derived from the Chronic Conditions Warehouse 2014 Part B non-institutional claim which we have used in prior rulemaking to inform existing policy under this program, we identified five occupations in the BLS estimates that most closely align with the practitioner specialties that order applicable imaging services. Because the BLS occupations do not provide all specialty specific estimates, the most specific occupations we were able to use to describe practitioner specialties that order applicable imaging services and their respective weighting based on order percentages identified in an analysis of the claims data are as follows: Physicians and Surgeons, All Others (69.57%), Internist, General (14.06%), Family and General Practitioners (10.53%), Physician Assistants (3.13%) and Nurse Practitioners (2.71%). Using these weights and the wage estimates for these practitioners, our burden estimates would be slightly lower. As such and because the program has not yet begun, we determined that the original methodology using Family and General Practitioners was a reasonable estimate. We will continue to monitor our estimates and could revisit for more precision once the program has begun.

During the 18-month voluntary participation period, we estimate 10,230,000 responses in the form of consultations based on market research from current applicants for the qualification of their CDSMs for advanced diagnostic imaging services. Based on feedback from CDSMs with experience in AUC consultation as well as standards recommended by the Office of the National Coordinator (ONC) and the Healthcare Information Management Systems Society (HIMSS), we estimate it would take 2 minutes at $193.08/hr for a family and general practitioner to use a qualified CDSM to consult specified applicable AUC. Per consultation, we estimate 2 minutes (0.033 hr) at a cost of $6.37 (0.033 hr × $193.08/hr). In aggregate, we estimate a one-time burden of 337,590 hours (0.033 hr × 10,230,000 consultations) at a cost of $65,181,877.20 (337,590 hr × $193.08/hr).

Annually, we estimate 112,530 hours (337,590 hr/3 yr) at a cost of $21,727,292.40 ($65,181,877.20/3 yr). We are annualizing the one-time burden (by dividing our estimates by OMB's 3-year approval period) since we do not anticipate any additional burden after the 18-month voluntary participation period ends.

Beginning January 1, 2020, we anticipate 43,181,818 responses in the form of consultations based on the aforementioned market research, as well as Medicare claims data for advanced diagnostic imaging services. As noted above, we estimate it would take 2 minutes (0.033 hr) at $193.08/hr for a family and general practitioner to use a qualified CDSM to consult specified applicable AUC. In this regard, we estimate 0.033 hours per consultation at a cost of $6.37 (0.033 hr × $193.08/hr). In aggregate, we estimate an annual burden of 1,425,000 hours (0.033 hr × 43,181,818 consultations) at a cost of $275,139,000 (1,425,000 hr × $193.08/hr).

The consultation requirements and burden have been submitted to OMB for approval under control number 0938-New (CMS–10654).

Consistent with section 1834(q)(4)(B) of the Act, we also proposed to implement a one-time 6-month voluntary reporting period beginning sometime in 2018, as well as a mandatory annual reporting requirement beginning January 1, 2019. Specifically, § 414.94(k) proposed to require that furnishing professionals report on the Medicare claims for advanced diagnostic imaging services, paid for under an applicable payment system (as defined in § 414.94(b)) and ordered on or after January 1, 2019, the following information: (1) Identify which qualified CDSM was consulted by the ordering professional; (2) identify whether the service ordered would adhere to specified applicable AUC, would not adhere to specified applicable AUC, or whether specified applicable AUC was not applicable to the service ordered; and (3) identify the NPI of the ordering professional (if different from the furnishing professional). As noted earlier in this section, in response to public comment the voluntary period has been extended to 18 months and the effective date for the AUC consulting and reporting requirements will be January 1, 2020. The reporting requirement will not have any impact on any Medicare claim forms because the forms' currently approved data fields, instructions, and burden are not expected to change. Consequently, there is no need for review by OMB under the authority of the PRA.

The timing and implementation of the voluntary consultation and reporting period is dependent on the readiness of the Medicare claims systems to accept and process claims including AUC consultation information. Currently, 99 percent of all Medicare claims are submitted electronically as a result of The Administrative Simplification Compliance Act amendment to section 1862(a) of the Act, which prescribes that no payment may be made under Part B of the Medicare Program for any expenses incurred for items or services for which a claim is received in a non-electronic form. Consequently, absent an applicable exception, paper claims

received by Medicare will not be paid. Continued developments in the deployment of CDSMs has produced research [45] and best practices [46] [47] [48] supporting our position that any such changes made to respondent IT systems would be a usual and customary business practice whose burden is exempt from the requirements of the PRA under 5 CFR 1320.3(b).

Based on the proposed consulting and reporting requirements, we received comments on our proposed estimates. We have included a summary of the comments received below, and note that we have finalized our policy in § 414.94(j) and (k) (82 FR 34195). We are largely adopting the proposed collection of information provisions with minimal changes to reflect the extension of the voluntary reporting period discussed earlier in this section.

Comment: Commenters acknowledged that the annual burden estimated for the program appears to outweigh the Congressional Budget Office estimated savings. A few commenters stated we should also compensate physicians for consulting AUC and recommended an imaging service volume-weighted average as an alternative to estimates based on the hourly rate of a family and general practitioner. Another commenter requested the estimate use a volume weighted average that includes specific specialties that are paid at a higher rate than family and general practitioner since they are paid at a lower rate. A few commenters stated the estimated 2 minutes was inaccurate, and instead proposed an additional 3–5 minutes to consult AUC. One commenter noted that such estimates were based on the Medicare Imaging Demonstration report to Congress (Timbie et al., Medicare Imaging Demonstration Final Evaluation: Report to Congress. Rand Health Q. 2015 Jul 15;5(1):4.). Other commenters disagreed and stated that impact on the workflow of ordering professionals would be minimal, and acknowledged that current processes are doing a poor job of reducing inappropriate utilization to protect Medicare beneficiaries.

Response: As discussed earlier in this section, we conducted an initial analysis of recalculations based on volume weighted averages specific to different specialties again using the BLS May 2016 National Occupational Employment and Wage Estimates, which included both higher paid physicians as suggested by the commenter and lower paid non-physician practitioners because advanced diagnostic imaging services are ordered by a variety of medical professionals and our claims data analysis supports such inclusion. The resulting estimates for both the collection of information and regulatory impact analysis were slightly lower than our original estimates using the mean hourly wage for family and general practitioner, so we did not adjust the estimates using specialty specific information. However, as the AUC program evolves we will continue to assess the burden and reevaluate the estimates, and we will update this PRA package as necessary going forward.

Comment: Some commenters recommended that we revisit the estimates to include the communication between ordering professional to the furnishing professional, as well as the reporting of AUC consultation information by the furnishing professional. Commenters stated that the proposed estimate does not include any time for the work the furnishing professional would perform to: (1) Validate information sent from the ordering professional; (2) recognize ordering professionals with a significant hardship exception; (3) training; and (4) add new or additional health IT interoperability between EHR systems. One commenter requested that additional consideration be made for costs to purchase or subscribe to specific proprietary CDSM products, and costs to build or incorporate software interfaces.

Response: We appreciate these commenters' views and agree that furnishing professionals will incur burden attributed to the AUC program. However, we do not foresee such burden being incurred during the voluntary reporting period. We note that during the voluntary reporting period that begins July 2018, furnishing professionals are not expected to change how they currently interact and communicate with ordering professionals and any information related to an AUC consultation will be communicated using existing methods. We also point out that in the CY 2019 PFS rule we will revisit the significant hardship exception to continue working toward alignment with MIPS. While we do not expect ordering professionals in need of a significant hardship exception to participate in the voluntary period, a significant hardship exception process will not be operationalized in time for the 2018 voluntary reporting period, therefore furnishing professionals will not have the ability to identify ordering professionals with the exception as none will have been granted yet. Generally, we expect very few changes to be made in the early part of the voluntary period, particularly in CY 2018. Rather, the voluntary period is most likely to be used by ordering professionals that are already consulting AUC using a qualified CDSM and be reported by furnishing professionals that are already within the same EHR system as the ordering professionals. With respect to costs incurred for IT, the AUC program has a qualified CDSM available free of charge and the statute does not provide for additional compensation to affected professionals to ensure compliance with program requirements. We will update estimates as necessary to reflect changes to this program as it moves from voluntary participation to required participation at which time we expect to see changes in behavior to comply with reporting requirements.

3. ICRs Regarding the Medicare Shared Savings Program (Part 425)

Section 1899(e) of the Act provides that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the PRA, does not apply to the Shared Savings Program.

C. Summary of Annual Burden Estimates and Requirements

TABLE 47—ANNUAL REQUIREMENTS AND BURDEN

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($/hr)	Total cost ($) *
§ 414.94(j) (voluntary consultations)	0938—New	10,230,000	3,410,000 (10,230,000/3)	0.033	112,530	193.08	21,727,292

[45] CDC Health Information Innovation Consortium, May 17 2016, available at *https://www.cdc.gov/ophss/chiic/forums/2016-05-17_index.html.*

[46] ONC eCQI resource for process improvement: *bit.ly/oncecqicds.*

[47] CMS CDS tipsheet: *bit.ly/cmscdstips.*

[48] HIMSS CDS Guidebook Series: *www.himss.org/cdsguide.*

TABLE 47—ANNUAL REQUIREMENTS AND BURDEN—Continued

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($/hr)	Total cost ($) *
§ 414.94(j) (mandatory consultations)	.....	43,181,818	43,181,818	0.033	1,425,000	193.08	275,139,000
Total	.....	53,411,818	46,591,818	.....	1,537,530	.....	296,866,292

* With respect to the PRA, this rule would not impose any non-labor costs.

We have submitted a copy of this rule to OMB for its review of the rule's information collection and burden requirements. The requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the collections discussed above, please visit CMS's Web site at Web site address *https://www.cms.gov/Regulations-andGuidance/Legislation/PaperworkReductionActof1995/PRAListing.html*, or call the Reports Clearance Office at 410–786–1326.

V. Regulatory Impact Analysis

A. Statement of Need

This final rule makes payment and policy changes under the Medicare PFS and implements required statutory changes under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the Achieving a Better Life Experience Act (ABLE), the Protecting Access to Medicare Act of 2014 (PAMA), section 603 of the Bipartisan Budget Act of 2015, and the Consolidated Appropriations Act of 2016. This final rule also makes changes to payment policy and other related policies for Medicare Part B, Part D, and Medicare Advantage.

B. Overall Impact

We examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate, as discussed in this section, that the PFS provisions included in this final rule would redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details see the SBA's Web site at *http://www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals and states are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this final rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

For example, the effects of changes to payment rates for practitioners, other providers, and suppliers are discussed in V.C. of this final rule. Alternative options considered to the proposed payment rates are discussed generally in section V.F of this final rule, while specific alternatives for individual codes are discussed throughout this rule, especially in section II.H.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on state, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2017, that threshold is approximately $148 million. This final rule will impose no mandates on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments,

preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. This final rule is considered an E.O. 13771 regulatory action because it is expected to result in regulatory costs.

We prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this final rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this final rule, we are implementing a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and implementing statutory provisions. We provide information for each of the policy changes in the relevant sections of this final rule. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this final rule. The relevant sections of this final rule contain a description of significant alternatives if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compare payment rates for CY 2017 with payment rates for CY 2018 using CY 2016 Medicare utilization. The payment impacts in this final rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and would depend on the mix of services he or she furnishes. The average percentage change in total revenues would be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are paid under the Clinical Laboratory Fee Schedule.

The annual update to the PFS conversion factor (CF) was previously calculated based on a statutory formula; for details about this formula, we refer readers to the CY 2015 PFS final rule with comment period (79 FR 67741 through 67742). Section 101(a) of the MACRA repealed the previous statutory update formula and amended section 1848(d) of the Act to specify the update adjustment factors for calendar years 2015 and beyond. For CY 2018, the specified update is 0.5 percent before applying other adjustments.

Section 220(d) of the PAMA added a new paragraph at section 1848(c)(2)(O) of the Act to establish an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes. Under section 1848(c)(2)(O)(ii) of the Act, if the net reduction in expenditures for the year is equal to or greater than the target for the year, reduced expenditures attributable to such adjustments shall be redistributed in a budget-neutral manner within the PFS in accordance with the existing budget neutrality requirement under section 1848(c)(2)(B)(ii)(II) of the Act. Section 1848(c)(2)(O)(iii) of the Act specifies that, if the estimated net reduction in PFS expenditures for the year is less than the target for the year, an amount equal to the target recapture amount shall not be taken into account when applying the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act. We estimate the CY 2018 net reduction in expenditures resulting from adjustments to relative values of misvalued codes to be 0.41 percent. Since this amount does not meet the 0.5 percent target under section 1848(c)(2)(O)(v) of the Act, payments under the fee schedule must be reduced by the difference between the target for the year and the estimated net reduction in expenditures, known as the target recapture amount. As a result, we estimate that the CY 2018 target recapture amount will produce a reduction to the conversion factor of −0.09 percent.

To calculate the final conversion factor for this year, we multiplied the product of the current year conversion factor and the update adjustment factor by the target recapture amount and the budget neutrality adjustment described in the preceding paragraphs. We estimate the CY 2018 PFS conversion factor to be 35.9996, which reflects the budget neutrality adjustment under section 1848(c)(2)(B)(ii)(II), the 0.5 percent update adjustment factor specified under section 1848(d)(18) of the Act, and the −0.09 percent target recapture amount required under section 1848(c)(2)(O)(iv) of the Act. We estimate the CY 2018 anesthesia conversion factor to be 22.1887, which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE 48—CALCULATION OF THE FINAL CY 2018 PFS CONVERSION FACTOR

CY 2017 Conversion Factor		35.8887
Statutory Update Factor	0.50 percent (1.0050)	
CY 2018 RVU Budget Neutrality Adjustment	−0.10 percent (0.9990)	
CY 2018 Target Recapture Amount	−0.09 percent (0.9991)	
CY 2018 Conversion Factor		35.9996

TABLE 49—CALCULATION OF THE FINAL CY 2018 ANESTHESIA CONVERSION FACTOR

CY 2017 National Average Anesthesia Conversion Factor		22.0454
Statutory Update Factor	0.50 percent (1.0050)	

TABLE 49—CALCULATION OF THE FINAL CY 2018 ANESTHESIA CONVERSION FACTOR—Continued

CY 2018 RVU Budget Neutrality Adjustment	−0.10 percent (0.9990)	
CY 2018 Target Recapture Amount	−0.09 percent (0.9991)	
CY 2018 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.34 percent (1.0034)	
CY 2018 Conversion Factor		22.1887

Table 50 shows the payment impact on PFS services of the proposals contained in this final rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues would be different from those shown in Table 50 (CY 2018 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 50.

- *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 2016 utilization and CY 2017 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 2018 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 2018 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 2018 impact on total allowed charges of the changes in the MP RVUs, which are primarily driven by the required five-year review and update of MP RVUs.
- *Column F (Combined Impact):* This column shows the estimated CY 2018 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 50—CY 2018 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *

Specialty	Allowed charges (mil)	Impact of work RVU changes (percent)	Impact of PE RVU changes (percent)	Impact of MP RVU changes (percent)	Combined impact (percent) **
(A)	(B)	(C)	(D)	(E)	(F)
TOTAL	$93,149	0	0	0	0
ALLERGY/IMMUNOLOGY	247	0	−3	0	−3
ANESTHESIOLOGY	2,018	−1	0	0	−1
AUDIOLOGIST	66	0	0	0	0
CARDIAC SURGERY	312	0	0	0	0
CARDIOLOGY	6,705	0	−1	0	1
CHIROPRACTOR	779	0	1	0	1
CLINICAL PSYCHOLOGIST	762	0	2	0	2
CLINICAL SOCIAL WORKER	670	0	3	0	3
COLON AND RECTAL SURGERY	167	0	0	0	0
CRITICAL CARE	334	0	0	0	0
DERMATOLOGY	3,485	0	1	0	1
DIAGNOSTIC TESTING FACILITY	773	0	−4	0	−4
EMERGENCY MEDICINE	3,191	0	0	0	0
ENDOCRINOLOGY	480	0	0	0	0
FAMILY PRACTICE	6,350	0	0	0	0
GASTROENTEROLOGY	1,801	0	0	0	0
GENERAL PRACTICE	458	0	0	0	0
GENERAL SURGERY	2,170	0	0	0	0
GERIATRICS	212	0	0	0	0
HAND SURGERY	201	0	0	0	0
HEMATOLOGY/ONCOLOGY	1,809	0	0	0	0
INDEPENDENT LABORATORY	690	0	−1	0	−1
INFECTIOUS DISEASE	656	0	0	0	1
INTERNAL MEDICINE	11,107	0	0	0	0
INTERVENTIONAL PAIN MGMT	834	0	0	0	0
INTERVENTIONAL RADIOLOGY	360	0	0	0	0
MULTISPECIALTY CLINIC/OTHER PHYS	140	0	0	0	0
NEPHROLOGY	2,270	0	0	0	0
NEUROLOGY	1,554	0	0	0	0
NEUROSURGERY	811	0	0	0	0
NUCLEAR MEDICINE	50	0	0	0	0
NURSE ANES/ANES ASST	1,243	−2	0	0	−2
NURSE PRACTITIONER	3,566	0	0	0	0
OBSTETRICS/GYNECOLOGY	662	0	0	0	0
OPHTHALMOLOGY	5,498	0	1	0	0

TABLE 50—CY 2018 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *—Continued

Specialty	Allowed charges (mil)	Impact of work RVU changes (percent)	Impact of PE RVU changes (percent)	Impact of MP RVU changes (percent)	Combined impact (percent) **
(A)	(B)	(C)	(D)	(E)	(F)
OPTOMETRY	1,269	0	0	0	0
ORAL/MAXILLOFACIAL SURGERY	57	0	−1	0	−1
ORTHOPEDIC SURGERY	3,801	0	0	0	0
OTHER	29	0	0	0	0
OTOLARNGOLOGY	1,237	0	−1	0	−2
PATHOLOGY	1,154	0	0	0	−1
PEDIATRICS	64	0	0	0	0
PHYSICAL MEDICINE	1,112	0	0	0	0
PHYSICAL/OCCUPATIONAL THERAPY	3,807	1	−2	0	−2
PHYSICIAN ASSISTANT	2,242	0	0	0	0
PLASTIC SURGERY	384	0	0	0	1
PODIATRY	1,994	0	1	0	1
PORTABLE X–RAY SUPPLIER	102	0	1	0	1
PSYCHIATRY	1,247	0	1	0	1
PULMONARY DISEASE	1,761	0	0	0	0
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	1,745	0	1	0	1
RADIOLOGY	4,896	0	0	0	0
RHEUMATOLOGY	554	0	1	0	1
THORACIC SURGERY	358	0	0	0	0
UROLOGY	1,777	0	0	0	−1
VASCULAR SURGERY	1,125	0	−1	0	−1

* Column F may not equal the sum of columns C, D, and E due to rounding.

2. CY 2018 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the final RVU changes are generally related to the changes to RVUs for specific services resulting from the Misvalued Code Initiative, including finalized RVUs for new and revised codes. The estimated impacts for some specialties, including behavioral health specialists, radiation oncology, and podiatry, reflect increases relative to other physician specialties. These increases can largely be attributed to increases in value for particular services following the recommendations from the American Medical Association (AMA)'s Relative Value Scale Update Committee (RUC) and CMS review and the change in allocation of indirect practice expense RVUs for office-based, face-to-face behavioral health services.

The estimated impacts for several specialties, including diagnostic testing facilities, allergy/immunology, physical/occupational therapy, otolaryngology, anesthesiology, and nurse anesthetists reflect decreases in payments relative to payment to other physician specialties as a result of revaluation of individual procedures reviewed by the AMA's RUC and CMS, decreases in relative payment as a result of the updates to prices for particular medical supplies, and continued implementation of previously finalized code-level reductions that are being phased-in over several years. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the Clinical Laboratory Fee Schedule. As a result, the estimated 1 percent reduction for CY 2018 is only applicable to approximately 17 percent of the Medicare payment to these entities.

The estimated impacts for many specialties are increases relative to the rates published in the proposed rule due to the decision to retain the professional liability premium data (from CY 2015) that was used for CY 2017, as opposed to utilizing the updated data for CY 2018 that were used to calculate the rates in the proposed rule. The estimated decrease to the physical/occupational therapy specialty as compared to the impacts in the proposed rule resulted from the decision to finalize the direct PE inputs recommended by the Health Care Professionals Advisory Committee (HCPAC) for approximately two dozen therapy codes reviewed in CY 2018, as opposed to retaining the CY 2017 direct PE inputs for these codes as proposed.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table, including comments received in response to the proposed rates. We remind stakeholders that although the estimated impacts are displayed at the specialty level, typically the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentages in the table are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty, and compared to the same summed total from the previous calendar year. They are therefore averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty.

b. Impact

Column F of Table 50 displays the estimated CY 2018 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 2018 PFS final rule Web site 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 Web site at *http://www.cms.gov/*

Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/.

D. Effect of Changes Related to Telehealth

As discussed in section II.D. of this final rule, we are adding several new codes to the list of Medicare telehealth services. Although we expect these changes to have the potential to increase access to care in rural areas, based on recent telehealth utilization of services already on the list, including services similar to the proposed additions, we estimate there will only be a negligible impact on PFS expenditures from the proposed additions. For example, for services already on the list, they are furnished via telehealth, on average, less than 0.1 percent of the time they are reported overall.

In addition, as discussed in section II.D. of this final rule, we are making CPT code 99091 separately payable for CY 2018. We note that this change will be implemented in a budget neutral manner, and we estimate that there will be a negligible impact on PFS expenditures from making this code separately payable.

E. Effect of Changes to Payment to Provider-Based Departments (PBDs) of Hospitals Paid Under the PFS

As discussed in section II.G of this final rule, for CY 2018, we are finalizing a PFS Relativity Adjuster of 40 percent, meaning that nonexcepted items and services furnished by nonexcepted off-campus PBDs would be paid under the PFS at a rate that is 40 percent of the OPPS rate. We estimate that this change will result in total Medicare Part B savings of $12 million for CY 2018 relative to maintaining the CY 2017 PFS Relativity Adjuster for CY 2018.

F. Other Provisions of the Final Regulation

1. New Care Coordination Services and Payment for RHCs and FQHCs

As discussed in section III.A of this final rule, we finalized the establishment of two new G codes for use by RHCs and FQHCs. The first new G code is a General Care Management code for RHCs and FQHCs with the payment amount set at the average of the 3 national non-facility PFS payment rates for the CCM and general BHI codes. The second new G code for RHCs and FQHCs is a Psychiatric CoCM code with the payment amount set at the average of the 2 national non-facility PFS payment rates for psychiatric CoCM services. The payment rate for each code will be updated annually, based on the national non-facility PFS payment rates for each code contained in the G code.

The methodology for payment of care coordination services is consistent with the RHC and FQHC payment principles of not paying for services based on time increments. It does not create additional reporting burden and is expected to promote beneficiary access to comprehensive care management services furnished by RHCs and FQHCs.

Establishment of the RHC and FQHC General Care Management code, which includes all levels of CCM and general BHI services, is projected to increase Medicare spending by $2.2 million in CY 2018 and by $25.5 million over 10 years. This estimate is based on the proposed per service allowed charge increase (from approximately $42.71 to $61.37) applied to historical 2017 CCM and BHI volume in RHCs and FQHCs. This volume was adjusted with an assumed 10 percent behavioral volume increase to reflect the increase in allowed charges per service.

Establishment of the RHC and FQHC Psychiatric CoCM code, which includes all levels of psychiatric CoCM services, is projected to increase Medicare spending by approximately $100,000 in CY 2018 and $4.0 million over 10 years. Because psychiatric CoCM is not billable currently by RHCs or FQHCs and is also new to practitioners billing under the PFS, this estimate is based on first quarter 2017 PFS psychiatric CoCM claims of 0.06 percent of psychiatric E/M visits, adjusted to an ultimate average rate of 0.28 percent based on the pattern of increase in CCM services in the PFS found in the first two and a half years of implementation. This rate was then applied to the number of 2017 RHC and FQHC mental health visits to get an estimate of CoCM volume, and then projected forward on a per-capita basis. PFS price updates were applied to the initial approximate $135 psychiatric CoCM payment amount to project future costs.

The combined increase in Medicare spending for both new G codes is estimated to be approximately $2.2 million in 2018, and approximately $29.5 million over 10 years. Although these services are expected to increase quality and improve efficiency over time, the programs are still new and the data is not available yet to demonstrate any cost savings. Therefore, no healthcare cost reductions were assumed as a result of increased care management.

TABLE 51—CALENDAR YEARS 2018–2027 PROJECTED SPENDING IMPACT OF NEW GENERAL CARE MANAGEMENT AND PSYCHIATRIC COCM CODES FOR RHCS AND FQHCS

[Millions] [49]

CY	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2018–2027
General Care Management	2.2	2.3	2.4	2.5	2.5	2.6	2.7	2.7	2.8	2.9	25.5
Psychiatric CoCM	0.1	0.4	0.4	0.4	0.4	0.4	0.4	0.5	0.5	0.5	4.0
Total	2.3	2.7	2.8	2.9	2.9	3.0	3.1	3.2	3.3	3.4	29.5

As discussed in section III.A. of this final rule, we considered 3 other options (for example, allowing any of the 7 codes to be separately added to a claim, bundling all 7 codes into one G code, and developing 3 separate G codes—one each for CCM, BHI, and CoCM services). We estimated that there would be no significant difference in the costs among the options because all of the options considered include the same services paid at the same rate and no data is available to estimate a different rate of billing for each code.

2. Payment for DME Infusion Drugs

As discussed in section III.B. of this final rule, we are finalizing our proposal to conform the regulation text at § 414.904(e)(2) to section 5004 of the Cures Act, which transitioned payment for DME infusion drugs from AWP-based pricing to the ASP-pricing methodology on January 1, 2017. Table 52 shows the effect of changes in drug payments to DME suppliers. We estimate adoption of the ASP+6 pricing methodology will result in total Medicare Part B savings ranging over the 10-year period from $40 million in FY 2017 to $110 million in FY 2026

[49] Figures may not sum to totals due to rounding.

with a 10-year total Medicare Part B savings of $960 million.

TABLE 52—IMPACT OF CURES SECTION 5004 ON PAYMENT FOR INFUSION DRUGS FURNISHED THROUGH AN ITEM OF DMS

[In millions]

FY	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	5-yr impact 2017–2021	10-yr impact 2017–2026
Benefits	(50)	(110)	(130)	(130)	(130)	(130)	(150)	(150)	(150)	(150)	(550)	(1,280)
Premium Offset	10	30	30	30	30	30	40	40	40	40	130	320
Total Part B	(40)	(80)	(100)	(100)	(100)	(100)	(110)	(110)	(110)	(110)	(420)	(960)

3. Payment for Biosimilar Biological Products Under Section 1847A of the Act

In section III.D. of this rule we discussed the payment of biosimilar biological products under section 1847A of the Act. We explained that under the current Medicare Part B policy, the payment amount 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. However, in this final rule, we are finalizing the policy to separately code and pay for biological biosimilar products under Medicare Part B. Effective on January 1, 2018, newly approved biosimilar biological products with a common reference product will no longer be grouped into the same billing code.

In the 2016 PFS rule, we stated that we anticipate that biosimilar biological products will have lower ASPs than the corresponding reference products (80 FR 71362). We also expected that Medicare would realize savings from the utilization of biosimilar biological products. However, we have limited experience under Medicare Part B with biosimilar biological products that have been approved under the FDA's biosimilar approval pathway. There are four approved Part B biosimilars: limited claims data on two is available, the third product was marketed in July 2017, the fourth is not yet marketed, and it is not clear when marketing will begin. Further, it is not clear how many more biosimilar products will be approved, when approval and marketing of various products will occur, what the market penetration of biosimilars in Medicare Part B will be, and what the cost differences between the biosimilars as well as the price differences between the biosimilars and the reference products will be. Therefore, with limited data, we are not able to quantify with certainty the potential savings or costs to Medicare Part B from changes to current policy. Similarly, we are not able to quantify the impact, if any, on physician offices that administer biosimilar biological products or the costs to beneficiaries.

Based on our limited experience with the first two biosimilar products marketed in the United States, filgrastim and infliximab, once ASP-based payment amounts take effect, savings (relative to the reference product) are realized under the current policy. However, as discussed in section III.D. of this rule, we believe that a policy that could potentially increase provider and patient choice is superior to existing policy and may lead to additional cost savings. If payment amounts limit manufacturers' willingness to invest in the development of new biosimilars, it could in the long term decrease the number of biosimilar biological products that are available to prescribe and thus impair price competition. Given that the United States' biosimilar biological product marketplace is still relatively new, it is important to have a payment policy that supports innovation, as well as reasonable pricing for consumers. The change in policy is expected to lead to greater competition and more products in the marketplace. We present a hypothetical example below to illustrate what would need to occur in the market for this policy change to achieve cost savings for Medicare.

We have assumed that biosimilar biological products will provide between 5 and 30 percent cost savings relative to the reference biological product. These differences are consistent with our limited experience in Part B with the biosimilar version of filgrastim and very limited experience with the first biosimilar version of infliximab, as well as comments received in the rule and estimates in the lay press. Uptake rates for the current policy are also consistent with our limited experience and commenters estimates. For simplicity and the purpose of this example, we have assumed that the Medicare payment amounts for biosimilar biological products will be comparable in both the grouped and separate code scenario. The slightly higher payment amounts for biosimilar biological products under the separate code scenario at year 1 (compared to payments for a grouped code) are expected because first quarter payment for each separately coded product would be based on Wholesale Acquisition Cost (WAC). However, this would be offset by a greater number of licensed biosimilar biological products by year 10 and higher uptake by year 10. The overall savings from using separate codes is expected to be greater over the 5 year period because the greater number of biosimilar biological products available in the marketplace is expected to provide greater choice for providers, and this should result in greater uptake of the products. In summary, Table 53 is intended to illustrate that at year 10 compared to current policy, separate codes are anticipated to decrease reference product prices (or at least keep them stable) and increase the number of products and uptake of biosimilars at year 10. In order to more clearly illustrate these points we assumed that payment amounts in this example would remain stable. However, as stated in section II.D. of this rule, over the long term, if the policy leads to greater competition and more products in the marketplace, we believe that it is reasonable to anticipate that the higher initial payments will be offset by savings. A greater uptake of products with a lower payment amount than a reference product is expected to yield overall savings. We note that savings could also occur from lower payment amounts due to increased competition.

TABLE 53—HYPOTHETICAL COMPARISON OF GROUPED AND SEPARATE PAYMENT FOR BIOSIMILAR BIOLOGICAL PRODUCTS

	Grouped payment using one HCPCS code		Separate codes for each biosimilar	
	Year 1	Year 10	Year 1	Year 10
Reference Product Payment Amount	Stable or slight increase.	Stable or increase	Stable	Stable or decrease.
Biosimilar Product Payment Amount	10% below reference product.	10–30% below reference product.	5–10% below reference product.	10–30% below reference product
Number of Licensed Biosimilars	1–2	2–3	1–3	3–4.
Uptake of Biosimilars	10%	10–20%	10%	>20%.

The economics literature seems to indicate that the competition and pricing outcomes of reference pricing policies are quite dependent on market characteristics and other parameters. (See, for example, Brekke *et al.*, 2007, Kanavos *et al.*, 2008, Zweimüller's discussion of Kanavos *et al.*, and Danzon and Ketcham, 2004.) [50] Due to time and other resource constraints, the results of this literature have not been incorporated into the illustrative calculation above and not been used to develop quantitative estimates of the biosimilars pricing provisions of this final rule. Other questions that could be a part of further analysis in this area, as the market develops include:

- Could small-molecule pharmaceutical pricing, utilization and models apply to the biosimilar product context? Although the literature on biosimilars is currently much less extensive than the literature on small-molecule drugs, are there studies that are relevant to the policy question of Medicare's biosimilars pricing?
- To what extent can experience with nationwide reference pricing (for example, in Europe) inform pricing policy implemented by Medicare, which is one of several payers?
- What are the key parameters for determining the optimal tradeoff between short-run price savings and long-run incentives to innovate? What insights on this question can be gleaned from the optimal patent exclusivity literature or other strains of research?

[50] Brekke, Kurt R., Ingrid Königbauer and Odd Rune Straume. ''Reference Pricing of Pharmaceuticals.'' *Journal of Health Economics* 26(3), 613–642. May 2007. Danzon, Patricia M. and Jonathan D. Ketcham. ''Reference Pricing of Pharmaceuticals for Medicare: Evidence from Germany, the Netherlands, and New Zealand.'' *Forum for Health Economics & Policy* 7(1). January 2004. Kanavos, Panos, Joan Costa-Font and Elizabeth Seeley. ''Competition in Off-Patent Drug Markets: Issues, Regulation and Evidence.'' *Economic Policy* 23(55), 500–544. July 2008. (Discussion by Josef Zweimüller begins on page 537.)

4. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

We are finalizing the effective date of January 1, 2020 on which the appropriate use criteria (AUC) consulting and reporting requirements will begin, and extending the voluntary consulting and reporting period to 18 months. We are not finalizing the proposed modifications to the significant hardship exception, but anticipate proposing policies in rulemaking for CY 2019 to address commenters' concerns and better align exceptions under the AUC program with those under existing quality programs. In the COI section of this document, we estimate the consulting requirement to result in an annual burden of 1,425,000 hours at a cost of $275,139,000. These updates to the AUC program will not result in claims denials in CY 2018, and thus, these proposals would not impact CY 2018 physician payments under the PFS. The Congressional Budget Office estimates that section 218 of the PAMA would save approximately $200 million over 10 years from FY 2014 through 2024, which could be the result of identification of outlier ordering professionals and also includes section 218(a) of the PAMA, which is a payment deduction for computed tomography equipment that is not up to a current technology standard. CMS has not estimated a score as such consultation and reporting is not required for FY 2018. Because we have not yet proposed a mechanism or calculation for outlier ordering professional identification and prior authorization, we are unable to quantify that impact at this time. We will provide an impact statement when applicable in future rulemaking.

5. Physician Quality Reporting System Criteria for Satisfactory Reporting for Individual EPs

a. Burden Estimate for PQRS Reporting

We previously discussed the burden estimate for PQRS regarding the satisfactory reporting criteria for the CY 2016 reporting period, which applies to the 2018 PQRS payment adjustment, in the CY 2016 PFS final rule (see 80 FR 71362 through 71367). The burden estimates for reporting that data have not changed since these data for the CY 2016 reporting period have already been reported; therefore, there are no added burden estimates for the policy change discussed in section III.F of this final rule.

b. Burden Savings Estimated Based on PQRS Measures Reduction Policy

Amending the policy to reduce the amount of measures needed to satisfactorily report to avoid the 2018 PQRS payment adjustment from 9 measures across 3 NQS domains to 6 measures (see section III.F. of this final rule) would increase the amount of satisfactory reporters for the CY 2016 reporting period, which would decrease those subject to the 2018 PQRS payment adjustment. Using data from the CY 2015 reporting period as the basis for our estimates, there were roughly 525,000 eligible professionals who failed the PQRS reporting requirements for the CY 2015 reporting period and received a downward payment adjustment in 2017 (see *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015_PQRS_Experience_Report.pdf*). We estimate that, based on 2015 results, approximately 4.5 percent of EPs that received a downward payment adjustment would be found successful under the amended policy, and therefore, would avoid the payment penalty. This equates to an estimated 23,625 EPs that would no longer be subject to the 2018 PQRS payment adjustment based on PQRS data for the CY 2015 reporting period.

Based on the estimated average payment adjustment of $937.02 in program year 2015, which was negative 2 percent based on 2015 PFS charges, an estimated ($937.02 × 23,625 = $22,137,097.50) would be the amount all EPs would receive as a result of not being subject to the 2018 PQRS payment adjustment due to the amended policy in this final rule for the CY 2016

reporting period, which applies to the 2018 PQRS payment adjustment.

6. Medicare EHR Incentive Program for EPs

a. Burden Estimate for the Medicare EHR Incentive Program for EPs Reporting

Previous burden impacts were discussed in the Medicare EHR Incentive Program Stage 2 final rule (77 FR 54126 through 54133). The burden estimates for reporting that data have not changed; therefore, there are no added burden estimates for the policy change discussed in section III.G. of this final rule.

b. Burden Savings Estimated Based on Amended Medicare EHR Incentive Program Policy

The changes in section III.G. of this final rule for the Medicare EHR Incentive Program for EPs reporting CQMs would have no additional estimated impacts as they would neither increase or decrease the number of successful meaningful EHR users in the Medicare EHR Incentive Program for EPs. Under this policy, the number of CQMs required to meet EHR Incentive Program requirements would not change for those EPs reporting their CQMs by attestation, thus the previously reported burden estimates for those EPs remains unchanged. For those EPs submitting CQMs electronically, this policy would reduce their reporting requirement from 9 measures across 3 NQS domains to 6 measures with no domain requirement. Based on our analysis of the data already reported for CY 2016, no additional EPs would have successfully demonstrated meaningful use.

7. Medicare Shared Savings Program

We proposed certain modifications to our rules regarding ACO assignment and financial calculations, quality measures and quality validation audits, TIN overlaps, and application requirements. Specifically we proposed: (1) Modifications to how services furnished by RHCs and FQHCs are used for purposes of beneficiary assignment to an ACO as a result of the 21st Century Cures Act, including reducing reporting burden for ACOs that include RHCs and FQHCs; (2) modifications to the assignment methodology to include new chronic care management and behavioral health integration codes in our definition of primary care services; (3) a policy to improve the quality validation audit process and, absent unusual circumstances, to use the results to proportionally modify an ACO's overall quality score; (4) a policy to address substantive changes to quality measures made under the Quality Payment Program; (5) revisions to our application requirements to reduce burden for ACO applicants seeking to participate in the Shared Savings Program and for ACOs applying to use the SNF 3-Day Rule Waiver; (6) changes to our ACO participant TIN overlap policies, specifically, to address situations in which overlapping ACO participant TINs begin billing for services that are used in beneficiary assignment during a benchmark or performance year; and (7) a policy to use only final beneficiary identifiable non-claims based payments in establishing benchmarks and performing financial reconciliation.

We are finalizing these proposed policies in this final rule. Although we believe the final policies will reduce burden for participating ACOs and applicants, we do not anticipate any significant economic impact for these policies in terms of overall program costs or savings.

8. Value-Based Payment Modifier and the Physician Feedback Program

Section 1848(p) of the Act requires that we establish a value-based payment modifier (VM) and apply it to specific physicians and groups of physicians the Secretary determines appropriate starting January 1, 2015, and to all physicians and groups of physicians by January 1, 2017. Section 1848(p)(4)(C) of the Act requires the VM to be budget neutral. Budget-neutrality means that, in aggregate, the increased payments to high performing physicians and groups equal the reduced payments to low performing physicians and groups, as well as those physicians and groups that failed to avoid the PQRS payment adjustment as a group or as individuals. The final payment adjustment period for the Value Modifier will be CY 2018 after which it will be replaced by the payment adjustments under the Merit-based Incentive Payment System (MIPS).

In the CY 2016 PFS final rule with comment period (80 FR 71277 and 71279), we established that, beginning with the CY 2018 payment adjustment period, the VM will apply to nonphysician EPs who are physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified registered nurse anesthetists (CRNAs) in groups with 2 or more EPs and to PAs, NPs, CNSs, and CRNAs who are solo practitioners.

We also previously finalized that, in CY 2018, the VM will be waived for groups and solo practitioners, as identified by their Taxpayer Identification Number (TIN), if at least one EP who billed for Medicare PFS items and services under the TIN during 2016 participated in the Pioneer ACO Model, the Comprehensive Primary Care initiative, Next Generation ACO Model, the Oncology Care Model, or the Comprehensive ESRD Care Initiative in 2016 (80 FR 71286 through 71288).

In the CY 2016 PFS final rule with comment period (80 FR 71280), we adopted a two-category approach for the CY 2018 VM based on participation in the PQRS by groups and solo practitioners. For the purposes of the CY 2018 VM, Category 1 represents groups and solo practitioners subject to the VM who met the criteria to avoid the CY 2018 PQRS payment adjustment (a) as a group practice participating in the PQRS GPRO, (b) groups that had at least 50 percent of the group's EPs meet the criteria to avoid the CY 2018 PQRS payment adjustment as individuals, (c) solo practitioners that met the criteria to avoid the CY 2018 PQRS payment adjustment as individuals, and (d) groups and solo practitioners that participated in a Shared Savings Program ACO, if the ACO in which they participated successfully reported quality data as required by the Shared Savings Program. Category 2 represents those groups and solo practitioners that are subject to the CY 2018 VM payment adjustment and do not fall within Category 1.

In section III.I. of this final rule, we are finalizing the proposed policy to reduce the CY 2018 VM payment adjustment amount for groups and solo practitioners in Category 2. We are finalizing that the automatic payment adjustment would be reduced from -4.0 percent to -2.0 percent for physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs and at least one physician and from -2.0 percent to -1.0 percent for physicians, PAs, NPs, CNSs, and CRNAs in groups with 2 to 9 EPs; PAs, NPs, CNSs, and CRNAs in groups comprised solely of nonphysician EPs; and physicians, PAs, NPs, CNSs, and CRNAs who are solo practitioners.

Additionally, in section III.I. in this final rule, we are finalizing the proposed policy that, under quality-tiering, which is the methodology for evaluating performance on quality and cost measures for the VM, there will be no downward adjustments for groups or solo practitioners in Category 1 for the VM for CY 2018. We are also finalizing the proposed policy to reduce the maximum upward adjustment under the quality-tiering methodology in CY 2018 for physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs and at least one physician that are

Category 1 from four times an adjustment factor (+4.0x) to two times an adjustment factor (+2.0x) for those classified as high quality/low cost and from two times an adjustment factor (+2.0x) to one times an adjustment factor (+1.0x) for those classified as either average quality/low cost or high quality/average cost. This final policy aligns the upward adjustment for groups of 10 or more EPs with those previously finalized for smaller groups and solo practitioners, as well as groups comprised solely of non-physician EPs and provides a smoother transition to MIPS.

As in previous years of the program, under the quality-tiering methodology, each group and solo practitioner's quality and cost composites will continue to be classified into high, average, and low categories depending upon whether the composites are at least one standard deviation above or below the mean and statistically different from the mean. We will compare their quality of care composite classification with the cost composite classification to determine their VM adjustment for the CY 2018 payment adjustment period according to the amounts in Table 54.

TABLE 54—CY 2018 VM AMOUNTS UNDER THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PAS, NPS, CNSS, AND CRNAS WHO ARE IN GROUPS OR SOLO PRACTITIONERS

Cost/quality	Low quality	Average quality	High quality
Low cost	+0.0%	*+1.0x	*+2.0x
Average cost	+0.0%	+0.0%	*+1.0x
High cost	+0.0%	+0.0%	+0.0%

*Groups and solo practitioners eligible for an additional +1.0x if reporting measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

Under the quality-tiering methodology, for groups and solo practitioners that participated in a Shared Savings ACO that successfully reports quality data for CY 2016, the cost composite will be classified as ''Average'' and the quality of care composite will continue to be based on ACO-level quality measures. We will compare their quality of care composite classification with the ''Average'' cost composite classification to determine their VM adjustment for the CY 2018 payment adjustment period. For groups and solo practitioners that participate in a Shared Savings Program ACO that did not successfully report quality data for CY 2016 and are Category 1 as a result of quality data reported to the PQRS outside of the ACO, the quality and cost composites will continue to be classified as ''Average''.

To achieve budget neutrality, we first aggregate the automatic downward payment adjustments of −1.0 percent or −2.0 percent for groups and solo practitioners subject to the VM that fall within Category 2. Using the aggregate downward payment adjustment amount, we then calculate the upward payment adjustment factor (x). Additionally, as we have done when calculating the upward payment adjustment factor for the 2017 VM, we will also incorporate adjustments made for estimated changes in physician behavior, including anticipated changes in the volume and/or intensity of services delivered and shifting of services to TINs that receive higher VM adjustments, and estimated impact of pending PQRS and VM informal reviews. These calculations will be done after the performance period has ended and announced around the start of the payment adjustment year after the informal review period ends.

On September 18, 2017, we made the 2016 Annual QRURs available to all groups and solo practitioners based on their performance in CY 2016. We also completed a preliminary analysis (based on results included in the 2016 Annual QRURs and prior to accounting for the informal review process) of the impact of the VM in CY 2018 on physicians, PAs, NPs, CNSs, and CRNAs in groups with 2 or more EPs and physicians, PAs, NPs, CNSs, and CRNAs who are solo practitioners based on their performance in CY 2016. A summary of the results for groups and solo practitioners subject to the 2018 VM is presented below.

There are 180,621 groups and solo practitioners (as identified by their TIN) consisting of 1,121,857 physicians, PAs, NPs, CNSs, and CRNAs whose payments under the Medicare PFS will be subject to the VM in the CY 2018 payment adjustment period. These counts include both TINs that participated in a Shared Savings Program ACO in CY 2016 and TINs that did not. Of all the physicians, PAs, NPs, CNSs, and CRNAs subject to the CY 2018 VM, approximately 75 percent (838,376) are in TINs that met the criteria for inclusion in Category 1 and are subject to the quality-tiering methodology in order to calculate their CY 2018 VM; and approximately 25 percent (283,481) are in TINs that are Category 2.

Physicians, PAs, NPs, CNSs, and CRNAs in Category 2 TINs with between 1 to 9 EPs and at least one physician and PAs, NPs, CNSs, and CRNAs in Category 2 TINs comprised solely of non-physician EPs will be subject to an automatic −1.0 percent payment adjustment, while physicians, PAs, NPs, CNSs, and CRNAs in Category 2 TINs with 10 or more EPs and at least one physician will be subject to an automatic −2.0 percent payment adjustment under the VM during the CY 2018 payment adjustment period for failing to meet the criteria to avoid the CY 2018 PQRS payment adjustment. The number of physicians, PAs, NPs, CNSs, and CRNAs receiving an automatic downward payment adjustment because their TIN failed to meet the criteria to avoid the PQRS adjustment declined by 8 percentage points to 25 percent for the 2018 VM (based on 2016 performance), down from 33 percent for the 2017 VM, despite the expansion of the VM from all physicians to all physicians and NPs, PAs, CNSs, and CRNAs in the 2018 payment year. We believe it is likely that many TINs that failed to meet the criteria to avoid the PQRS adjustment and as a result are in Category 2 and are subject to automatic downward payment adjustments under the CY 2018 VM will be excluded from MIPS in CY 2019, due to the low-volume threshold. Furthermore, the lower percent of clinicians who do not meet the criteria to avoid the PQRS adjustment, coupled with lower downward adjustments and upward adjustments based on performance will likely result in payment adjustments that are more in line with MIPS level adjustments.

For physicians, PAs, NPs, CNSs, and CRNAs (838,376) that are in Category 1 TINs (77,337) in CY 2018, Table 55 shows their distribution into the various

quality and cost tiers. The results show that 3,121 TINs consisting of 19,862 physicians, PAs, NPs, CNSs, and CRNAs will receive an upward payment adjustment; and 74,216 TINs consisting of 818,514 physicians, PAs, NPs, CNSs, and CRNAs will receive a neutral payment adjustment under the VM in CY 2018. Out of those receiving a neutral payment adjustment in CY 2018, 7,387 TINs consisting of 88,706 physicians, PAs, NPs, CNSs, and CRNAs were held harmless from downward adjustments.

TABLE 55—PRELIMINARY DISTRIBUTION OF CATEGORY 1 TINS (AND PHYSICIANS, PAS, NPS, CNSS, AND CRNAS IN THE TINS) UNDER THE CY 2018 VM

[77,337 TINs; 838,376 physicians, PAs, NPs, CNSs, and CRNAs]

Cost/quality	Low quality	Average quality	High quality
Low Cost	+0.0% (18 TINs; 2,522 clinicians)	+1.0x (57 TINs; 1,017 clinicians) +2.0x* (68 TINs; 4,245 clinicians)	+2.0x (5 TINs; 218 clinicians). +3.0x* (11 TINs; 51 clinicians).
Average Cost	+0.0% (5,721 TINs; 61,628 clinicians)	+0.0% (66,780 TINs; 727,032 clinicians).	+1.0x (2,158 TINs; 10,132 clinicians). +2.0x* (822 TINs; 4,199 clinicians).
High Cost	+0.0% (499 TINs; 7,689 clinicians)	+0.0% (1,167 TINs; 19,389 clinicians)	+0.0% (31 TINs; 254 clinicians).

*These TINs were eligible for an additional +1.0x for reporting measures and having an average beneficiary risk score in the top 25 percent of all beneficiary risk scores.

The term 'clinicians' refers to the physicians, PAs, NPs, CNSs, and CRNAs in the TINs.

The numbers presented above are preliminary numbers and may be subject to change as a result of the informal review process. In early 2018, after the conclusion of the informal review period, we will release updates to the number of TINs receiving upward, neutral, and downward adjustments, along with the adjustment factor for the CY 2018 VM on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/2016-QRUR.html*. Preliminary estimates indicated that the implementation of the finalized policies discussed above would reduce the adjustment factor to below 10 percent.

9. MACRA Patient Relationship Categories and Codes

We proposed that Medicare claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018, should voluntarily include any of these five HCPCS modifiers: X1 (Continuous/broad services), X2 (Continuous/focused services) X3 (Episodic/broad services, X4 (Episodic/focused services) and X5 (Only as ordered by another physician). In addition to the modifiers, Medicare claims should include the NPI of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner). Our plan is not to tie the collection of the codes with payment until we are sure clinicians have gained ample experience and education in using these modifiers. Therefore, there is no impact to CY 2018 physician payments under the PFS. There may be a burden associated with clinicians and their administrative staff having to learn which codes to use and how to submit them properly.

a. Collection of Information Burden Cost Estimate

CMS will provide a voluntary 25-minute training/instruction manual and a one-time 60-minute (1 hour) webinar for practice manager or billing/coding staff who seek further knowledge to be able to report these new HCPCS modifiers correctly. Although there are a total of five HCPCS modifiers, we expect one out of the five usually will be reported.

For a practice manager or billing/coding staff who may voluntarily study the whole 25 minutes training document, we estimate a one-time total cost burden of training of $150.00 × 0.25hrs = $37.50 for the reading of the coding manual, and a burden of $150.00 × 1hr = $150.00 for participating in the webinar (or later watching the recorded webinar videos), totaling an overall burden of training of $150.00 + $37.50 = $187.50. The practice manager or billing/coding staff who may decide to study only one HCPCS modifier or only the whole training manual or participate in just the webinar may experience a lesser burden than the estimate provided above, resulting in a lower information burden cost.

10. Effects of Proposals Relating to the Medicare Diabetes Prevention Program Expanded Model

In section III.K of the preamble of this final rule, we discuss our proposals to further implement the MDPP expanded model under the authority of section 1115A of the Act, which authorizes the Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid and CHIP beneficiaries. The MDPP expanded model was established in the November 15, 2016 MDPP final rule (81 CFR 80459 through 80483) as an additional preventive service with a model effective date of January 1, 2018. Many of the policies for the MDPP expanded model were deferred to future rulemaking and, therefore, are being finalized in this rule. 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). This regulatory impact assessment is not an updated certification; rather, it is based on estimates of this final rule and provides a revised 10-year savings estimate of $182 million which differs slightly from the 10-year savings estimate of $186 million included in the proposed rule. The $4 million reduction in savings can be explained by two factors. First, CMS is finalizing more payment for the MDPP services based on beneficiary attendance and weight loss. Thus, this increases projected costs and reduces projected savings. Second, we are finalizing a MDPP service period of 2 years. A shortened period of maintenance sessions available slightly reduces long term program effectiveness while also reducing potential savings. However, reducing the program length from 3 years to 2 years cuts the total possible payment for each participant from $810 to $670 which offsets most of the costs of higher performance payments and reduced effectiveness.

Diabetes affects more than 25 percent of Americans aged 65 or older and its prevalence is projected to increase approximately two-fold for all U.S. adults (ages 18–79) by 2050 if current trends continue.[51] Furthermore, the risk

[51] Centers for Medicare & Medicaid Services, ''Chronic Conditions Among Medicare Beneficiaries, Chartbook: 2012 Edition,'' *Centers for*

of progression to type 2 diabetes in an individual with prediabetes is 5–10 percent per year, or 5–20 times higher than in individuals with normal blood glucose.[52] We estimate that Medicare spent $42 billion more in the single year of 2016 on fee-for-service, non-dual eligible, over age 65 beneficiaries with diabetes and related comorbidities than it would have spent if those beneficiaries did not have diabetes, including $20 billion more for Part A, $17 billion more for Part B, and $5 billion more for Part D.[53] The goal of the MDPP expanded model is to reduce the incidence rate of type 2 diabetes among Medicare beneficiaries with prediabetes through a structured behavioral change program where the primary outcome is weight loss. Weight loss is a key indicator of success among persons enrolled in a Diabetes Prevention Program due to the strong association between weight loss and reduction in the risk of type 2 diabetes. In reducing the incidence rate of type 2 diabetes we expect to reduce Medicare spending while improving quality of care for eligible beneficiaries. In this final rule, we finalized a value-based payment structure for the MDPP expanded model. Instead of traditional fee-for-service payment, our payment structure shifts risk from Medicare to the rendering supplier by making payments for MDPP services to MDPP suppliers based on the achievement of performance goals.

a. Anticipated Effects

(1) Effects on Beneficiaries

The MDPP expanded model is expected to have a positive impact on beneficiaries' health that will generally lead to reduced beneficiary spending on Part A, Part B, and Part D health care services over time due to a reduced need for Part A, Part B, and Part D services. This regulatory impact analysis does not include anticipated savings from Medicare Part D. As a new preventive service, the MDPP services are available to eligible Medicare beneficiaries without cost-sharing. The CDC estimates that approximately 50 percent of adults aged 65 and over living in the United States have prediabetes and that awareness of the condition among those who have it is relatively low—approximately 15 percent for the general population.[54] Therefore, we anticipate that up to 3 million Medicare beneficiaries who are aware of their prediabetes would be eligible for the MDPP services at the start of the MDPP expanded model. This estimate does not take into account any increased beneficiary awareness of their prediabetes due to the availability of MDPP services. We also expect there to be pent-up demand, with the number of beneficiaries utilizing the MDPP services greater in the initial few years (roughly 65,000 to 110,000 per year) but then leveling off afterwards (to a base demand of roughly 50,000 participants per year).

To arrive at our participation estimate we developed projections for pent-up demand and ongoing demand. To develop the projection for pent-up demand we first analyzed data from the CDC National Diabetes Prevention Recognition Program (DPRP). Specifically, we analyzed State-by-State DPRP in-person utilization for ages 65 or older in 2015. Because the Health Care Innovation Award (HCIA) DPP model test was still serving beneficiaries during this period, and the HCIA DPP organizations are also part of the DPRP, we used its enrollment data to inform what Medicare beneficiary participation may look like when Medicare pays for MDPP services. Given that HCIA participation seemed to drive most of the DPRP participation in an HCIA awardee's region, we determined that a well-defined HCIA region would be a reasonable proxy for the rest of the nation. We found the state with the highest HCIA saturation, and calculated the percentage of fee for service beneficiaries that received services from a DPRP DPP. This percentage was applied to all fee for service beneficiaries nationwide in order to get a national pent-up demand estimate. We added this pent-up demand to a stable level of demand based on the number of new beneficiaries utilizing the obesity management benefit each year. Given the limited nationwide Medicare DPP participation data, there is a great amount of uncertainty in these estimates.

We believe that the eligibility criteria for continued participation in the set of MDPP services incentivizes beneficiaries to lose 5-percent body weight from baseline. Beneficiaries are incentivized to lose weight because continued eligibility for the services after the first 12 months is contingent upon achieving 5-percent weight loss and the set of MDPP services is a once per lifetime set of services. In addition to prevention of type 2 diabetes, we believe participating beneficiaries would likely receive other possible health benefits including prevention of obesity for those who are overweight upon receiving MDPP services, prevention of sleep apnea, and reduced risk for heart disease, coronary artery disease and stroke.[55] Furthermore, we believe the MDPP expanded model could improve mental health and wellbeing by affording beneficiaries social interaction with their peers during sessions and could lead to reduced social isolation. [56] The

Medicare & Medicaid Services, 2012, *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/chronic-conditions/downloads/2012chartbook.pdf.* James Boyle, et al., ''Projection of the Year 2050 Burden of Diabetes in the US Adult Population: Dynamic Modeling of Incidence, Mortality, and Pre- Diabetes Prevalence,'' *Population Health Metrics* 8, no. 29 (2010): 1–12.

[52] X Zhang et al., ''A1C Level and Future Risk of Diabetes: A Systematic Review,'' *Diabetes Care* 33, no. 7 (2010): 1665–1673.

[53] Erkan Erdem and Holly Korda, ''Medicare Fee-For-Service Spending for Diabetes: Examining Aging and Comorbidities,'' *Diabetes & Metabolism* 5, no. 3 (2014); The Boards of Trustees: Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, ''2016 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds,'' *Centers for Medicare & Medicaid Services,* 2016, *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFu2016.pdf.*; and CMS estimates.

[54] *https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.*

[55] Orchard, T.J., et al. (2005). ''The effect of metformin and intensive lifestyle intervention on the metabolic syndrome: the Diabetes Prevention Program randomized trial.'' *Ann Intern Med* 142(8): 611–619; Orchard, T.J., et al. (2013). ''Long-term effects of the Diabetes Prevention Program interventions on cardiovascular risk factors: a report from the DPP Outcomes Study.'' Diabet Med 30(1): 46–55; Li, G., et al. (2014). ''Cardiovascular mortality, all-cause mortality, and diabetes incidence after lifestyle intervention for people with impaired glucose tolerance in the Da Qing Diabetes Prevention Study: a 23-year follow-up study.'' Lancet Diabetes Endocrinol 2(6): 474–480; Mudaliar, U., et al. (2016). ''Cardiometabolic Risk Factor Changes Observed in Diabetes Prevention Programs in US Settings: A Systematic Review and Meta-analysis.'' PLoS Med 13(7): e1002095; Kuna, S.T., et al. (2013). ''Long-term effect of weight loss on obstructive sleep apnea severity in obese patients with type 2 diabetes.'' Sleep 36(5): 641–649a; Mitchell, L. J., et al. (2014). ''Weight loss from lifestyle interventions and severity of sleep apnoea: a systematic review and meta-analysis.'' Sleep Med 15(10): 1173–1183; Thomasouli, M.A., et al. (2013). ''The impact of diet and lifestyle management strategies for obstructive sleep apnoea in adults: a systematic review and meta-analysis of randomised controlled trials.'' Sleep Breath 17(3): 925–935; U.S. Department of Health and Human Services. *2008 Physical Activity Guidelines for Americans.* Washington (DC): U.S. Department of Health and Human Services; 2008. ODPHP Publication No. U0036. Available at: *http://www.health.gov/paguidelines;* U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015—2020 Dietary Guidelines for Americans.* 8th Edition. December 2015. Available at *http://health.gov/dietaryguidelines/2015/guidelines/.*

[56] Florez, H., et al. (2012). ''Impact of lifestyle intervention and metformin on health-related quality of life: the diabetes prevention program randomized trial.'' J Gen Intern Med 27(12): 1594–1601; Ackermann, R. T., et al. (2009). ''Changes in health state utilities with changes in body mass in the Diabetes Prevention Program.'' Obesity (Silver Spring) 17(12): 2176–2181; Weinhold, K. R., et al.

Continued

prevention of type 2 diabetes and these other potential health benefits of MDPP services may result in reduced beneficiary expenditures for health care services over time as services will not be needed to treat health conditions that are avoided.

(2) Effects on the Market

Currently, more than 1,400 organizations nationally are providing DPP services with some level of recognition through the CDC. Service delivery is primarily to individuals with private or employer-sponsored insurance, as well as some Medicare Advantage plans. The majority of existing DPP organizations are not participating in the Medicare program. We anticipate that the addition of MDPP services as new preventive services in Medicare would result in growth in the market, including growth in the number of individuals served per year by existing DPP suppliers, as well as the introduction of new suppliers into the market. There are burdens associated with obtaining CDC recognition and enrolling into Medicare as an MDPP supplier. There is also burden associated with submitting claims to Medicare for payment. Below we have provided an estimate of the financial burden to suppliers.

(3) Burden Related to Information Collection Requirements

(a) Wage Estimates

To derive average costs for use throughout the subsequent sections, we used data from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/current/oes_nat.htm*). Table 56 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 56—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Medical records and health information technician	29–2071	19.93	19.93	39.84
Office and administrative support worker	43–9000	16.31	16.31	32.62
Billing and posting Clerk	43–3011	18.09	18.09	36.18

(b) Interim Preliminary Recognition

Our regulations at § 424.205 provide that an entity is eligible to enroll in Medicare as an MDPP supplier if it has MDPP interim preliminary recognition, as determined by CMS. In order to receive MDPP interim preliminary recognition, we finalized that the entity must have pending CDC recognition and must submit a full 12 months of data on at least one completed cohort of participants to CDC (among other criteria). In order to receive pending recognition from CDC, organizations are required to submit an application for recognition to CDC and agree to CDC's curriculum, duration and intensity requirements. CMMI plans to engage CDC's services to assist CMMI in administering its interim preliminary recognition standard. CMMI would make the final determination of which entities qualify to receive interim preliminary recognition.

The burden associated with the preceding requirements is the time for MDPP supplier staff to: Submit an application for pending recognition to CDC and then collect and submit a full 12 months of data (including session attendance, body weight documentation, physical activity minutes documentation, and weight loss achieved) on at least one completed cohort of participants to CDC for the purposes of being evaluated for interim preliminary recognition.

We estimate that it will take a medical records and health information technician 12 hours, at $39.84/hour to collect and report these data for one cohort of participants, and an office or administrative worker 1 hour, at $32.62/hour, to complete the CDC application for pending recognition. The estimated cost per supplier to achieve interim preliminary recognition is $510.70.

(c) Supplier Standards

Our regulations at § 424.205 and § 424.59 will require that an MDPP supplier certify in its enrollment application that it meets a set of standards. This application will be designated as CMS–20134. As this new enrollment application is being created specifically for the MDPP expanded model, we have determined that it is exempt from the Paperwork Reduction Act in accordance with section 1115A(d)(3) of the Act. We estimate that it will take an office or administrative support worker 3 hours, at $32.62/hour, to complete the MDPP supplier enrollment application using the internet-based Provider Enrollment, Chain and Ownership System (PECOS). The provider/supplier enrollment fee for CY 2017 is $560. We note that in accordance with § 424.514 MDPP suppliers may submit a written request to CMS for a hardship exception to the application fee. CMS determines such exceptions on a case-by-case basis. The estimated cost to complete the MDPP supplier enrollment application, without a hardship exception, is $654.62. If a provider is granted a hardship exception from the enrollment fee, then the estimated cost to complete the enrollment process is $94.62.

We also note that access to the HIPAA Eligibility Transaction System (HETS), which a supplier could use to check factors of eligibility for the MDPP services, including the beneficiary's Part B eligibility and whether the beneficiary is eligible for Medicare based on end-stage renal disease (as described in § 406.13), is free to suppliers, as long as they are active Medicare fee-for-service providers or suppliers in PECOS.

Suppliers also will be required to maintain documentation of all beneficiary contact regarding complaints or questions, as specified in § 424.205(d)(11), and maintain and submit to CMS a crosswalk file that indicates how participant identifications for the purposes of CDC performance data correspond to beneficiary identifiers (Medicare Beneficiary Identifiers or beneficiary health insurance claims numbers) for each beneficiary receiving MDPP services. We estimate that creating and maintaining documentation of beneficiary contact regarding complaints or questions will take an

(2015). ''A Randomized Controlled Trial Translating the Diabetes Prevention Program to a University Worksite, Ohio, 2012–2014.'' Preventing Chronic Disease 12: E210.

office or administrative support worker 1 hour, at $32.62/hour, per complaint or question request to create and maintain documentation of the request. We have no way to estimate how many complaints or questions MDPP suppliers will receive from beneficiaries, and we expect that may differ based on many factors, so we have not included an overall cost in this burden estimate. Further, we estimate that it will take an office and administrative support worker approximately 4 hours, at $32.62/hour, to create and submit the crosswalk file for a cohort of 100 beneficiaries participating in the MDPP services, for a total cost of $130.48 per cohort of 100 beneficiaries. The crosswalk is to be submitted quarterly. Therefore, for a year of delivering the set of MDPP services the estimated total cost to create and submit the crosswalk file would be $521.92 per cohort of 100 beneficiaries. We believe the incremental costs to meet this requirement would decrease with the addition of beneficiaries to a cohort, because the work and time to establish the file and submit it would be the same for a cohort of 100 and a cohort of 1,000. What would be different is the collection of the information from the beneficiaries, and the addition of these data points to the file. We estimate that, for every additional 100 beneficiaries added to the file, the office and administrative support worker would add 1 hour, at $32.62/hour. We estimate the total incremental cost over 1 year for each additional 100 beneficiaries above the cohort of 100 beneficiaries is $130.48.

Our regulations at § 424.205 also will require that suppliers meet a set of standards that includes maintaining a physical facility on an appropriate site and maintaining a primary business telephone that is operating at the appropriate site. Because we have no way to estimate how many beneficiaries each MDPP supplier may provide the set of MDPP services to, and we expect this will differ based on many factors, including but not limited to the size of the supplier, the number of coaches the supplier employs, the physical space the supplier uses to furnish MDPP services, and the supplier's geographic location, we have not included an overall cost for these requirements in this burden estimate.

(d) Payment for MDPP Services

Our regulations at § 414.84 specify the payments MDPP suppliers may be eligible to receive for furnishing MDPP services and meeting performance targets related to beneficiary weight loss and/or attendance. MDPP suppliers would be paid by CMS by submitting claims for MDPP beneficiaries using claim form CMS–1500 (*https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf*), and as a condition for payment, claims submitted by MDPP suppliers must be for services furnished to eligible beneficiaries in accordance with § 414.84(b) and (c). Our regulations at § 424.205 will require MDPP suppliers to include an attestation that the MDPP beneficiary for which it is submitting a claim has met the performance goals. Section § 424.205 also requires MDPP suppliers to report the NPI of the coach on MDPP claims as a program integrity safeguard. To meet these requirements for submitting claims, we estimate that it would take a billing and posting clerk 10 minutes per beneficiary to fill out the claim form and submit it to CMS at $36.18/hour. Based on this time and wage, we estimate the total cost per beneficiary per claim to be $6.03. As mentioned previously, we have no way to estimate how many beneficiaries to whom each MDPP supplier may furnish MDPP services. Therefore, we have not included an estimate of the overall cost of submitting claims in the burden estimate.

(4) Effects on the Medicare Program

(a) Estimated 10-Year Impact of MDPP

The set of MDPP services is an optional set of services for beneficiaries who meet the eligibility requirements described elsewhere in the final rule. MDPP services will be furnished by a new supplier type in Medicare. The CDC recognizes DPPs nationwide; these programs effectively deliver lifestyle-changing services that reduce the incidence of type 2 diabetes. The number of CDC-recognized DPPs is growing rapidly, increasing by nearly 90 percent from September 2015 to March 2017. The historical participation rate suggests that the vast majority of these organizations are not serving a significant volume of new participants, aside from those served in the DPP model test.

This estimate is based on the initial methodology used for the estimate of the MDPP expanded model as set out in the certification memorandum, but with differences in several program features including the payment parameters. It also includes the impact of improved longevity among those who participate in the MDPP expanded model. This cost of improved longevity was ignored for certification purposes, as noted in that memorandum.

The model is dependent on the number of eligible participants, the annual take-up rate, and the savings per participant, all of which are uncertain. The methodology determines gross savings as the result of an assumed reduction in the number of beneficiaries transitioning from prediabetes to diabetes and a marginal cost difference between the individuals with diabetes and those that are prediabetic. The Office of the Actuary assumed that the initial savings per beneficiary for avoiding diabetes is $3,000 per year. The progression rate from prediabetes to diabetes absent the intervention is expected to be roughly 5 percent per year. Based on observed results, we assume that the set of MDPP services will reduce the progression rate among those receiving the services by 50 percent in the first year and that the reduction will be 5 percent less in each subsequent year until leveling off at a rate of 5 percent. Due to a cessation of payments for participating beneficiaries after 2 years, there is an additional reduction of 5 percent in the third year. The program costs in this estimate include payments to MDPP suppliers in the initial year of the MDPP services period and in the maintenance year. Overall, the payments under the expanded model would occur for a maximum of 2 years, but the expected reduction in medical costs would occur over a long period following the intervention. For the leading cohort of 2018, we would expect savings in excess of costs by 2019 (the second year), with cumulative savings by 2021 (after 3 years). Yearly net savings reduce slightly each subsequent year but do not result in a cost to Medicare during the 10-year projection window.

Table 57 shows the 10-year impact of the MDPP expanded model, net of payments to MDPP providers but gross of any other model costs, based on our expected enrollment per year. The 10-year impact is a savings to Medicare of $182 million. The estimate is expected to cross into a cumulative savings to Medicare in the sixth year of the MDPP expanded model.

TABLE 57—ESTIMATED 10-YEAR IMPACT OF MDPP ON NET CLAIMS COSTS, PAYMENTS TO PROVIDERS, AND NET SAVINGS FOR CYS 2018 THROUGH 2027

[In millions, negative values indicate savings]

Year	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Total
Net Claim Costs	−$5	−$16	−$29	−$40	−$51	−$59	−$65	−$69	−$70	−$70	−$472
Provider Payments	23	45	39	26	24	25	26	26	27	28	290
Annual Net Savings	19	30	10	−14	−27	−34	−39	−42	−43	−42	−182
Cumulative Net Savings	19	48	59	44	18	−16	−55	−97	−14	−182	

(b) Sensitivity Testing

MDPP is a new Medicare expanded model that was tested in the HCIA DPP model using a small percentage of the population. As a result, the estimated impact from the expanded MDPP model is very uncertain. In particular, it is unknown how many beneficiaries will be interested in participating in MDPP and how quickly MDPP suppliers available will be able to serve those individuals. To understand how various participation scenarios would affect the financial results, we have prepared the estimates under two other participation scenarios. The first shows the results if half of the beneficiaries shown in the best estimate participate, and the second uses twice as many beneficiaries. The details are shown in Tables 58 and 59.

TABLE 58—SCENARIO TEST OF MDPP 10-YEAR IMPACT OF HALF THE EXPECTED PARTICIPANTS ON NET CLAIMS COSTS, PAYMENTS TO PROVIDERS, AND NET SAVINGS FOR CYS 2018 THROUGH 2027

Year	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Total
Net Claim Costs	−$2	−$8	−$14	−$20	−$25	−$29	−$32	−$34	−$35	−$35	−$236
Provider Payments	12	23	19	13	12	12	13	13	14	14	145
Annual Net Savings	9	15	5	−7	−13	−17	−20	−21	−21	−21	−91

TABLE 59—SCENARIO TEST OF MDPP 10-YEAR IMPACT OF DOUBLE THE EXPECTED PARTICIPANTS ON NET CLAIMS COSTS, PAYMENTS TO PROVIDERS, AND NET SAVINGS FOR CYS 2018 THROUGH 2027

Year	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Total
Net Claim Costs	−$9	−$31	−$58	−$81	−$101	−$117	−$129	−$137	−$140	−$139	−$944
Provider Payments	46	91	78	52	48	50	51	53	55	56	580
Annual Net Savings	37	59	20	−29	−53	−68	−78	−84	−86	−83	−364

In conclusion, we estimate that the 10-year impact of the MDPP expanded model, net of payments to MDPP providers but gross of any other program costs, based on our expected enrollment per year would be a savings to Medicare of $182 million. The estimate is expected to cross into a cumulative savings to Medicare in the sixth year of the MDPP expanded model.

Comment: MedPAC commented that OACT certified the DPP for expansion into the FFS program based on the payment schedule CMS initially proposed—with a maximum amount per beneficiary of $630. CMS has not provided detail regarding whether the newly proposed payment amount and schedule would still meet the Actuary's certification.

Response: OACT has certified that the MDPP expanded model, as implemented in this final rule is expected to reduce (or not increase) net program spending. The memo may be accessed at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Recertification-2017-11-01.pdf.*

Comment: One commenter suggested that CMS underestimated pent-up demand for the DPP service stating that even the highest saturation Health Care Innovation Award (HCIA) is likely a low-end estimate of pent-up demand, connected to inadequate funding during the award period.

Response: We acknowledge that there is some uncertainty with our beneficiary participation estimates given that this is a new preventive service being furnished by a new type of Medicare supplier. We derived our participation estimates using data from the HCIA model test because that is the best data available to inform our estimates. We provide sensitivity analysis that examines the impact of a higher-than-expected rate of utilization.

Comment: One commenter stated that while the burden estimates may be accurate for clinical practices with existing infrastructure, they underestimate the start-up (for example, recognition) and ongoing (for example, record-keeping) costs for new community-based suppliers without existing infrastructure and staff training. The commenter suggested that CMS create a mechanism for verifying differentials in overhead and staffing costs for clinical and community-based suppliers. Another commenter stated that the proposed rule seemed to account for all of the start-up costs with the exception of delivering the program itself. A third commenter similarly noted that the burden estimates did not include the total cost of delivering the MDPP services.

Response: We were only able to include burden estimates that were not expected to vary widely between suppliers, for example the cost of enrolling as a Medicare supplier. We did not include burden estimates for hiring and training coaches or other start-up costs because there will be great variability between suppliers for these costs. There is great variability for a number of reasons including but not limited to the size of the supplier, the number of coaches the supplier employs, the physical space the supplier uses to furnish MDPP services,

the supplier's geographic location, and the number of beneficiaries they will serve. In addition there are no restrictions in terms of labor categories/educational background for coaches. Coaches can be anything from health care professionals to trained lay persons. For these reasons we cannot provide burden estimates in these areas.

We acknowledge that costs will be higher for suppliers that are new to delivering DPP as costs would be higher for starting up any new business. In addition, our performance-based payment structure does not incorporate start-up costs as such costs are typically considered the cost of doing business.

F. Alternatives Considered

This final rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our final policies and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this final rule, we presented the estimated impact on total allowed charges by specialty. The alternatives we considered, as discussed in the preceding preamble sections, would result in different payment rates, and therefore, result in different estimates than those shown in Table 49 (CY 2018 PFS Estimated Impact on Total Allowed Charges by Specialty).

G. Impact on Beneficiaries

There are a number of changes in this final rule that would have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through regular updates to the inputs used to calculate payments under the PFS, would have a positive impact and improve the quality and value of care provided to Medicare beneficiaries.

For example, in finalizing our policies to provide separate payment for codes describing the insertion and removal of drug implants to treat opioid addiction, as well as a code describing remote patient monitoring, we are improving Medicare beneficiary access to these important services. This rule also finalizes policies necessary for the implementation of the Medicare Diabetes Prevention Program expanded model which is expected to improve the quality of patient care for Medicare beneficiaries and make MDPP services available to beneficiaries in addition to existing Medicare services. MDPP services are designated under the MDPP expanded model to be covered as additional preventive services under Medicare, as defined in section 1861(ddd) of the Act, and therefore not subject to cost-sharing. These new covered services for beneficiaries under the MDPP expanded model will have a positive impact on the health of beneficiaries because they are expected to be effective in preventing diabetes onset through attendance of MDPP sessions and weight loss. More details can be found in section III.K of this final rule, and the CY 2017 PFS (81 CFR 80170 through 80562). These and all other improvements to payment accuracy that we are finalizing for CY 2018 are described in greater detail in this final rule.

Most of the aforementioned proposed policy changes could result in a change in beneficiary liability as relates to coinsurance (which is 20 percent of the fee schedule amount, if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in our public use file Impact on Payment for Selected Procedures available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/,* the CY 2017 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) was $109.46, which means that in CY 2017, a beneficiary would be responsible for 20 percent of this amount, or $21.89. Based on this final rule, using the CY 2018 CF, the CY 2018 national payment amount in the nonfacility setting for CPT code 99203, as shown in the Impact on Payment for Selected Procedures table, is $109.80, which means that, in CY 2018, the final beneficiary coinsurance for this service would be $21.96.

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 assume that the total number of unique commenters on last year's rule will be the number of reviewers of this rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcomed any comments on the approach in estimating the number of entities which will review this rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $105.16 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately 8.0 hours for the staff to review half of this rule. For each facility that reviews the rule, the estimated cost is $841 (8.0 hours × $105.16). Therefore, we estimated that the total cost of reviewing this regulation is $2,169,780 ($841 × 2,580 reviewers).

I. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Tables 60 and 61 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2017 to CY 2018 based on the FY 2018 President's Budget baseline.

TABLE 60—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2018 Annualized Monetized Transfers	Estimated increase in expenditures of $0.3 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 61—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfer
CY 2018 Annualized Monetized Transfers of beneficiary cost coinsurance.	$0.1 billion.
From Whom to Whom?	Beneficiaries to Federal Government.

TABLE 62—ESTIMATED COSTS, COST SAVINGS AND BENEFITS

Category	Costs	Cost savings or benefits
ICR Burden	$296 million.	
MDPP		$182 million.
Regulatory Familiarization	* $2 million.	

* Regulatory familiarization costs occur upfront only, whereas other impacts listed in the table are expected to continue into the future.

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 a Regulatory Impact Analysis. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Biologics, Drugs, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 2. Section 405.2413 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, and the Psychiatric Collaborative Care Model 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.

* * * * *

■ 3. Section 405.2415 is amended by revising paragraph (a)(5) to read as follows:

§ 405.2415 Incident to services and direct supervision.

(a) * * *

(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, and the Psychiatric Collaborative Care model 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.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 4. The authority citation for part 410 is revised to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd).

■ 5. Section 410.79 is amended by—

■ a. Revising the section heading and paragraph (a).

■ b. Under paragraph (b):

■ i. Revising the definition of ''Baseline weight'';

■ ii. Removing the definition of ''Coach'';

■ iii. Revising the definition of ''Core maintenance session'';

■ iv. Adding in alphabetical order a definition for ''Core maintenance session interval'';

■ v. Revising the definition of ''Core session'';

■ vi. Removing the definitions of ''Maintenance of weight loss''and ''Maintenance session bundle'';

■ vii. Adding in alphabetical order the definitions for ''Make-up session''and ''MDPP beneficiary'';

■ viii. Removing the definitions of ''MDPP core benefit'', and ''MDPP eligible beneficiary'';

■ ix. Revising the definition of ''MDPP services'';

■ x. Adding in alphabetical order definitions for ''MDPP services period'', and ''MDPP session'';

■ xi. Revising the definitions of ''MDPP supplier'' and ''Medicare Diabetes Prevention Program (MDPP)'';

■ xii. Adding in alphabetical order a definition for ''Ongoing maintenance session interval'';

■ xiii. Revising the definition of ''Ongoing maintenance sessions'';

■ xiv. Adding in alphabetical order definitions for ''Set of MDPP services'' and ''Virtual make-up session''; and
■ c. Revising paragraphs (c) and (d).

The revisions and additions read as follows:

§ 410.79 Medicare Diabetes Prevention Program expanded model: Conditions of coverage.

(a) Medicare Diabetes Prevention Program (MDPP) services will be available beginning on April 1, 2018.

(b) * * *

Baseline weight means the MDPP beneficiary's body weight recorded during that beneficiary's first core session.

* * * * *

Core maintenance session means an MDPP service that—

(i) Is furnished by an MDPP supplier to an MDPP beneficiary during a core maintenance session interval;

(ii) Is approximately 1 hour in length; and

(iii) Adheres to a CDC-approved DPP curriculum for maintenance sessions.

Core maintenance session interval 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.

Core session means an MDPP service that—

(i) Is furnished by an MDPP supplier to an MDPP beneficiary during months 1 through 6 of the MDPP services period;

(ii) Is approximately 1 hour in length; and

(iii) Adheres to a CDC-approved DPP curriculum for core sessions.

* * * * *

Make-up session means a core session, a core maintenance session, or an ongoing maintenance session furnished to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session, core maintenance session, or ongoing maintenance session.

MDPP beneficiary means a Medicare beneficiary who meets the criteria specified in paragraph (c)(1)(i) of this section, who has initiated the MDPP services period by attending the first core session, and for whom the MDPP services period has not ended as specified in paragraph (c)(3) of this section.

MDPP services means structured health behavior change sessions that are furnished under the MDPP expanded model with the goal of preventing diabetes among Medicare beneficiaries with prediabetes, and that follow a CDC-approved curriculum. The sessions provide practical training in long-term dietary change, increased physical activity, and problem-solving strategies for overcoming challenges to maintaining weight loss and a healthy lifestyle.

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, one or more ongoing maintenance session intervals during the ongoing services period described in paragraph (c)(2)(ii) of this section.

MDPP session means a core session, a core maintenance session, or an ongoing maintenance session.

MDPP supplier means an entity that is enrolled in Medicare to furnish MDPP services as provided in § 424.205 of this chapter.

Medicare Diabetes Prevention Program (MDPP) refers to a model test expanded under section 1115A(c) of the Act that makes MDPP services available to MDPP beneficiaries.

* * * * *

Ongoing maintenance session means an MDPP service that—

(i) Is furnished by an MDPP supplier to an MDPP beneficiary during an ongoing maintenance session interval;

(ii) Is approximately 1 hour in length; and

(iii) Adheres to a CDC-approved DPP curriculum for maintenance sessions.

Ongoing maintenance session interval means one of the up to four consecutive 3-month time periods during the ongoing services period described in paragraph (c)(2)(ii) of this section, during which an MDPP supplier offers at least one ongoing maintenance session to an MDPP beneficiary per month.

* * * * *

Set of MDPP services means the series of MDPP sessions, composed of core sessions, core maintenance sessions, and subject to paragraph (c)(3) of this section, ongoing maintenance sessions, offered over the course of the MDPP services period.

Virtual make-up session means a make-up session that is not furnished in person and that is furnished in a manner consistent with the DPRP standards for virtual sessions.

(c) Coverage for *MDPP services*—(1) *Beneficiary eligibility.* (i) A Medicare beneficiary is eligible for MDPP services offered during the core services period described in paragraph (c)(2)(i) of this section if the beneficiary meets all of the following criteria:

(A) Is enrolled under Medicare Part B;

(B) Attended the first core session within the most recent 12-month time period and, prior to attending this first core session, had not previously received the set of MDPP services in his or her lifetime;

(C) Has, on the date of attendance at the first core session, a body mass index (BMI) of at least 25 if not self-identified as Asian or a BMI of at least 23 if self-identified as Asian;

(D) Has received, within the 12-month time period prior to the date of attendance at the first core session, a hemoglobin A1c test with a value of between 5.7 and 6.4 percent, a fasting plasma glucose test with a value of between 110 and 125 mg/dL, or a 2-hour plasma glucose test (oral glucose tolerance test) with a value of between 140 and 199 mg/dL;

(E) Has, as of the date of attendance at the first core session, no previous diagnosis of diabetes, other than gestational diabetes; and

(F) Does not have end-stage renal disease (ESRD).

(ii) An MDPP beneficiary is eligible for the first ongoing maintenance session interval only if the beneficiary:

(A) Attends at least one in-person core maintenance session during the final core maintenance session interval; and

(B) Achieves or maintains the required minimum weight loss at a minimum of one in-person core maintenance session during the final core maintenance session interval.

(iii) An MDPP beneficiary is eligible for a subsequent ongoing maintenance session interval only if the beneficiary:

(A) Attends at least two ongoing maintenance sessions during the previous ongoing maintenance session interval, including at least one in-person ongoing maintenance session; and

(B) Maintains the required minimum weight loss at a minimum of one in-person ongoing maintenance session furnished during the previous ongoing maintenance session interval.

(iv) Weight measurements used to determine the achievement or maintenance of the required minimum weight loss must be taken in person by an MDPP supplier during an MDPP session.

(2) *MDPP services period.* An MDPP beneficiary's MDPP services period is composed of the following periods and intervals:

(i) The core services period, which is the first 12 months of the MDPP services period, and consists of:

(A) At least 16 core sessions offered at least one week apart during months

1 through 6 of the MDPP services period; and

(B) Two 3-month core maintenance session intervals offered during months 7 through 12 of the MDPP services period.

(ii) Subject to paragraph (c)(3) of this section, the ongoing services period, which consists of up to four 3-month ongoing maintenance session intervals offered during months 13 through 24 of the MDPP services period.

(3) *Limitations on the MDPP services period.* (i) The MDPP services period ends upon completion of the core services period described in paragraph (c)(2)(i) of this section, unless the MDPP beneficiary qualifies for the first ongoing maintenance session interval, in accordance with paragraph (c)(1)(ii) of this section.

(ii) If the MDPP beneficiary qualifies for the first ongoing maintenance session interval as described in paragraph (c)(3)(i) of this section, the MDPP services period ends upon completion of this first ongoing maintenance session interval or any subsequent ongoing maintenance session interval, unless the beneficiary meets the eligibility requirements under paragraph (c)(1)(iii) of this section.

(iii) Unless sooner ended in accordance with this paragraph (c)(3), the MDPP services period ends automatically upon the completion of the fourth ongoing maintenance session interval.

(d) *Make-up sessions.* (1) An MDPP supplier may offer a make-up session to an MDPP beneficiary who missed a regularly scheduled session. If an MDPP supplier offers one or more make-up sessions to an MDPP beneficiary, each such session must be furnished in accordance with the following requirements:

(i) The curriculum furnished during the make-up session must address the same CDC-approved DPP curriculum topic as the regularly scheduled session that the beneficiary missed;

(ii) The MDPP supplier may furnish to the beneficiary a maximum of one make-up session on the same day as a regularly scheduled session; and

(iii) The MDPP supplier may furnish to the beneficiary a maximum of one make-up session per week.

(2) An MDPP supplier may offer virtual make-up sessions only if consistent with the requirements in paragraph (d)(1) of this section. Virtual make-up sessions are also subject to the following requirements:

(i) Virtual make-up sessions must be furnished in a manner consistent with the DPRP standards for virtual sessions;

(ii) An MDPP supplier may only offer virtual make-up sessions based on an individual MDPP beneficiary's request; and

(iii) An MDPP supplier may offer to an MDPP beneficiary:

(A) No more than 4 virtual make-up sessions within the core services period described in paragraph (c)(2)(i) of this section, of which no more than 2 virtual make-up sessions are core maintenance sessions; and

(B) No more than 3 virtual make-up sessions that are ongoing maintenance sessions.

(3) Make-up sessions furnished in accordance with paragraph (d)(1) of this section that an MDPP beneficiary attends in person are counted toward meeting the attendance requirements described in paragraph (c)(1) of this section and toward achieving the performance goals described in § 414.84(b) of this chapter as if the MDPP beneficiary attended a regularly scheduled session. Virtual make-up sessions furnished in accordance with paragraph (d)(2) of this section are also counted toward such attendance requirements and performance goals, subject to the following limitations:

(i) The MDPP beneficiary receives no more than 4 virtual make-up sessions within the core services period described in paragraph (c)(2)(i) of this section, of which no more than 2 virtual make-up sessions may be core maintenance sessions; and

(ii) The MDPP beneficiary receives no more than 3 virtual make-up sessions that are ongoing maintenance sessions.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 6. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

■ 7. Section 414.84 is added to read as follows:

§ 414.84 Payment for MDPP services.

(a) *Definitions.* In addition to the definitions specified at § 410.79(b) and § 424.205(a) of this chapter, the following definitions apply to this section.

Bridge payment means a one-time payment to an MDPP supplier for furnishing its first MDPP session to an MDPP beneficiary who has previously received one or more MDPP services from a different MDPP supplier.

Performance goal means an attendance or weight loss goal that an MDPP beneficiary must achieve during the MDPP services period for an MDPP supplier to be paid a performance payment.

Performance payment means a payment made to an MDPP supplier for furnishing certain MDPP services to an MDPP beneficiary when the MDPP beneficiary achieves the applicable performance goal.

(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 seven types of performance payments are as follows:

(1) *Performance Goal 1: Attends the first core session that initiates the MDPP services period.* CMS makes a performance payment to an MDPP supplier if an MDPP beneficiary attends the first core session, which initiates the MDPP services period, and that first core session was furnished by that supplier. An MDPP supplier that has been paid this performance payment for an MDPP beneficiary is not eligible to be paid a bridge payment described in paragraph (c) of this section for that MDPP beneficiary. The amount of this performance payment is determined as follows:

(i) For a first core session furnished April 1 through December 31, 2018. $25.

(ii) For a first core session furnished during a calendar year subsequent to CY 2018. The performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(2) *Performance Goal 2: Attends four core sessions.* CMS makes a performance payment to an MDPP supplier if an MDPP beneficiary achieves attendance at the fourth core session upon attendance at a core session furnished by that supplier. The

amount of this performance payment is determined as follows:

(i) For a fourth core session furnished April 1 through December 31, 2018. $50.

(ii) For a fourth core session furnished during a calendar year subsequent to CY 2018. The performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(3) *Performance Goal 3: Attends nine core sessions.* CMS makes a performance payment to an MDPP supplier if an MDPP beneficiary achieves attendance at the ninth core session upon attendance at a core session furnished by that supplier. The amount of this performance payment is determined as follows:

(i) For a ninth core session furnished April 1 through December 31, 2018. $90.

(ii) For a ninth core session furnished during a calendar year subsequent to CY 2018. The performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(4) *Performance Goal 4: Attends two core maintenance sessions during a core maintenance session interval.* CMS makes a performance payment to an MDPP supplier if an MDPP beneficiary attends two core maintenance sessions in a core maintenance session interval and achieves attendance at the second core maintenance session upon attendance at a core maintenance session furnished by that supplier. CMS makes this performance payment to an MDPP supplier only once per MDPP beneficiary per core maintenance session interval. The amount of this performance payment is determined as follows:

(i) If the beneficiary also achieves or maintains the required minimum weight loss as measured in-person during a core maintenance session furnished during the applicable core maintenance session interval:

(A) For a second core maintenance session furnished April 1 through December 31, 2018. $60.

(B) For a second core maintenance session furnished during a calendar year subsequent to CY 2018. The performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(ii) If the beneficiary does not achieve or maintain the required minimum weight loss as measured in-person during a core maintenance session furnished during the applicable core maintenance session interval:

(A) For a second core maintenance session furnished April 1 through December 31, 2018. $15.

(B) For a second core maintenance session furnished during a calendar year subsequent to CY 2018. The performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(5) *Performance Goal 5: Attends two ongoing maintenance sessions and maintains the required minimum weight loss during an ongoing maintenance session interval.* CMS makes a performance payment to an MDPP supplier if an MDPP beneficiary attends two ongoing maintenance sessions during an ongoing maintenance session interval, achieves attendance at that second ongoing maintenance session upon attendance at an ongoing maintenance session furnished by that supplier, and achieves or maintains the required minimum weight loss as measured in-person during an ongoing maintenance session furnished during the applicable ongoing maintenance session interval. CMS makes this performance payment to an MDPP supplier only once per MDPP beneficiary per ongoing maintenance session interval. The amount of this performance payment is determined as follows:

(i) For a second ongoing maintenance session furnished April 1 through December 31, 2018. $50.

(ii) For a second ongoing maintenance session furnished during a calendar year subsequent to CY 2018. The performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(6) *Performance Goal 6: Achieves the required minimum weight loss.* CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who achieves the required minimum weight loss as measured in-person during a core session or core maintenance session furnished by that supplier. The amount of this performance payment is determined as follows:

(i) For a core session or core maintenance session, as applicable, furnished April 1 through December 31, 2018. $160.

(ii) For a core session or core maintenance session, as applicable, furnished during a calendar year subsequent to CY 2018. The performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(7) *Performance Goal 7: Achieves 9-percent weight loss.* CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who achieves at least a 9-percent weight loss as measured in-person during a core session, core maintenance session, or ongoing maintenance session furnished by that supplier. The amount of this performance payment is determined as follows:

(i) For a core session, core maintenance session, or ongoing maintenance session, as applicable, furnished April 1 through December 31, 2018. $25.

(ii) For a core session, core maintenance session, or ongoing maintenance session, as applicable, furnished during a calendar year subsequent to CY 2018. The performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(c) *Bridge payment.* CMS makes a bridge payment to an MDPP supplier only for a core session, core maintenance session, or ongoing maintenance session furnished to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier. An MDPP supplier that has previously been paid either a bridge payment or a performance payment for an MDPP beneficiary is not eligible to be paid a bridge payment for that beneficiary. A bridge 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 bridge payment only to an MDPP supplier that complies with all applicable enrollment and program requirements, and only for MDPP services 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 amount of the bridge payment is determined as follows:

(1) For a core session, core maintenance session, or ongoing maintenance session, as applicable, furnished April 1 through December 31, 2018. $25.

(2) For a core session, core maintenance session, or ongoing maintenance session, as applicable, furnished during a calendar year subsequent to CY 2018. The bridge payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(d) *Updating performance payments and the bridge payment.* The performance 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.

■ 8. Section 414.90 is amended by revising paragraphs (j)(8)(i)(A)(*1*)(*i*), (j)(8)(ii)(A)(*1*)(*i*), (j)(8)(ii)(A)(*2*), (j)(8)(iii) and (iv), and (j)(9)(ii) through (vi) and (viii), adding a heading to paragraph (k)(3) introductory text, revising paragraph (k)(5)(i), and adding paragraph (k)(5)(ii) to read as follows:

§ 414.90 Physician Quality Reporting System (PQRS).

* * * * *

(j) * * *

(8) * * *

(i) * * *

(A) * * *

(*1*)(*i*) Report at least 6 measures and report each measure for at least 50 percent of the eligible professional's Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable, and report each measure for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).

* * * * *

(ii) * * *

(A) * * *

(*1*)(*i*) Report at least 6 measures and report each measure for at least 50 percent of the eligible professional's Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable, and report each measure for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies.

* * * * *

(*2*) Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).

* * * * *

(iii) *Via EHR direct product.* For the 12-month 2018 PQRS payment adjustment reporting period, report 6 measures. If an eligible professional's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the eligible professional must report all of the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR data submission vendor.* For the 12-month 2018 PQRS payment adjustment reporting period, report at least 6 measures. If an eligible professional's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the eligible professional must report all of the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(9) * * *

(ii) *Via qualified registry.* For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report at least 6 measures and report each measure for at least 50 percent of the group practice's Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable, and report each measure for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted (unless they are inverse measures where a lower rate reflects better performance).

(iii) *Via EHR direct product.* For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report 6 measures. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR data submission vendor.* For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report 6 measures. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(v) *Via a certified survey vendor in addition to a qualified registry.* For a group practice of 2 or more eligible professionals that elects to report via a certified survey vendor in addition to a qualified registry for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report at least 3 additional measures using the qualified registry and report each measure for at least 50 percent of the group practice's Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. If less than 3 measures apply to the group practice, the group practice must report on each measure that is applicable, and report each measure for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted (unless they are inverse measures where a lower rate reflects better performance).

(vi) *Via a certified survey vendor in addition to a direct EHR product or EHR data submission vendor.* For a group practice of 2 or more eligible professionals that elects to report via a certified survey vendor in addition to a direct EHR product or EHR data submission vendor for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report at least 3 additional measures using the direct EHR product or EHR data submission vendor product. If less than 3 measures apply to the group practice, the group practice must report all of the measures for which there is patient data. Of the additional 3 measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice must report

on at least 1 measure for which there is Medicare patient data.

* * * * *

(viii) If the CAHPS for PQRS survey is applicable to the practice, group practices comprised of 100 or more eligible professionals that register to participate in the GPRO may administer the CAHPS for PQRS survey, regardless of the GPRO reporting mechanism selected.

(k) * * *

(3) *Satisfactory participation criteria for individual eligible professionals for the 2016 PQRS payment adjustment.*

* * *

* * * * *

(5) * * *

(i) *Individual eligible professional.* For the applicable 12-month reporting period, report at least 6 measures available for reporting under a QCDR and report each measure for at least 50 percent of the eligible professional's patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable, and report each measure for at least 50 percent of the eligible professional's patients.

(ii) *Group practices.* For the applicable 12-month reporting period, report at least 6 measures available for reporting under a QCDR and report each measure for at least 50 percent of the group practice's patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable, and report each measure for at least 50 percent of the group practice's patients. If a group practice reports the CAHPS for PQRS survey measures, apply reduced criteria as follows: 3 measures, as applicable.

* * * * *

■ 9. Section 414.94 is amended by adding paragraphs (j) and (k) to read as follows:

§ 414.94 Appropriate use criteria for advanced diagnostic imaging services.

* * * * *

(j) *Consulting.* Ordering Professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on or after January 1, 2020.

(k) *Reporting.* Furnishing Professionals must report the following information on Medicare claims for advanced diagnostic imaging services furnished in an applicable setting, paid for under an applicable payment system defined in paragraph (b) of this section, and ordered on or after January 1, 2020:

(1) The qualified CDSM consulted by the ordering professional.

(2) Information indicating:

(i) Whether the service ordered would adhere to specified applicable AUC;

(ii) Whether the service ordered would not adhere to specified applicable AUC; or

(iii) Whether the specified applicable AUC consulted was not applicable to the service ordered.

(3) The NPI of the ordering professional who consulted specified applicable AUC as required in paragraph (j) of this section, if different from the furnishing professional.

■ 10. Section 414.904 is amended by revising paragraph (e)(2) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(e) * * *

(2) *Infusion drugs furnished through a covered item of durable medical equipment.* The payment limit for an infusion drug furnished before January 1, 2017, through a covered item of durable medical equipment is calculated using 95 percent of the average wholesale price in effect on October 1, 2003.

* * * * *

■ 11. Section 414.1270 is amended by revising paragraph (d)(1) to read as follows:

§ 414.1270 Determination and calculation of the Value-Based Payment Modifier adjustments.

* * * * *

(d) * * *

(1) A downward payment adjustment of −1.0 percent will be applied to a solo practitioner, a group with two to nine eligible professionals, and a group consisting only of nonphysician eligible professionals subject to the value-based payment modifier and no physicians; and a downward payment adjustment of −2.0 percent will be applied to a group with 10 or more eligible professionals and at least one physician if, during the applicable performance period as defined in § 414.1215, the following apply:

(i) For groups:

(A) Such group does not meet the criteria as a group to avoid the PQRS payment adjustment for CY 2018 as specified by CMS; and

(B) Fifty percent of the eligible professionals in such group do not meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2018 as specified by CMS.

(ii) For solo practitioners, such solo practitioner does not meet the criteria as an individual to avoid the PQRS payment adjustment for CY 2018 as specified by CMS.

* * * * *

■ 12. Section 414.1275 is amended by revising paragraphs (c)(4), (d)(3)(i) and (ii) to read as follows:

§ 414.1275 Value-based payment modifier quality-tiering scoring methodology.

* * * * *

(c) * * *

(4) The following value-based payment modifier percentages apply to the CY 2018 payment adjustment period, for physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists who are solo practitioners or who are in groups of any size:

CY 2018 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS, CLINICAL NURSE SPECIALISTS, AND CERTIFIED REGISTERED NURSE ANESTHETISTS

Cost/quality	Low quality	Average quality	High quality
Low Cost	+0.0%	*+1.0x	*+2.0x
Average Cost	+0.0%	+0.0%	*+1.0x
High Cost	+0.0%	+0.0%	+0.0%

*Eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

(d) * * *

(3) * * *

(i) Classified as high quality/low cost receive an upward adjustment of +3x (rather than +2x); and

(ii) Classified as either high quality/average cost or average quality/low cost receive an upward adjustment of +2x (rather than +1x).

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 13. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 14. Section 424.55 is amended by adding paragraph (d) to read as follows:

§ 424.55 Payment to the supplier.

* * * * *

(d) For purposes of claims for services submitted by an MDPP supplier (as defined at § 410.79(b) of this chapter), Medicare deems such claims to have been assigned by the beneficiary (or the person authorized to request payment on the beneficiary's behalf) and the assignment accepted by the MDPP supplier.

§ 424.59 [Removed]

■ 15. Remove § 424.59.

■ 16. Subpart I, consisting of §§ 424.200 through 424.210, is added to read as follows:

Subpart I—Requirements for Medicare Diabetes Prevention Program Suppliers and Beneficiary Engagement Incentives Under the Medicare Diabetes Prevention Program Expanded Model

Sec.

424.200 Scope.
424.205 Requirements for Medicare Diabetes Prevention Program suppliers.
424.210 Beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model.

Subpart I—Requirements for Medicare Diabetes Prevention Program Suppliers and Beneficiary Engagement Incentives Under the Medicare Diabetes Prevention Program Expanded Model

§ 424.200 Scope.

This subpart specifies the requirements for Medicare Diabetes Prevention Program suppliers and beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model.

§ 424.205 Requirements for Medicare Diabetes Prevention Program suppliers.

(a) *Definitions.* In addition to the definitions specified at § 410.79(b) and § 414.84(a) of this subchapter, the following definitions apply to this section:

Administrative location means a physical location associated with the MDPP supplier's operations where they are the primary operator in the space, from where coaches are dispatched or based, and where MDPP services may or may not be furnished.

Coach means an individual who furnishes MDPP services on behalf of an MDPP supplier as an employee, contractor, or volunteer.

Coach eligibility end date means the end date indicated by the MDPP supplier in submitting a change to the supplier's MDPP enrollment application in accordance with paragraph (d)(5) of this section that removed the coach's information, or the date the supplier itself was revoked from or withdrew its Medicare enrollment as an MDPP supplier.

Coach eligibility start date, means the start date indicated by the MDPP supplier when submitting the coach's information on the MDPP enrollment application.

Community setting means a location where the MDPP supplier furnishes MDPP services outside of their administrative locations. A community setting is a location open to the public not primarily associated with the supplier. Community settings may include, for example, church basements or multipurpose rooms in recreation centers.

Eligible coach means an individual who CMS has screened and has determined can provide MDPP services on behalf of an MDPP supplier in accordance with paragraph (e) of this section.

Ineligible coach means an individual whom CMS has screened and has determined cannot provide MDPP services on behalf of an MDPP supplier in accordance with paragraph (e) of this section.

MDPP interim preliminary recognition means a status that CMS has granted to an entity in accordance with paragraph (c) of this section.

(b) *Conditions for MDPP supplier enrollment.* An entity may enroll as an MDPP supplier only if it satisfies the following requirements and all other applicable Medicare enrollment requirements:

(1) Has either an MDPP preliminary recognition, as defined in paragraph (c)(1) of this section or a full CDC DPRP recognition.

(2) Maintains an active and valid TIN and NPI at the organizational level.

(3) Has passed screening requirements as follows:

(i) Upon initial enrollment, at a ''high'' categorical risk in accordance with § 424.518(c)(2); and

(ii) Upon revalidation, at a ''moderate'' categorical risk in accordance with § 424.518(b)(2).

(4) Maintains, and submits to CMS through the CMS-approved enrollment application, a roster of all coaches who will be furnishing MDPP services on the entity's behalf that includes each coach's first and last names, middle initial (if applicable), date of birth, Social Security Number (SSN), active and valid NPI, coach eligibility start date, and coach eligibility end date (if applicable). This roster must be updated in accordance with paragraph (d)(5) of this section.

(5) Meets and certifies in its CMS-approved enrollment application that it meets and will continue to meet the supplier enrollment standards described in paragraph (d) of this section.

(6) Revalidates its Medicare enrollment every 5 years after the effective date of enrollment.

(c) *MDPP preliminary recognition.* For the purposes of this section, an MDPP preliminary recognition may include either:

(1) Any preliminary recognition established by CDC for the purposes of the DPRP; or

(2) An MDPP interim preliminary recognition.

(i) *MDPP interim preliminary recognition application period.* Entities may apply to CDC for CMS' MDPP interim preliminary by submitting information at the time and in the form and manner specified by CMS.

(ii) *MDPP Interim preliminary recognition requirements.* An entity may qualify for MDPP interim preliminary recognition if—

(A) The entity has pending CDC recognition.

(B) The entity submits a full 12 months of performance data to CDC on at least one completed cohort. The 12 month data submission includes at least 5 participants who attended at least 3 sessions in the first 6 months and whose time from first session attended to last session of the lifestyle change program was at least 9 months, at least 60 percent of whom attended at least 9 sessions in months 1 through 6, and at least 60 percent of whom attended at least 3 sessions in months 7 through 12.

(d) *Medicare Diabetes Prevention Program supplier standards.* An MDPP supplier must meet and must certify in its CMS-approved enrollment application that it meets and will continue to meet the following standards.

(1) The MDPP supplier must have and maintain MDPP preliminary recognition, as defined under paragraph (c)(1) of this section, or a full CDC DPRP recognition.

(2) The MDPP supplier must not currently have its billing privileges terminated for-cause or be excluded by a State Medicaid agency.

(3) The MDPP supplier must not include on the roster of coaches, described in paragraph (b)(4) of this section and updated in accordance with paragraph (d)(5) of this section, nor permit MDPP services to be furnished by, any individual coach who meets any of ineligibility criteria outlined in paragraph (e)(1) of this section.

(4) The MDPP supplier must maintain at least one administrative location. All administrative locations maintained by the MDPP supplier must be located at an appropriate site and be reported on the CMS-approved enrollment application. An appropriate site for such an administrative location would include all of the following characteristics:

(i) Signage posted on the exterior of the building or suite, in a building directory, or on materials located inside of the building. Such signage may include, for example, the MDPP supplier's legal business name or DBA, as well as hours of operation.

(ii) Open for business during stated operational hours.

(iii) Employees, staff, or volunteers present during operational hours; and

(iv) Not a private residence.

(5) The MDPP supplier must update its enrollment application within 30 days of any changes of ownership, changes to the coach roster (including due to coach ineligibility or because the coach is no longer an employee, contractor, or volunteer of the MDPP supplier), and final adverse action history, and report all other changes, including but not limited to changes in the MDPP supplier's administrative location(s), to CMS within 90 days of the reportable event.

(6) The MDPP supplier must maintain a primary business telephone that operates either at administrative locations described in paragraph (d)(4) of this section or directly where services are furnished, if services are furnished in community settings. The associated telephone number must be listed with either the legal or doing business as name of the supplier in public view, including on Web sites, flyers, and materials.

(7) The MDPP supplier must not knowingly sell to or allow another individual or entity to use its supplier billing number.

(8) Subject to paragraph (d)(8)(i) of this section, the MDPP supplier must not deny an MDPP beneficiary access to MDPP services during the MDPP services period described in § 410.79(c)(2) of this chapter, including on the basis of the beneficiary's weight, health status, or achievement of performance goals.

(i) Suppliers may deny an MDPP beneficiary access to MDPP services during the MDPP services period only under one of the following conditions:

(A) The MDPP beneficiary no longer meets the eligibility criteria for MDPP services under § 410.79(c)(1) of this chapter.

(B) The MDPP supplier lacks the self-determined publicly-posted capacity to furnish MDPP services to a given MDPP beneficiary.

(C) The MDPP supplier determines that the MDPP beneficiary significantly disrupts the session for other MDPP beneficiaries or becomes abusive.

(ii) MDPP suppliers must maintain a record of the number of MDPP beneficiaries for whom it declined access away for the reasons outlined in paragraphs (d)(8)(i)(B) and (C) of this section, to include the date each such beneficiary was declined access. For beneficiaries who were declined access for the reasons described in paragraph (d)(8)(i)(C) of this section, the MDPP supplier must document details of the occurrence(s), including date(s) of the behavior, any remediation efforts taken by the MDPP supplier, and final action (for example, dismissal from an MDPP session or denial from future sessions) in the beneficiary's MDPP records.

(9) The MDPP supplier and other individuals or entities performing functions or services related to MDPP services on the MDPP supplier's behalf must not unduly coerce an MDPP beneficiary's decision to change or not to change to a different MDPP supplier, including through the use of pressure, intimidation, or bribery.

(10) Except as allowed under paragraph (d)(8) of this section, the MDPP supplier must offer an MDPP beneficiary no fewer than all of the following:

(i) 16 in-person core sessions no more frequently than weekly for the first 6 months of the MDPP services period, which beginnings on the date of attendance at the first such core session.

(ii) 1 in-person core maintenance session each month during months 7 through 12 (6 months total) of the MDPP services period.

(iii) 1 in-person ongoing maintenance session each month for months 13 through 24 of the MDPP services period, as long as the beneficiary maintains eligibility to receive such services in accordance with § 410.79(c)(1)(ii) and (iii) of this chapter.

(11) Before the initial core session is furnished, the MDPP supplier must disclose detailed information about the set of MDPP services to each MDPP beneficiary to whom it wishes to begin furnishing MDPP services. Such information must include all of the following:

(i) Eligibility requirements under § 410.79(c)(1) of this chapter, including the once-per-lifetime nature of MDPP services.

(ii) Minimum coverage requirements under § 410.79(c)(2).

(iii) The MDPP supplier standards as specified in paragraph (d) of this section.

(12) The MDPP supplier must answer MDPP beneficiaries' questions about MDPP services and respond to MDPP-related complaints within a reasonable timeframe. An MDPP supplier must implement a complaint resolution protocol and maintain documentation of all beneficiary contact regarding such complaints, including the name and Medicare Beneficiary Identifier of the beneficiary, a summary of the complaint, related correspondences, notes of actions taken, and the names and/or NPIs of individuals who took such actions on behalf of the MDPP supplier. Failure to maintain a complaint resolution protocol or to retain information regarding MDPP related complaints in accordance with paragraph (g) of this section may be considered evidence that the MPPP supplier standards have not been met. This information must be kept at each administrative location and made available to CMS or its contractors upon request.

(13) The MDPP supplier must maintain a crosswalk file which indicates how beneficiary identifications for the purposes of CDC performance data requirements correspond to corresponding beneficiary health insurance claims numbers or Medicare Beneficiary Identifiers for each MDPP beneficiary receiving MDPP services from the MDPP supplier. The MDPP supplier must submit the crosswalk file to CMS or its contractor.

(14) The MDPP supplier must submit performance data for MDPP beneficiaries who attend ongoing maintenance sessions with data elements consistent with the CDC's DPRP standards for data elements required for the core services period.

(15) The MDPP supplier must allow CMS or its agents to conduct onsite inspections or recordkeeping reviews in order to ascertain the MDPP supplier's

compliance with these standards, and must adhere to the documentation requirements as outlined in paragraph (g) of this section.

(e) *Coach eligibility*—(1) *Criteria.* To furnish MDPP services to a beneficiary, an MDPP coach must not:

(i) Currently have Medicare billing privileges revoked and be currently subject to the reenrollment bar.

(ii) Currently have its Medicaid billing privileges terminated for-cause or be excluded by a State Medicaid agency.

(iii) Currently be excluded from any other Federal health care program, as defined in 42 CFR 1001.2, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(iv) Currently be debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement program or activity in accordance with the Federal Acquisition Streamlining Act implementing regulations and the Department of Health and Human Services nonprocurement common rule at 45 CFR part 76.

(v) Have, in the previous 10 years, one of the following State or Federal felony convictions:

(A) Crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion.

(C) Any felony that placed Medicare or its beneficiaries at immediate risk, such as a malpractice suit that results in the individual being convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion of criminal neglect or misconduct.

(D) Any felonies for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion that would result in mandatory exclusion under section 1128(a) of the Act.

(2) *CMS determination of coach eligibility.* CMS will screen each individual identified on the roster of coaches included with the supplier's enrollment application described in paragraph (b)(4) of this section and updated in accordance with paragraph (d)(5) of this section to verify that the individual coach does not meet any of the conditions specified in paragraph (e)(1) of this section and that the coach can provide MDPP services on behalf of an MDPP supplier. For each individual coach successfully screened by CMS, his or her eligibility start date becomes effective and remains effective until an MDPP supplier or CMS takes action that results in an eligibility end date.

(f) *Effective date for billing privileges.* (1) For MDPP suppliers initially enrolling and for newly established administrative locations that result in a new enrollment record or Provider Transaction Access Number, the effective date for Medicare billing privileges for MDPP suppliers is—

(i) The later of—

(A) The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor;

(B) The date of filing of a corrective action plan that was subsequently approved by a Medicare contractor; or

(C) The date that the supplier first began furnishing services at a new administrative location that resulted in a new enrollment record or Provider Transaction Access Number.

(ii) Under no circumstances should the effective date of billing privileges for any MDPP supplier be prior to April 1, 2018.

(2) For any newly established administrative locations that do not result in a new enrollment record or Provider Transaction Access Number, the existing billing privilege effective date for their Provider Transaction Access Number will apply, but not earlier than April 1, 2018.

(g) *Documentation retention and provision requirements.* An MDPP supplier must maintain all documentation related to participation in the MDPP in accordance with all applicable Federal and State laws. The MDPP supplier must provide to CMS, a contractor acting on CMS' behalf, the Office of the Inspector General, and the Comptroller General or their designee(s) scheduled and unscheduled access to the MDPP supplier's records, including, but not limited to, all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the MDPP supplier's compliance with the MDPP expanded model's requirements, including the MDPP expanded model requirements for in-kind beneficiary incentive engagements in § 424.210 of this chapter in the event that the MDPP supplier chooses to offer such incentives to any MDPP beneficiary.

(1) The documentation for the first core session must be established contemporaneous with the furnishing of MDPP services and must include at least all of the following:

(i) Organizational information, including MDPP supplier name, CDC DPRP number, and NPI.

(ii) Basic beneficiary information for each MDPP beneficiary in attendance, including but not limited to beneficiary name, HICN, or MBI, age.

(iii) Evidence that each such beneficiary satisfied the eligibility requirements under § 410.79(c) of this chapter at the time of service.

(2) The documentation for each MDPP session attended by an MDPP must be established contemporaneous with the furnishing of MDPP services and must include at least all of the following:

(i) Documentation of the type of session, whether a core session, a core maintenance session, an ongoing maintenance session, an in-person make-up session, or a virtual make-up session.

(ii) Identification of which CDC-approved DPRP curriculum was associated with the session.

(iii) The NPI of the coach who furnished the session.

(iv) The date and place of service of the session.

(v) Each MDPP's beneficiary's weight and date weight taken, in a form and manner as specified by CMS.

(3) If an MDPP supplier chooses to offer in-kind beneficiary engagement incentives to MDPP beneficiaries as permitted under § 424.210, the records maintained by the MDPP supplier in accordance with this section must also include the information required by § 424.210(e).

(4) An MDPP supplier is required to maintain and handle any beneficiary information related to MDPP, including Personally Identifiable Information (PII) and Protected Health Information (PHI), as would be required under HIPAA, other applicable state and federal privacy laws, and CMS standards.

(5) The MDPP supplier's records must include an attestation from the MDPP supplier that, as applicable, the MDPP beneficiary for which it is submitting a claim—

(i) Has attended their first, fourth or ninth core session, as applicable, if the claim submitted is for a performance payment under § 414.84(b)(1), (2), or (3) of this chapter.

(ii) Has attended at least three core maintenance sessions, achieved required minimum weight loss, or both, as applicable, if the claim submitted is for a performance payment under § 414.84(b)(4) of this chapter.

(iii) Has achieved the required minimum weight loss and attended at least three ongoing maintenance

sessions within an ongoing maintenance session interval, if the claim submitted is for a performance payment under § 414.84(b)(5) of this chapter, if the claim submitted is for a performance payment under § 414.84(b)(6) of this chapter.

(iv) Has achieved required minimum weight loss as measured in-person 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)(6) of this chapter.

(v) Has achieved at least a 9-percent weight loss percentage as measured in-person during a core session, core maintenance session, or ongoing maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(7) of this chapter.

(6) The MDPP supplier must maintain all records required under this section for a period of 10 years from the last day of the MDPP beneficiary's receipt of MDPP services provided by the MDPP supplier or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless either of the following apply:

(i) CMS determines that there is a special need to retain a particular record or group of records for a longer period and notifies the MDPP supplier at least 30 calendar days before the normal disposition rate; or

(ii) There has been a dispute or allegation of fraud or similar fault against the MDPP supplier, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault, as defined at § 405.902 of this chapter.

(h) *Denial or revocation of MDPP supplier enrollment.* (1) An MDPP supplier is subject to enrollment denial or revocation of its MDPP supplier enrollment for one or more of the following reasons:

(i) *Failure to meet enrollment requirements.* The MDPP supplier does not satisfy the conditions specified in paragraph (b) of this section.

(A) An enrollment denial under this paragraph (h)(1)(i) is considered an enrollment denial under § 424.530(a)(1).

(B) A revocation under this paragraph (h)(1)(i) is considered a revocation under § 424.535(a)(1).

(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 MDPP preliminary recognition or full CDC DPRP recognition, and successfully enrolls again in Medicare as an MDPP supplier after any applicable reenrollment bar has expired.

(ii) *Failure to meet MDPP supplier standards.* The MDPP supplier fails to meet the standards specified in paragraph (d) of this section.

(A) An enrollment denial under this paragraph (h)(1)(ii) is considered an enrollment denial under § 424.530(a)(1).

(B) A revocation under this paragraph (h)(1)(ii) is considered a revocation under § 424.535(a)(1).

(iii) *Application of existing enrollment denial reasons.* One of the enrollment denial reasons specified in § 424.530(a) applies.

(iv) *Application of existing revocation reasons.* One of the revocation reasons specified in § 424.535(a) applies.

(v) *Use of an ineligible coach.* (A) The MDPP supplier knowingly allows an ineligible coach to furnish MDPP services to Medicare beneficiaries. Knowingly means that the MDPP supplier received an enrollment denial or revocation notice based on failing to meet the standard specified in § 424.205(d)(3), was provided notice by CMS or contractors working on its behalf of this coach's ineligibility including the reason(s) for ineligibility, submitted a corrective action plan (CAP) to remove the coach and become compliant therefore maintaining its enrollment, but continued to allow the coach to provide MDPP services in violation of the CAP.

(B) Revocation under this paragraph (h)(1)(v) is subject to the following requirements:

(*1*) The revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the MDPP supplier.

(*2*) For the revocation authority under this paragraph (h)(1)(v), MDPP suppliers are barred from participating in the Medicare program from the date of the revocation, which begins 30 days after CMS or its contractor mails notice of the revocation, until the end of the reenrollment bar, which lasts a minimum of 1 year, but not greater than 3 years, depending on the severity of the basis for revocation.

(*3*) A revoked MDPP supplier must, within 60 calendar days after the effective date of revocation, submit all claims for items and services furnished before the date of the revocation letter.

(2) An MDPP supplier may appeal an enrollment denial or revocation decision in accordance with the procedures specified in part 498 of this chapter. References to suppliers in that section apply to MDPP suppliers.

§ 424.210 Beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model.

(a) *Definitions.* In addition to the definitions specified at § 410.79(b) and § 424.205(a) of this chapter, the following definition applies to this section:

Engagement incentive period means the period of time during which an MDPP supplier may furnish in-kind beneficiary engagement incentives to a given MDPP beneficiary to whom the MDPP supplier is furnishing MDPP services. This period begins when an MDPP supplier furnishes any MDPP service to an MDPP eligible beneficiary and ends when one of the following occurs, whichever occurs first:

(i) The MDPP beneficiary's MDPP services period ends as described in § 410.79(c)(3) of this chapter.

(ii) The MDPP supplier knows the MDPP beneficiary will no longer be receiving MDPP services from the MDPP supplier.

(iii) The MDPP supplier has not had direct contact, either in-person, by telephone, or via other telecommunications technology, with the MDPP beneficiary for more than 90 consecutive calendar days during the MDPP services period.

(b) *General.* An MDPP supplier may choose to furnish an item or service as an in-kind beneficiary engagement incentive to an MDPP beneficiary only during the engagement incentive period, subject to the following conditions:

(1) The item or service must be furnished directly to an MDPP beneficiary by an MDPP supplier or by an agent of the MDPP supplier, such as a coach, under the MDPP supplier's direction and control.

(2) The item or service must be reasonably connected to the CDC-approved DPP curriculum furnished to the MDPP beneficiary during a core session, core maintenance session, or ongoing maintenance session furnished by the MDPP supplier.

(3) The item or service must be a preventive care item or service or an item or service that advances a clinical goal, as specified in paragraph (d) of this section, for an MDPP beneficiary by engaging him or her in better managing his or her own health.

(4) The item or service must not be tied to the receipt of items or services outside of the MDPP services.

(5) The item or service must not be tied to the receipt of items or services from a particular provider, supplier, or coach.

(6) The availability of the item or service must not be advertised or promoted as an in-kind beneficiary

engagement incentive available to an MDPP beneficiary receiving MDPP services from the MDPP supplier except that an MDPP beneficiary may be made aware of the availability of the item or service at the time the MDPP beneficiary could reasonably benefit from it during the engagement incentive period.

(7) The cost of the item or service must not be shifted to another Federal health care program, as defined at section 1128B(f) of the Act.

(8) The cost of the item or service must not be shifted to an MDPP beneficiary.

(c) *Technology furnished to an MDPP beneficiary.* In-kind beneficiary engagement incentives involving technology furnished by an MDPP supplier to an MDPP beneficiary are subject to the following conditions:

(1) Items or services involving technology may not, in the aggregate, exceed $1,000 in retail value for any one MDPP beneficiary.

(2) Items or services involving technology must be the minimum necessary to advance a clinical goal, as specified in paragraph (d) of this section, for an MDPP beneficiary.

(3) Items involving technology exceeding $100 in retail value must—

(i) Remain the property of the MDPP supplier; and

(ii) Be retrieved from the MDPP beneficiary at the end of the engagement incentive period. The MDPP supplier must document all retrieval attempts, including the ultimate date of retrieval, in accordance with paragraph (e)(3) of this section. Documented diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

(d) *Clinical goals of the MDPP expanded model.* The following are the clinical goals for MDPP beneficiaries that may be advanced through in-kind beneficiary engagement incentives:

(1) Attendance at core sessions, core maintenance sessions, or ongoing maintenance sessions.

(2) Weight loss.

(3) Long-term dietary change.

(4) Adherence to long-term health behavior changes.

(e) *Documentation of beneficiary engagement incentives.* In addition to the documentation requirements at § 424.205(g), an MDPP supplier must maintain documentation of items and services furnished as in-kind beneficiary engagement incentives that exceed $25 in retail value.

(1) The documentation must be established contemporaneous with the furnishing of the in-kind items and services and must include at least the following:

(i) The date the item or service is furnished.

(ii) The identity of the MDPP beneficiary to whom the item or service is furnished.

(iii) The agent of the MDPP supplier that furnished the item or service, if applicable.

(iv) A description of the item or service.

(v) The retail value of the item or service.

(vi) Documentation establishing that the item or service was furnished to the MDPP beneficiary during the engagement incentive period.

(2) Documentation regarding items or services that are furnished to the MDPP beneficiary for use on an ongoing basis during the engagement incentive period, including items involving technology exceeding $100 in retail value, must also include contemporaneous documentation establishing that the MDPP beneficiary is in the engagement incentive period throughout the time period that the MDPP beneficiary possesses or has access to the item or service furnished by the MDPP supplier.

(3) The documentation regarding items involving technology exceeding $100 in retail value must also include contemporaneous documentation of any attempt to retrieve the item as required by paragraph (c)(3)(ii) of this section.

(4) The MDPP supplier must retain and provide access to the documentation required in this section in accordance with § 424.205(g).

■ 17. Section 424.502 is amended by revising the definition for ''Institutional provider'' to read as follows.

§ 424.502 Definitions.

* * * * *

Institutional provider means any provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (not including physician and nonphysician practitioner organizations), CMS–855S, CMS–20134, or an associated Internet-based PECOS enrollment application.

* * * * *

■ 18. Section 424.516 is amended by revising paragraph (e) introductory text to read as follows.

§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

* * * * *

(e) *Reporting requirements for all other providers and suppliers.* Reporting requirements for all other providers and suppliers not identified in paragraphs (a) through (d) of this section, with the exception of MDPP suppliers whose reporting requirements are established at § 424.205(d), must report to CMS the following information within the specified timeframes:

* * * * *

■ 19. Section 424.518 is amended by adding paragraphs (b)(1)(xi) and (c)(1)(iii) to read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers.

* * * * *

(b) * * *

(1) * * *

(xi) Revalidating MDPP suppliers.

* * * * *

(c) * * *

(1) * * *

(iii) Prospective (newly enrolling) MDPP suppliers

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 20. The authority citation for part 425 continues to read as follows:

Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302, 1306 1395hh, and 1395jjjj).

■ 21. Section 425.20 is amended by revising the definitions of ''Primary care physician'' and ''Primary care services'' to read as follows:

§ 425.20 Definitions.

* * * * *

Primary care physician means:

(1) For performance years 2012 through 2015, a physician included in an attestation by the ACO as provided under § 425.404 for services furnished in an FQHC or RHC, or a physician who has a primary care specialty designation of internal medicine, general practice, family practice, or geriatric medicine;

(2) For performance years 2016 through 2018, a physician included in an attestation by the ACO as provided under § 425.404 for services furnished in an FQHC or RHC, or a physician who has a primary care specialty designation of internal medicine, general practice, family practice, geriatric medicine, or pediatric medicine; and

(3) For performance year 2019 and subsequent years, a physician who has a primary care specialty designation of internal medicine, general practice, family practice, geriatric medicine, or pediatric medicine.

Primary care services means the set of services identified by the HCPCS and revenue center codes designated under § 425.400(c).

* * * * *

■ 22. Section 425.112 is amended —

■ a. In paragraph (a)(3)(i) by removing the phrase ''Explain how it will require

ACO participants'' and adding in its place the phrase ''Require ACO participants'';

■ b. In paragraph (a)(3)(ii) by removing the phrase ''Explain how it will employ its internal assessments'' and adding in its place the phrase ''Employ its internal assessments''; and

■ c. Revising paragraph (b)(4)(ii).

The revision reads as follows:

§ 425.112 Required processes and patient-centeredness criteria.

* * * * *

(b) * * *

(4) * * *

(ii) Have a written plan to:

(A) Implement an individualized care program that promotes improved outcomes for, at a minimum, the ACO's high-risk and multiple chronic condition patients.

(B) Identify additional target populations that would benefit from individualized care plans. Individualized care plans must take into account the community resources available to the individual.

(C) Encourage and promote use of enabling technologies for improving care coordination for beneficiaries. Enabling technologies may include one or more of the following:

(*1*) Electronic health records and other health IT tools.

(*2*) Telehealth services, including remote patient monitoring.

(*3*) Electronic exchange of health information.

(*4*) Other electronic tools to engage beneficiaries in their care.

(D) Partner with long-term and post-acute care providers, both inside and outside the ACO, to improve care coordination for its assigned beneficiaries.

■ 23. Section 425.204 is amended by—

■ a. Revising paragraph (c)(1) introductory text;

■ b. Removing paragraph (c)(5)(iii);

■ c. Redesignating paragraph (c)(5)(iv) as new paragraph (c)(5)(iii); and

■ d. Revising paragraph (d).

The revisions read as follows:

§ 425.204 Content of the application.

* * * * *

(c) * * *

(1) As part of its application, an ACO must certify that the ACO satisfies the requirements set forth in this part. Upon request, the ACO must submit the following supporting materials to demonstrate that it satisfies the requirements set forth in this part:

* * * * *

(d) *Distribution of savings.* As part of its application to participate in the Shared Savings Program, an ACO must certify it has a mechanism and plan to receive and use payments for shared savings, including criteria for distributing shared savings among its ACO participants and ACO providers/suppliers.

* * * * *

■ 24. Section 425.306 is amended by revising paragraph (b)(2) to read as follows:

§ 425.306 Participant agreement and exclusivity of ACO participants.

* * * * *

(b) * * *

(2) Each ACO participant that submits claims for services used to determine the ACO's assigned population under subpart E of this part must be exclusive to one Shared Savings Program ACO. If, during a benchmark or performance year (including the 3-month claims runout for such benchmark or performance year), an ACO participant that participates in more than one ACO submits claims for services used in assignment under subpart E of this part, then:

(i) CMS will not consider any services billed through the TIN of the ACO participant when performing assignment under subpart E of this part for the benchmark or performance year.

(ii) The ACO may be subject to the pre-termination actions set forth in § 425.216, termination under § 425.218, or both.

■ 25. Section 425.400 is amended by adding paragraph (a)(1)(iii) and revising paragraph (c) to read as follows:

§ 425.400 General.

(a) * * *

(1) * * *

(iii) In determining final assignment for a benchmark or performance year, CMS will exclude any services furnished during the benchmark or performance year that are billed through the TIN of an ACO participant that is an ACO participant in more than one ACO.

* * * * *

(c) Primary care services for purposes of assigning beneficiaries are identified by selected HCPCS/CPT codes, or revenue center codes.

(1) Primary care service codes are as follows:

(i) For performance years 2012 through 2015:

(A) CPT codes:

(*1*) 99201 through 99215.

(*2*) 99304 through 99340.

(*3*) 99341 through 99350.

(B) HCPCS codes G0402 (the code for the Welcome to Medicare visit) and G0438 and G0439 (codes for the annual wellness visits).

(C) Revenue center codes 0521, 0522, 0524, and 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

(ii) For performance year 2016 as follows:

(A) CPT codes:

(*1*) 99201 through 99215.

(*2*) 99304 through 99340.

(*3*) 99341 through 99350.

(*4*) 99495, 99496, and 99490.

(B) HCPCS codes:

(*1*) G0402 (the code for the Welcome to Medicare visit) and

(*2*) G0438 and G0439 (codes for the annual wellness visits).

(*3*) G0463 for services furnished in ETA hospitals.

(C) Revenue center codes 0521, 0522, 0524, and 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

(iii) For performance years 2017 and 2018 as follows:

(A) CPT codes:

(*1*) 99201 through 99215.

(*2*) 99304 through 99318 (excluding claims including the POS 31 modifier).

(*3*) 99319 through 99340.

(*4*) 99341 through 99350.

(*5*) 99495, 99496, and 99490.

(B) HCPCS Codes:

(*1*) G0402 (the code for the Welcome to Medicare visit) and

(*2*) G0438 and G0439 (codes for the annual wellness visits).

(*3*) G0463 for services furnished in ETA hospitals.

(C) Revenue center codes 0521, 0522, 0524, and 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

(iv) For performance year 2019 and subsequent performance years as follows:

(A) CPT codes:

(*1*) 99201 through 99215.

(*2*) 99304 through 99318 (excluding claims including the POS 31 modifier).

(*3*) 99319 through 99340.

(*4*) 99341 through 99350.

(*5*) 99487 and 99489.

(*6*) 99495, 99496, and 99490.

(B) HCPCS Codes:

(*1*) G0402 (the code for the Welcome to Medicare visit) and

(*2*) G0438 and G0439 (codes for the annual wellness visits).

(*3*) G0463 for services furnished in ETA hospitals.

(*4*) G0506 (code for chronic care management).

(*5*) G0502, G0503, G0504 and G0507 (codes for behavioral health integration).

■ 26. Section 425.404 is amended by—

■ a. Amending the introductory text by removing the phrase ''with two special conditions:'' and adding in its place the phrase ''with special conditions:'';

■ b. Revising paragraphs (a) and (b).
The revisions read as follows:

§ 425.404 Special assignment conditions for ACOs including FQHCs and RHCs.

* * * * *

(a) For performance years 2012 through 2018—

(1) Such ACOs are required to identify, through an attestation, physicians who directly provide primary care services in each FQHC or RHC that is an ACO participant and/or ACO provider/supplier in the ACO.

(2) Under the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim as a primary care service—

(i) If the claim includes a HCPCS or revenue center code that meets the definition of primary care services under § 425.20;

(ii) Performed by a primary care physician if the NPI of a physician identified in the attestation provided under paragraph (a)(1) of this section is reported on the claim for a primary care service (as described in paragraph (a)(2)(i) of this section) as the attending provider; and

(iii) Performed by a non-physician ACO professional if the NPI reported on the claim for a primary care service (as described in paragraph (a)(2)(i) of this section) as the attending provider is an ACO professional but is not identified in the attestation provided under paragraph (a)(1) of this section.

(b) For performance year 2019 and subsequent performance years, under the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim as a primary care service performed by a primary care physician.

§ 425.500 [Amended]

■ 27. Section 425.500 is amended by—
■ a. In paragraph (e)(2) by removing the phrase ''of this section is less than 90 percent, absent unusual circumstances,'' and adding in its place the phrase ''of this section is less than 80 percent, absent unusual circumstances,''; and
■ b. In paragraph (e)(3) by removing the phrase ''determines there is a match rate of less than 90 percent, the ACO'' and adding in its place the phrase ''determines there is a match rate of less than 80 percent, the ACO''.

§ 425.502 [Amended]

■ 28. Section 425.502 is amended in paragraph (a)(5) by removing the phrase ''or causes patient harm.'' and adding in its place the phrase ''or causes patient harm, or when there is a determination under the Quality Payment Program that the measure has undergone a substantive change.''

■ 29. Section 425.602 is amended by adding paragraphs (a)(1)(ii)(A) through (C) to read as follows:

§ 425.602 Establishing, adjusting, and updating the benchmark for an ACO's first agreement period.

(a) * * *
(1) * * *
(ii) * * *

(A) For agreement periods beginning before 2018, this calculation considers all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot or time limited program.

(B) For agreement periods beginning in 2018 and subsequent years, this calculation considers individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(C) For the 2018 performance year and subsequent performance years in agreement periods beginning in 2015, 2016 and 2017, the benchmark is adjusted to reflect only individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

* * * * *

■ 30. Section 425.603 is amended by adding paragraphs (c)(1)(ii)(A) through (C) and (e)(2)(ii)(A) through (C) to read as follows:

§ 425.603 Resetting, adjusting, and updating the benchmark for a subsequent agreement period.

* * * * *

(c) * * *
(1) * * *
(ii) * * *

(A) For agreement periods beginning before 2018, considers all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot or time limited program.

(B) For agreement periods beginning in 2018 and subsequent years, considers individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(C) For the 2018 and 2019 performance years in agreement periods beginning in 2017, the benchmark is adjusted to reflect only individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

* * * * *

(e) * * *
(2) * * *
(ii) * * *

(A) For agreement periods beginning before 2018, considers all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot or time limited program.

(B) For agreement periods beginning in 2018 and subsequent years, considers individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(C) For the 2018 and 2019 performance years in agreement periods beginning in 2017, risk adjusted county fee-for-service expenditures are adjusted to reflect only individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

* * * * *

■ 31. Section 425.604 is amended by adding paragraphs (a)(6)(ii)(A) and (B) to read as follows:

§ 425.604 Calculation of savings under the one-sided model.

(a) * * *
(6) * * *
(ii) * * *

(A) For performance years beginning before 2018, these calculations will take into consideration all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot or time limited program.

(B) For performance year 2018 and subsequent performance years, these calculations will take into consideration individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

* * * * *

■ 32. Section 425.606 is amended by adding paragraphs (a)(6)(ii)(A) and (B) to read as follows:

§ 425.606 Calculation of shared savings and losses under Track 2.

(a) * * *
(6) * * *
(ii) * * *

(A) For performance years beginning before 2018, these calculations will take into consideration all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot or time limited program.

(B) For performance year 2018 and subsequent performance years, these calculations will take into consideration individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

* * * * *

■ 33. Section 425.610 is amended by adding paragraphs (a)(6)(ii)(A) and (B) to read as follows:

§ 425.610 Calculation of shared savings and losses under Track 3.

(a) * * *

(6) * * *

(ii) * * *

(A) For performance years beginning before 2018, these calculations will take into consideration all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot or time limited program.

(B) For performance year 2018 and subsequent performance years, these calculations will take into consideration individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

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§ 425.612 [Amended]

■ 34. Section 425.612 is amended by removing paragraphs (a)(1)(i)(A)(*4*) and (a)(1)(i)(C).

Dated: October 23, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 24, 2017.

Eric D. Hargan,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2017–23953 Filed 11–2–17; 4:15 pm]

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