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42 CFR Parts 405, 410, 411, *et al.*
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 417, 422, 423, 424, 425, and 460

[CMS–1654–P]

RIN 0938–AS81

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model

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

ACTION: Proposed rule.

SUMMARY: This major proposed rule addresses changes to the physician fee schedule and other Medicare Part B payment policies, such as changes to the Value Modifier, to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This proposed rule also includes proposals related to the Medicare Shared Saving Program, and the release of certain pricing data from Medicare Advantage bids and medical loss ratio reports from Medicare health and drug plans. In addition, this rule proposes to expand the Medicare Diabetes Prevention Program model.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 6, 2016.

ADDRESSES: In commenting, please refer to file code CMS–1654–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *www.regulations.gov*. Follow the instructions for ''submitting a comment.''

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1654–P, P.O. Box 8013, Baltimore, MD 21244–8013.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1654–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT:

Jessica Bruton, (410) 786–5991 for issues related to any physician payment issues not identified below.

Gail Addis, (410) 786–4522, for issues related to diabetes self-management training.

Jaime Hermansen, (410) 786–2064, for issues related to moderate sedation coding and anesthesia services.

Jessica Bruton, (410) 786–5991, for issues related to identification of potentially misvalued services.

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

Ken Marsalek, (410) 786–4502, for issues related to telehealth services.

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

Emily Yoder, (410) 786–1804, for primary care issues related to resource intensive services and other primary care issues.

Lindsey Baldwin, (410) 786–1694, for primary care issues related to behavioral health integration services.

Geri Mondowney, (410) 786–4584, and Donta Henson, (410) 786–1947, for issues related to geographic practice cost indices.

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

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

Patrick Sartini, (410) 786–9252, for issues related to malpractice RVUs, radiation treatment, mammography and other imaging services.

Kathy Bryant, (410) 786–3448, for issues related to collecting data on resources used in furnishing global services.

Donta Henson, (410) 786–1947, for issues related to pathology and ophthalmology services.

Corinne Axelrod, (410) 786–5620, for issues related to rural health clinics or federally qualified health centers for comprehensive care management services furnished incident to.

Simone Dennis (410) 786–8409, for issues related to FQHC-specific market basket.

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

Erin Skinner (410) 786–0157, for issues related to open payments.

Sean O'Grady (410) 786–2259, or Julie Uebersax (410) 786–9284, for issues related to release of pricing data from Medicare Advantage bids and release of medical loss ratio data submitted by Medicare Advantage organizations and Part D sponsors.

Sara Vitolo (410) 786–5714, for issues related to prohibition on billing qualified Medicare beneficiary individuals for Medicare cost-sharing.

Michelle Peterman (410) 786–2591, for issues on the technical correction for PQRS.

Katie Mucklow (410) 786–0537 or John Spiegel (410) 786–1909, for issues related to Provider Enrollment Medicare Advantage Program.

Jen Zhu (410) 786–3725, Carlye Burd (410) 786–1972, or Nina Brown (410)

786–6103, for issues related to Medicare Diabetes Prevention Program model expansion.

Rabia Khan or Terri Postma, (410) 786–8084 or *ACO@cms.hhs.gov*, for issues related to Medicare Shared Savings Program.

Sabrina Ahmed (410) 786–7499, or Fiona Larbi (410) 786–7224, for issues related to Value-based Payment Modifier and Physician Feedback Program.

Lisa Ohrin Wilson (410) 786–8852, or Gabriel Scott (410) 786–3928, for issues related to physician self-referral updates.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

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Acronyms

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

A1c—Hemoglobin A1c
AAA—Abdominal aortic aneurysms
ACO—Accountable care organization
AMA—American Medical Association
ASC—Ambulatory surgical center
ATA—American Telehealth Association
ATRA—American Taxpayer Relief Act (Pub. L. 112–240)
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)
CAD—Coronary artery disease
CAH—Critical access hospital
CBSA—Core-Based Statistical Area
CCM—Chronic care management
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
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
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)
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)
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
PLI—Professional Liability Insurance
PMA—Premarket approval
PPM—Provider-Performed Microscopy
PQRS—Physician Quality Reporting System
PPIS—Physician Practice Expense Information Survey
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) 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
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 proposed rule are available through the Internet 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 2017 PFS Proposed Rule, refer to item CMS–1654–P. Readers who experience any problems accessing any of the Addenda or other documents referenced in this rule and posted on the CMS Web site identified above should contact Jessica Bruton at (410) 786–5991.

CPT (Current Procedural Terminology) Copyright Notice

I. Executive Summary and Background

A. Executive Summary

1. Purpose

This major proposed rule proposes to revise payment polices under the Medicare Physician Fee Schedule (PFS) and make other policy changes related to Medicare Part B payment. These changes would be applicable to services furnished in CY 2017. In addition, this proposed rule includes proposals related to: the Medicare Shared Savings Program and release of pricing data submitted to CMS by Medicare Advantage (MA) organizations; and medical loss ratio reports submitted by MA plans and Part D plans. These additional proposals are addressed in section III. of this proposed rule.

2. Summary of the Major Provisions

The statute requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: work, practice expense (PE); and malpractice (MP) expense; 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 proposed rule, we are proposing to establish RVUs for CY 2017 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 proposed rule includes discussions and proposals regarding:

- Potentially Misvalued PFS Codes.
- Telehealth Services.
- Establishing Values for New, Revised, and Misvalued Codes.
- Target for Relative Value Adjustments for Misvalued Services.
- Phase-in of Significant RVU Reductions.
- Chronic Care Management (CCM) and Transitional Care Management (TCM) Supervision Requirements in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).
- FQHC-Specific Market Basket.
- Appropriate Use Criteria for Advanced Diagnostic Imaging Services.
- Reports of Payments or Other Transfers of Value to Covered Recipients: Solicitation of Public Comments.
- Release of Part C Medicare Advantage Bid Pricing Data and Part C and Part D Medical Loss Ratio (MLR) Data.
- Prohibition on Billing Qualified Medicare Beneficiary Individuals for Medicare Cost-Sharing.
- Recoupment or Offset of Payments to Providers Sharing the Same Taxpayer Identification Number.
- Accountable Care Organization (ACO) Participants Who Report Physician Quality Reporting System (PQRS) Quality Measures Separately.
- Medicare Advantage Provider Enrollment.
- Proposed Expansion of the Diabetes Prevention Program (DPP) Model.
- Medicare Shared Savings Program.
- Value-Based Payment Modifier and the Physician Feedback Program.
- Physician Self-referral Updates.

3. 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. In addition, several changes proposed in this proposed rule would affect the specialty distribution of Medicare expenditures. When considering the combined impact of proposed work, PE, and MP RVU changes, the projected payment impacts would be small for most specialties; however, the impact would be larger for a few specialties.

We have determined that this major proposed rule is economically significant. For a detailed discussion of the economic impacts, see section VI. of this proposed rule.

B. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Social Security Act (the Act), ''Payment for Physicians' Services.'' The system 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 proposed rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for 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 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.B.2. of this proposed 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 five-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 five-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, which requires 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 VI.C. of this proposed 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 did 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 fee schedule payment amount for a given service and fee schedule area can be expressed as:

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

3. Separate Fee Schedule Methodology for Anesthesia Services

Section 1848(b)(2)(B) of the Act specifies that the fee schedule amounts for anesthesia services are to be based on a uniform relative value guide, with appropriate adjustment of an anesthesia conversion factor, 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 conversion factor 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.

4. Most Recent Changes to the Fee Schedule

Section 220(d) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93, enacted on April 1, 2014) (PAMA) added a new subparagraph (O) to section 1848(c)(2) of the Act to establish an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes. If the estimated net reduction in expenditures for a year is equal to or greater than the target for that year, the provision specifies that reduced expenditures attributable to such adjustments shall be redistributed in a budget-neutral manner within the PFS. The provision specifies that the amount by which such reduced expenditures exceed the target for a given year shall be treated as a reduction in expenditures for the subsequent year for purposes of determining whether the target for the subsequent year has been met. The provision also specifies that an amount equal to the difference between the target and the estimated net reduction in expenditures, called 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. The PAMA amendments originally made the target provisions applicable for CYs 2017 through 2020 and set the target for reduced expenditures at 0.5 percent of estimated expenditures under the PFS for each of those 4 years.

Subsequently, section 202 of the Achieving a Better Life Experience Act of 2014 (Division B of Pub. L. 113–295, enacted December 19, 2014) (ABLE) accelerated the application of the target, amending section 1848(c)(2)(O) of the Act to specify that target provisions apply for CYs 2016, 2017, and 2018; and setting a 1 percent target for reduced expenditures for CY 2016 and a 0.5 percent target for CYs 2017 and 2018. The implementation of the target legislation was finalized in the CY 2016 PFS final rule with comment period, and proposed revisions are discussed in section II.G. of this proposed rule.

Section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, specified 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. Section 220(e) of the PAMA required the phase-in of RVU reductions of 20 percent or more to begin for 2017. Section 1848(c)(7) of the Act was later amended by section 202 of the ABLE Act to require instead that the phase-in must begin in CY 2016. The implementation of the phase-in legislation was finalized in the CY 2016 PFS final rule with comment period and proposed revisions in this year's rulemaking are discussed in section II.H. of this proposed rule.

II. Provisions of the Proposed Rule for PFS

A. 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 Five-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 practice expense per hour (PE/HR) by specialty that was obtained from the AMA's Socioeconomic Monitoring Surveys (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 nonphysician practitioners (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 continue previous crosswalks for specialties that did not participate in the PPIS. However, beginning in CY 2010 we changed the PE/HR crosswalk for portable X-ray suppliers from radiology to IDTF, a more appropriate crosswalk because these specialties are more similar to each other for work time.

For registered dietician services, the resource-based PE RVUs have been calculated in accordance with the final policy that crosswalks the specialty to the ''All Physicians'' PE/HR data, as adopted in the CY 2010 PFS final rule with comment period (74 FR 61752) and discussed in more detail in the CY 2011 PFS final rule with comment period (75 FR 73183). We have incorporated the available utilization data for interventional cardiology, which became a recognized Medicare specialty during 2014. We finalized the use of a proxy PE/HR value for interventional cardiology in the CY 2016 final rule with comment period (80 FR 70892), as there are no PPIS data for this specialty, by crosswalking the PE/HR for from

Cardiology, since the specialties furnish similar services in the Medicare claims data.

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

Section II.A.2.b. of this proposed rule describes the current data sources for specialty-specific indirect costs used in our PE calculations. We allocated 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 incorporated the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we used 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, represented 25 percent of total costs for the specialties that furnished 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 RVUs of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, we added 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 work RVUs of 4.00 and the clinical labor portion of the direct PE RVUs 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 hospital or other facility setting, 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. Medicare makes a separate payment to the facility for its costs of furnishing a service.

(4) Services With Technical Components (TCs) and Professional Components (PCs)

Diagnostic services are generally composed 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 2017 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* This file contains a table that illustrates the calculation of PE RVUs as described below for individual PFS 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, calculate a direct PE scaling factor 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 factor to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not

influence the final direct cost PE RVUs, as long as the same CF is used in Step 2 and Step 5. Different CFs will result in different direct PE scaling factors, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling factors 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 use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. As we stated in the CY 2016 final rule with comment period (80 FR 70894), we believe that the 3-year average will mitigate the need to use dominant or expected specialty instead of the claims data. Because we are incorporating CY 2015 claims data for use in the CY 2017 proposed rates, we believe that the proposed PE RVUs associated with the CY 2017 PFS proposed rule provide a first opportunity to determine whether service-level overrides of claims data are necessary. Currently, in the development of PE RVUs we apply only the overrides that also apply to the MP RVU calculation. Since the proposed PE RVUs include a new year of claims into the 3 year average for the first time, we are seeking comment on the proposed CY 2017 PFS rates and whether or not the incorporation of a new year of utilization data into a three year average mitigates the need for alternative service-level overrides such as a claims-based approach (dominant specialty) or stakeholder-recommended approach (expected specialty) in the development of PE (and MP) RVUs for low-volume codes. Prior year RVUs are available at several locations on the PFS Web site located at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

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 will be allocated using the work RVUs, and for the TC service, indirect PEs will 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 of 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 section.)

(e) Setup File Information

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

TABLE 1—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION

Specialty code	Specialty description
49	Ambulatory surgical center.
50	Nurse practitioner.
51	Medical supply company with certified orthotist.
52	Medical supply company with certified prosthetist.
53	Medical supply company with certified prosthetist-orthotist.
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist.
56	Individual certified prosthetist.
57	Individual certified prosthetist-orthotist.
58	Medical supply company with registered pharmacist.
59	Ambulance service supplier, *e.g.,* private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies.
61	Voluntary health or charitable agencies.
73	Mass immunization roster biller.
74	Radiation therapy centers.
87	All other suppliers (*e.g.,* drug and department stores).
88	Unknown supplier/provider specialty.
89	Certified clinical nurse specialist.
96	Optician.
97	Physician assistant.
A0	Hospital.
A1	SNF.
A2	Intermediate care nursing facility.
A3	Nursing facility, other.
A4	HHA.
A5	Pharmacy.
A6	Medical supply company with respiratory therapist.
A7	Department store.
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.

TABLE 2—APPLICATION OF PAYMENT MODIFIERS TO UTILIZATION FILES—Continued

Modifier	Description	Volume adjustment	Time adjustment
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 proposed rule.

(6) Equipment Cost Per Minute

The equipment cost per minute is calculated as:

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

Where:

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

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.

Maintenance: This factor for maintenance was proposed and finalized during rulemaking for CY 1998 PFS (62 FR 33164).

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. The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The interest rates are listed in Table 3. (See 77 FR 68902 for a thorough discussion of this issue.) We are not proposing any changes to these interest rates for CY 2017.

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

d. Proposed Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2017 direct PE input database, which is available on our Web site under downloads for the CY 2017 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

(1) PE Inputs for Digital Imaging Services

Prior to the CY 2015 PFS rulemaking cycle, the RUC provided a recommendation regarding the PE inputs for digital imaging services. Specifically, the RUC recommended that we remove supply and equipment items associated with film technology from a previously specified list of codes since these items were no longer typical resource inputs. The RUC also recommended that the Picture Archiving and Communication System (PACS) equipment be included for these imaging services since these items had been become typically used in furnishing imaging services. However, since we did not receive any invoices for the PACS system prior to that year's proposed rule, we were unable to determine the appropriate pricing to use for the inputs. For CY 2015, we finalized our proposal to remove the film supply and equipment items, and to create a new equipment item as a proxy for the PACS workstation as a direct expense (79 FR 67561–67563). We used the price associated with ED021 (computer, desktop, w-monitor) to price the new item, ED050 (PACS Workstation Proxy), pending receipt of invoices to facilitate pricing specific to the PACS workstation. Subsequent to establishing payment rates for CY 2015, we received information from several stakeholders regarding pricing for items related to the digital acquisition and storage of images. We received invoices from one stakeholder that facilitated a proposed price update for the PACS workstation in the CY 2016 PFS proposed rule, and we updated the price for the PACS workstation to $5,557 in the CY 2016 PFS final rule with comment period (80 FR 70899).

In addition to the workstation used by the clinical staff acquiring the images and furnishing the TC of the services, a stakeholder also submitted more detailed information regarding a workstation used by the practitioner interpreting the image in furnishing the PC of many of these services.

As we stated in the CY 2015 PFS final rule with comment period (79 FR 67563), we generally believe that workstations used by these practitioners

are more accurately considered indirect costs associated with the PC of the service. However, we understand that the professional workstations for interpretation of digital images are similar in principle to some of the previous film inputs incorporated into the global and technical components of the codes, such as the view box equipment. Given that the majority of these services are reported globally in the nonfacility setting, we believe it is appropriate to include these costs as direct inputs for the associated HCPCS codes. Based on our established methodology in which single codes with professional and technical components are constructed by assigning work RVUs exclusively to the professional component and direct PE inputs exclusively to the technical components, these costs would be incorporated into the PE RVUs of the global and technical component of the HCPCS code.

We stated in the CY 2016 PFS final rule with comment period that the costs of the professional workstation may be analogous to costs related to the use of film previously incorporated as direct PE inputs for these services. We also solicited comments on whether including the professional workstation as a direct PE input for these codes would be appropriate, given that the resulting PE RVUs would be assigned to the global and technical components of the codes. Commenters responded by indicating their approval of the concept of a professional PACS workstation used for interpretation of digital images. We received invoices for the pricing of a professional PACS workstation, as well as additional invoices for the pricing of a mammography-specific version of the professional PACS workstation. The RUC also included these new equipment items in its recommendations for the CY 2017 PFS rulemaking cycle.

Based on our analysis of submitted invoices, we are proposing to price the professional PACS workstation (ED053) at $14,616.93. We are not proposing a change in price for the current technical PACS workstation (ED050), which will remain at a price of $5,557.00.

The price of the professional PACS workstation is based upon individual invoices submitted for the cost of a PC Tower ($1531.52), a pair of 3 MP monitors ($10,500.00 in total), a keyboard and mouse ($84.95), a UPS power backup devices for TNP ($1098.00), and a switch for PACS monitors/workstations ($1402.46).

We are proposing to add the professional PACS workstation to many CPT codes in the 70000 series that use the current technical PACS workstation (ED050) and include professional work for which such a workstation would be used. We are not proposing to add the equipment item to add-on codes since the base codes would include minutes for the item. We are also not proposing to add the item to codes that are therapeutic in nature, as the professional PACS workstation is intended for use in diagnostic services. We are therefore not proposing to add the item to codes in the Radiation Therapy section (77261 through 77799) or the Nuclear Medicine Cardiology section (78414–78499). We also are not proposing to add the item to image guidance codes where the dominant provider is not a radiologist (77002, 77011, 77071, 77077, and 77081) according to the most recent year of claims data, since we believe a single workstation would be more typical in those cases. We have identified approximately 426 codes to which we are proposing to add a professional PACS workstation. Please see Table 4 for the full list of affected codes.

For the professional PACS workstation, we are proposing to assign equipment time equal to the intraservice work time plus half of the preservice work time associated with the codes, since the work time generally reflects the time associated with the professional interpretation. We are proposing half of the preservice work time for the professional PACS workstation, as we do not believe that the practitioner would typically spend all of the preservice work period using the equipment. For older codes that do not have a breakdown of physician work time by service period, and only have an overall physician work time, we are proposing to use half the total work time as an approximation of the intraservice work time plus one half of the preservice work time. In our review of services that contained an existing PACS workstation and had a breakdown of physician work time, we found that half of the total time was a reasonable approximation for the value of intraservice work time plus one half of preservice work time where no such breakdown existed. We also considered using an equipment time formula of the physician intraservice time plus 1 minute (as a stand-in for the physician preservice work time). We are seeking public comment on the most accurate equipment time formula for the professional PACS workstation.

We are seeking public comment on the proposed list of codes that would incorporate either the professional PACS workstation. We are interested in public comment on the codes for which a professional PACS workstation should be included, and whether one of these professional workstations should be included for codes outside the 70000 series. In cases within the 70000 series where radiologists are not the typical specialty reporting the code, such as CPT codes 77002 and 77011, we are asking whether it would be appropriate to add one of the professional PACS workstations to these services.

TABLE 4—CODES WITH PROFESSIONAL PACS WORKSTATION IN THE PROPOSED DIRECT PE INPUT DATABASE

HCPCS	ED053 minutes
70015	12
70030	3
70100	3
70110	4
70120	3
70130	4
70134	4
70140	3
70150	4
70160	3
70190	3
70200	4
70210	3
70220	4
70240	3
70250	4
70260	7
70300	2
70310	3
70320	3
70328	3
70330	22
70332	6
70336	20
70350	3
70355	5
70360	3
70370	4
70371	9
70380	3
70390	5
70450	12
70460	15
70470	18
70480	13
70481	13
70482	14
70490	13
70491	13
70492	14
70540	14
70542	19
70543	19
70544	13
70545	18
70546	18
70547	13
70548	20
70549	25
70551	21
70552	23
70553	28
70554	43
71010	4
71015	3

TABLE 4—CODES WITH PROFESSIONAL PACS WORKSTATION IN THE PROPOSED DIRECT PE INPUT DATABASE—Continued

HCPCS	ED053 minutes
71020	4
71021	4
71022	4
71023	5
71030	4
71034	5
71035	3
71100	5
71101	4
71110	4
71111	5
71120	3
71130	3
71250	18
71260	17
71270	13
71275	28
71550	15
71551	30
71552	28
71555	33
72020	3
72040	4
72050	6
72052	6
72070	4
72072	3
72074	3
72080	3
72081	6
72082	7
72083	8
72084	9
72100	4
72110	6
72114	6
72120	4
72125	18
72126	12
72127	12
72128	18
72129	12
72130	12
72131	18
72132	12
72133	12
72141	23
72142	26
72146	23
72147	26
72148	23
72149	26
72156	28
72157	28
72158	28
72159	31
72170	5
72190	3
72191	28
72192	12
72193	12
72194	12
72195	30
72196	26
72197	30
72198	28
72200	3

TABLE 4—CODES WITH PROFESSIONAL PACS WORKSTATION IN THE PROPOSED DIRECT PE INPUT DATABASE—Continued

HCPCS	ED053 minutes
72202	3
72220	3
72240	19
72255	18
72265	18
72270	23
72275	36
72285	9
72295	9
73000	3
73010	3
73020	3
73030	5
73040	6
73050	3
73060	4
73070	3
73080	4
73085	6
73090	3
73092	3
73100	4
73110	4
73115	6
73120	4
73130	4
73140	3
73200	18
73201	11
73202	12
73206	35
73218	25
73219	25
73220	30
73221	23
73222	23
73223	35
73225	31
73501	4
73502	5
73503	6
73521	5
73522	6
73523	7
73525	6
73551	4
73552	5
73560	4
73564	6
73565	4
73580	6
73590	4
73592	3
73600	4
73610	4
73615	6
73620	4
73630	4
73650	3
73660	3
73700	18
73701	11
73702	12
73706	35
73718	20
73719	25
73720	30

TABLE 4—CODES WITH PROFESSIONAL PACS WORKSTATION IN THE PROPOSED DIRECT PE INPUT DATABASE—Continued

HCPCS	ED053 minutes
73721	23
73722	24
73723	32
73725	33
74000	4
74010	3
74020	4
74022	4
74150	14
74160	17
74170	21
74174	33
74175	28
74176	25
74177	28
74178	33
74181	15
74182	28
74183	35
74185	33
74210	5
74220	5
74230	12
74240	7
74241	7
74245	9
74246	7
74247	18
74249	9
74250	5
74251	33
74260	6
74261	43
74262	48
74263	42
74270	7
74280	23
74283	19
74290	4
74400	18
74410	6
74415	6
74430	4
74440	5
74455	4
74485	6
74710	4
74712	68
74740	5
75557	45
75559	58
75561	50
75563	66
75571	13
75572	25
75573	38
75574	35
75600	6
75605	11
75625	11
75630	13
75635	50
75658	13
75705	20
75710	11
75716	13
75726	11

TABLE 4—CODES WITH PROFESSIONAL PACS WORKSTATION IN THE PROPOSED DIRECT PE INPUT DATABASE—Continued

HCPCS	ED053 minutes
75731	11
75733	13
75736	11
75741	13
75743	16
75746	11
75756	11
75791	33
75809	5
75820	7
75822	11
75825	11
75827	11
75831	11
75833	14
75840	11
75842	14
75860	11
75870	11
75872	11
75880	7
75885	14
75887	14
75889	11
75891	11
75893	6
75901	11
75902	13
75962	6
75966	13
75978	6
75984	8
75989	12
76000	3
76010	3
76080	6
76098	3
76100	6
76101	6
76102	6
76120	5
76376	8
76380	10
76390	28
76506	10
76536	12
76604	9
76700	14
76705	11
76770	13
76775	11
76776	13
76800	14
76801	18
76805	18
76811	35
76813	23
76815	8
76816	18
76817	13
76818	35
76819	28
76820	13
76821	13
76825	45
76826	11
76830	13

TABLE 4—CODES WITH PROFESSIONAL PACS WORKSTATION IN THE PROPOSED DIRECT PE INPUT DATABASE—Continued

HCPCS	ED053 minutes
76831	30
76856	13
76857	10
76870	10
76872	20
76873	40
76881	18
76885	20
76886	15
76936	71
76942	19
76970	8
77012	11
77014	9
77021	53
77053	5
77054	5
77058	50
77059	55
77072	3
77074	5
77075	6
77076	12
77084	15
78012	8
78013	13
78014	13
78015	31
78016	49
78018	29
78070	13
78071	18
78072	23
78075	38
78102	18
78103	22
78104	20
78135	48
78140	40
78185	16
78190	40
78195	30
78201	16
78202	20
78205	20
78206	25
78215	13
78216	22
78226	13
78227	18
78230	19
78231	23
78232	28
78258	27
78261	21
78262	25
78264	13
78265	18
78266	23
78278	18
78290	18
78291	31
78300	15
78305	22
78306	11
78315	11
78320	24

TABLE 4—CODES WITH PROFESSIONAL PACS WORKSTATION IN THE PROPOSED DIRECT PE INPUT DATABASE—Continued

HCPCS	ED053 minutes
78579	8
78580	13
78582	15
78597	13
78598	13
78600	16
78601	18
78605	21
78606	22
78607	29
78610	10
78630	24
78635	36
78645	32
78647	15
78650	40
78660	16
78700	17
78701	18
78707	22
78708	32
78709	40
78710	21
78740	30
78761	20
78800	28
78801	32
78802	24
78803	43
78804	35
78805	25
78806	23
78807	37
79440	24
G0389	9
767X1	13

(2) Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS rule (79 FR 67640–67641), we continue to work on revisions 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 at once for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

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) Clinical Labor Tasks Associated With Digital Imaging

In the CY 2015 PFS rule, we noted that the RUC recommendation regarding inputs for digital imaging services indicated that, as each code is reviewed under the misvalued code initiative, the clinical labor tasks associated with digital technology (instead of film) would need to be addressed. When we reviewed that recommendation, we did not have the capability of assigning standard clinical labor times for the hundreds of individual codes since the direct PE input database did not previously allow for comprehensive adjustments for clinical labor times based on particular clinical labor tasks. Therefore, consistent with the recommendation, we proposed to remove film-based supply and equipment items but maintain clinical labor minutes that were assigned based on film technology.

As noted in the paragraphs above, we continue to improve the direct PE input database by specifying for each code the minutes associated with each clinical labor task. Once completed, this work would allow adjustments to be made to minutes assigned to particular clinical labor tasks related to digital technology that occur in multiple codes, consistent with the changes that were made to individual supply and equipment items. In the meantime, we believe it would be appropriate to establish standard times for clinical labor tasks associated with all digital imaging services for purposes of reviewing individual services at present, and for possible broad-based standardization once the changes to the direct PE input database facilitate our ability to adjust time across services. During the CY 2016 PFS rulemaking cycle, we proposed appropriate standard minutes for five different clinical labor tasks associated with services that use digital imaging technology. In the CY 2016 PFS final rule with comment period (80 FR 70901), we finalized appropriate standard minutes for four of those five activities, which are listed in Table 5.

TABLE 5—CLINICAL LABOR TASKS ASSOCIATED WITH DIGITAL IMAGING TECHNOLOGY

Clinical labor task	Typical minutes
Availability of prior images confirmed	2
Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	2
Review examination with interpreting MD	2
Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	1

We did not finalize standard minutes for the activity ''Technologist QC's images in PACS, checking for all images, reformats, and dose page.'' We agreed with commenters that this task may require a variable length of time depending on the number of images to be reviewed. We stated that it may be appropriate to establish several different standard times for this clinical labor task for a low/medium/high quantity of images to be reviewed, in the same fashion that the clinical labor assigned to clean a surgical instrument package has two different standard times depending on the use of a basic pack (10 minutes) or a medium pack (30 minutes). We solicited public comment and feedback on this subject, with the anticipation of including a proposal in the CY 2017 proposed rule.

We received many comments suggesting that this clinical labor activity should not have a standard time value. Commenters stated that the number of minutes varies significantly for different imaging modalities; and the time is not simply based on the quantity of images to be reviewed, but also the complexity of the images. The commenters recommended that time for this clinical labor activity should be assigned on a code by code basis. We agree with the commenters that the amount of clinical labor needed to check images in a PACS workstation may vary depending on the service. However, we do not believe that this precludes the possibility of establishing standards for clinical labor tasks as we have done in the past by creating multiple standard times, for example, those assigned to cleaning different kinds of scopes. 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. We are proposing to establish a range of appropriate standard minutes for the clinical labor activity Technologist QCs images in PACS, checking for all images, reformats, and dose page. These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We are proposing 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, and 4 minutes as the standard for the complex case. We are proposing the simple case of 2 minutes as the standard for the typical procedure code involving routine use of imaging. These values are based upon a review of the existing minutes assigned for this clinical labor activity; we have determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values. We are proposing to use 2 minutes for services involving routine x-rays (simple), 3 minutes for services involving CTs and MRIs (intermediate), and 4 minutes for the most highly complex services which would exceed these more typical cases. We are soliciting comments regarding the most accurate category—simple, intermediate, or complex for existing codes, and in particular what criteria

might be used to identify complex cases systematically.

(b) Pathology Clinical Labor Tasks

As with the clinical labor tasks associated with digital imaging, many of the currently assigned times for the specialized clinical labor tasks associated with pathology services are not consistent across codes. In reviewing past RUC recommendations for pathology services, we have not identified information that supports the judgment that the same tasks take significantly more or less time depending on the individual service for which they are performed, especially given the high degree of specificity with which the tasks are described. We continue to believe that, in general, a clinical labor task will tend to take the same amount of time to perform as the same clinical labor task when it is performed in a clinically similar service.

Therefore, we developed standard times for clinical labor tasks that we have used in finalizing direct PE inputs in recent years, starting in the CY 2012 PFS final rule with comment period (76 FR 73213). These times were based on our review and assessment of the current times included for these clinical labor tasks in the direct PE input database. We proposed in the CY 2016 PFS proposed rule to establish standard times for a list of 17 clinical labor tasks related to pathology services, and solicited public feedback regarding our proposed standards. Many commenters stated in response to our proposal that they did not support the standardization of clinical labor activities across pathology services. Commenters stated that establishing a single standard time for each clinical labor task was infeasible due to the differences in batch size or number of blocks across different pathology procedures. Several commenters indicated that it might be possible to standardize across codes with the same batch sizes, and urged us to consider pathology-specific details, such as batch size and block number, in the creation of any future standard times for clinical labor tasks related to pathology services.

As we stated in the CY 2016 PFS proposed rule, we developed the proposed standard times based on our review and assessment of the current times included for these clinical labor tasks in the direct PE input database. We believe that, generally speaking, clinical labor tasks with the same description are comparable across different pathology procedures. We believe this to be true based on the comparability of clinical labor tasks in non-pathology services, as well as the high degree of specificity with which most pathology tasks are described relative to clinical labor tasks associated with other PFS services. We concurred with commenters that accurate clinical labor times for pathology codes may be dependent on the number of blocks or batch size typically used for each individual service. However, we also believe that it is appropriate and feasible to establish ''per block'' standards or standards varied by batch size assumptions for many clinical labor activities that would be comparable across a wide range of individual services. We have received detailed information regarding batch size and number of blocks during review of individual pathology services on an intermittent basis in the past. We requested regular submission of these details on the PE worksheets supplied by the RUC as part of the review process for pathology services, as a means to assist in the determination of the most accurate direct PE inputs.

We also stated our belief that many of the clinical labor activities for which we proposed to establish standard times were tasks that do not depend on number of blocks or batch size. Clinical labor activities such as ''Clean room/equipment following procedure'' and ''Dispose of remaining specimens'' would typically remain standard across different services without varying by block number or batch size, with the understanding that additional time may be required above the standard value for a clinical labor task that is part of an unusually complex or difficult service. As a result, we ultimately finalized standard times for 6 of the 17 proposed clinical labor activities in the CY 2016 final rule with comment period (80 FR 70902). We have listed the finalized standard times in Table 6. We are currently proposing no further action on the remaining 11 clinical labor activities pending further action by the RUC (see below).

TABLE 6—STANDARD TIMES FOR CLINICAL LABOR TASKS ASSOCIATED WITH PATHOLOGY SERVICES

Clinical labor task	Standard clinical labor time (minutes)
Accession specimen/prepare for examination	4
Assemble and deliver slides with paperwork to pathologists	0.5
Assemble other light microscopy slides, open nerve biopsy slides, and clinical history, and present to pathologist to prepare clinical pathologic interpretation	0.5
Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure)	1
Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste	1
Prepare, pack and transport specimens and records for in-house storage and external storage (where applicable)	1

We remain committed to the process of establishing standard clinical labor times for tasks associated with pathology services. This may include establishing standards on a per-block or per-batch basis, as we indicated during the previous rulemaking cycle. However, we are aware that the PE Subcommittee of the RUC is currently working to standardize the pathology clinical labor activities they use in making their recommendations. We believe the RUC's efforts to narrow the current list of several hundred pathology clinical labor tasks to a more manageable number through the consolidation of duplicative or highly similar activities into a single description may serve PFS relativity and facilitate greater transparency in PFS ratesetting. We also believe that the RUC's standardization of pathology clinical labor tasks would facilitate our capacity to establish standard times for pathology clinical labor tasks in future rulemaking. Therefore, we are not proposing any additional change to clinical labor tasks associated with pathology services at this time.

(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 are proposing standalone prices for each scope, and separate prices for the video systems that are used with scopes. We would 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 is the ''video system, endoscopy (processor, digital capture, monitor, printer, cart)'' equipment item (ES031), which we are proposing 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 are proposing to use for this re-pricing. We understand that there may be other accessories associated with the use of scopes; we are proposing 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 are also proposing 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 video scope 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 are proposing 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 are proposing 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 plan to propose input prices for these equipment items through future rulemaking.

We have proposed these changes only for the reviewed codes that make use of scopes; this applies to the codes in the Flexible Laryngoscopy family (CPT codes 31575, 31576, 31577, 31578, 315X1, 315X2, 315X3, 31579) (see section II.L) and the Laryngoplasty family (CPT codes 31580, 31584, 31587, 315Y1, 315Y2, 315Y3, 315Y4, 315Y5, 315Y6) (see section II.L) along with updated prices for the equipment items related to scopes utilized by these services. We are also soliciting comment on this separate pricing structure for scopes, scope video systems, and scope accessories, which we could consider proposing to apply to other PFS codes in future rulemaking.

(4) Technical Corrections to Direct PE Input Database

Subsequent to the publication of the CY 2016 PFS final rule with comment period, stakeholders alerted us to several clerical inconsistencies in the direct PE database. We propose to correct these inconsistencies as described below and reflected in the CY 2017 direct PE input database displayed on our Web site under downloads for the CY 2017 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

For CY 2017, we are proposing the following technical corrections:

- For CPT codes 72081–72084, a stakeholder informed us that the equipment time for the PACS workstation (ED050) should be equal to the clinical labor during the service period; the equipment time formula we used for these codes for CY 2016 erroneously included 4 minutes of preservice clinical labor. We agree with the stakeholder that the PACS workstation should use the standard equipment time formula for a PACS workstation for these codes. As a result, we are proposing to refine the ED050 equipment time to 21 minutes for CPT code 72081, 36 minutes for CPT code 72082, 44 minutes for CPT code 72083, and 53 minutes for CPT code 72084 to reflect the clinical labor time associated with these codes. This same commenter also indicated that a number of clinical labor activities had been entered in the database in the incorrect service period for CPT codes 37215, 50432, 50694, and 72081. These clinical labor activities were incorrectly listed in the ''postservice'' period instead of the ''service post'' period. We are proposing to make these technical corrections as well so that the minutes are assigned to the appropriate service period within the direct PE input database.
- Another stakeholder alerted us that Ileoscopy codes 44380, 44381 and 44382 did not include the direct PE input equipment item called the Gomco suction machine (EQ235) and indicated that this omission appeared to be inadvertent. We agree that it was. We have included the item EQ235 in the proposed direct PE input database for CPT code 44380 at a time of 29 minutes, for CPT code 44381 at a time of 39 minutes, and to CPT code 44382 at a time of 34 minutes.

The PE RVUs displayed in Addendum B on our Web site were calculated with the inputs displayed in the CY 2017 direct PE input database.

(5) Restoration of Inputs

Several of the PE worksheets included in the RUC recommendations for CY 2016 contained time for the equipment item ''xenon light source'' (EQ167). Because there appeared to be two special light sources already present (the fiberoptic headlight and the endoscope itself) in the services for which this equipment item was recommended by the RUC, we believed that the use of only one of these light sources would be typical and removed the xenon light equipment time. In the CY 2016 PFS final rule with comment period, we restored the xenon light (EQ167) and removed the fiberoptic headlight (EQ170) with the same number of equipment minutes for CPT codes 30300, 31295, 31296, 31297, and 92511.

We received comments expressing approval for the restoration of the xenon light. However, the commenters also stated that the two light sources were not duplicative, but rather, both a headlight and a xenon light source are required concurrently for otolaryngology procedures when scopes are utilized. The commenters requested that the fiberoptic headlight be restored to these codes.

We agree with the commenters that the use of both light sources would be typical for these procedures. We are therefore proposing to add the fiberoptic headlight (EQ170) to CPT codes 30300,

31295, 31296, 31297, and 92511 at the same number of equipment minutes as the xenon light (EQ167).

(6) 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 2017, we are proposing the following price updates for existing direct PE inputs:

Several commenters wrote to discuss the price of the Antibody Estrogen Receptor monoclonal (SL493). We received information including three invoices with new pricing information regarding the SL493 supply. We are proposing to use this information to propose for the supply item SL493 a price of $14.00 per test, which is the average price based on the invoices that we received in total for the item.

We are also proposing to update the price for two supplies in response to the submission of new invoices. The proposed price for ''antigen, venom'' supply (SH009) reflects an increase from $16.67 to $20.14 per milliliter, and the proposed price for ''antigen, venom, trivespid'' supply (SH010) reflects an increase from $30.22 to $44.05 per milliliter.

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 2017, we note that some stakeholders have submitted invoices for new, revised, or potentially misvalued codes since the February deadline established for code valuation recommendations. To be included a given year's proposed rule, we generally need to receive invoices by the same February deadline. Of course, we will consider invoices submitted as public comments during the comment period following the publication of the proposed rule, and will consider any invoices received after February and/or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices.

B. 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 expense (MP). As required by section 1848(c)(2)(C)(iii) of the Act, beginning in CY 2000, MP RVUs are resource based. Malpractice RVUs for new codes after 1991 were extrapolated from similar existing codes or as a percentage of the corresponding work RVU. 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 uses three primary kinds of data: Specialty-level risk factors based on the collection of specialty-specific MP premium data that represent the actual expense incurred by practitioners to obtain MP insurance; Medicare claims data to determine service level risk factors based on a weighted average risk factors of the specialties that furnish each service, and the higher of the work RVU or clinical labor RVU to adjust the service level risk factor for the intensity and complexity of the service. 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 adjust (or scale) 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 were 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 is applied for the new/revised code and source code, but the work RVU for the new/revised code is 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 for 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. We stated that under this approach, 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.

For CY 2016, we did not propose to discontinue our current approach for determining MP RVUs for new/revised codes. For the new and revised codes for which we proposed work RVUs and PE inputs, we also published the proposed MP crosswalks used to determine their MP RVUs. We address comments regarding valuation of new and revised codes in section II.L of this proposed rule, which makes clear the codes with interim final values for CY 2016 have newly proposed values for CY 2017, all of which are again open for comment. The MP crosswalks for new and revised codes with interim final values were established in the CY 2016 PFS final rule with comment period; we will respond to comments regarding these interim final values in the CY 2017 PFS final rule.

2. Updating Specialty Specific Risk Factors

The proposed CY 2017 GPCI update (eighth update), discussed in section II.E of this proposed rule, reflects updated MP premium data, collected for the purpose of proposing updates to the MP GPCIs. While we could use the updated MP premium data obtained for the purposes of the proposed eighth GPCI update to propose updates to the specialty risk factors used in the calculation of MP RVUs, this would not be consistent with the policy we previously finalized in the CY 2016 PFS final rule with comment period. In that rule, 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. Additionally, consistent with the statutory requirement at section 1848(e)(1)(C) of the Act, only ½ of the adjustment to MP GPCIs would be applied for CY 2017 based on the new

MP premium data. As such, we do not think it would be appropriate to propose to update the specialty risk factors for CY 2017 based on the updated MP premium data that is reflected in the proposed CY 2017 GPCI update. Therefore, we are not currently proposing to update the specialty-risk factors based on the new premium data collected for the purposes of the 3-year GPCI update for CY 2017 at this time. However, we seek comment on whether we should consider doing so, perhaps as early as for 2018, prior to the fourth review and update of MP RVUs that must occur no later than CY 2020.

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 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 and language access for persons with limited English proficiency, as required under Title VI of the Civil Rights Act of 1964. 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 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. With regard to geographic qualifications, § 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 Office of Federal Rural Health Policy (FORHP) 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 the CMS 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 December 31, 2002 **Federal Register** (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. Under this process, we assign any qualifying request to make additions to the list of telehealth services to one of two categories. Revisions to criteria that

we use to review requests in the second category were finalized in the November 28, 2011 **Federal Register** (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 proposed 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 deliver 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.

For the list of telehealth services, see the CMS Web site at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.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. For example, qualifying requests submitted before the end of CY 2016 will be considered for the CY 2018 proposed rule. 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 the CMS 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 2017

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 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 2015 to add various services as Medicare telehealth services effective for CY 2017. The following presents a discussion of these requests, and our proposals for additions to the CY 2017 telehealth list. Of the requests received, we found that four services were sufficiently similar to ESRD-related services currently on the telehealth list to qualify on a category 1 basis. Therefore, we propose to add the following services to the telehealth list on a category 1 basis for CY 2017:

- CPT codes 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; 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).

As we indicated in the CY 2015 final rule (80 FR 41783) for the ESRD-related services (CPT codes 90963–90966) added to the telehealth list for CY 2016, the required clinical examination of the catheter access site must be furnished face-to-face ''hands on'' (without the use of an interactive telecommunications system) by a physician, CNS, NP, or PA. This requirement also applies to CPT codes 90967–90970.

While we did not receive a specific request, we also propose to add two advance care planning services to the telehealth list. We have determined that these services are similar to the annual wellness visits (HCPCS codes G0438 & G0439) currently on the telehealth list:

- CPT codes 99497 (advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family member(s), or surrogate); and 99498 (advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; each additional 30 minutes (list separately in addition to code for primary procedure)).

We also received requests to add services to the telehealth list that do not meet our criteria for Medicare telehealth services. We are not proposing to add the following procedures for the reasons noted:

a. Observation Care: CPT codes—

- 99217 (observation care discharge day management (this code is to be utilized to report all services provided to a patient on discharge from ''observation status'' if the discharge is on other than the initial date of ''observation status.'' To report services to a patient designated as ''observation status'' or ''inpatient status'' and discharged on the same date, use the codes for observation or inpatient care services [including admission and discharge services, 99234–99236 as appropriate.]));
- 99218 (initial observation care, per day, for the evaluation and management

of a patient which requires these three 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 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 family's needs. Usually, the problem(s) requiring admission to ''observation status'' are of low severity. Typically, 30 minutes are spent at the bedside and on the patient's hospital floor or unit);

- 99219 (initial observation care, per day, for the evaluation and management of a patient, which requires these three key components: A comprehensive history; a comprehensive examination; and medical decision making of moderate complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the problem(s) requiring admission to ''observation status'' are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit);
- 99220 (initial observation care, per day, for the evaluation and management of a patient, which requires these three key components: A comprehensive history; a comprehensive examination; and medical decision making of high complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the problem(s) requiring admission to ''observation status'' are of high severity. Typically, 70 minutes are spent at the bedside and on the patient's hospital floor or unit);
- 99224 (subsequent observation care, per day, for the evaluation and management of a patient, which requires at least two of these three key components: Problem focused interval history; problem focused examination; medical decision making that is straightforward or of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the patient is stable, recovering, or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit);
- 99225 (subsequent observation care, per day, for the evaluation and management of a patient, which requires at least two of these three key components: An expanded problem focused interval history; an expanded problem focused examination; medical decision making of moderate complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the bedside and on the patient's hospital floor or unit);
- 99226 (subsequent observation care, per day, for the evaluation and management of a patient, which requires at least two of these three key components: A detailed interval history; a detailed examination; medical decision making of high complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit);
- 99234 (observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these three 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 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 family's needs. Usually the presenting problem(s) requiring admission are of low severity. Typically, 40 minutes are spent at the bedside and on the patient's hospital floor or unit);
- 99235 (observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these three key components: A comprehensive history; a comprehensive examination; and medical decision making of moderate complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually the presenting problem(s) requiring admission are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit);
- 99236 (observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these three key components: A comprehensive history; a comprehensive examination; and medical decision making of high complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually the presenting problem(s) requiring admission are of high severity. Typically, 55 minutes are spent at the bedside and on the patient's hospital floor or unit);

The request to add these observation services referenced various studies supporting the use of observation units. The studies indicated that observation units provide safe, cost effective care to patients that need ongoing evaluation and treatment beyond the emergency department visit by having reduced hospital admissions, shorter lengths of stay, increased safety and reduced cost. Additional studies cited indicated that observation units reduce the work load on emergency department physicians, and reduce emergency department overcrowding.

In the CY 2005 PFS proposed rule (69 FR 47510), we considered a request but did not propose to add the observation CPT codes 99217–99220 to the list of Medicare telehealth services on a category two basis for the reasons described in that rule. The most recent request did not include any information that would cause us to question the previous evaluation under the category one criterion, which has not changed, regarding the significant differences in patient acuity between these services and services on the telehealth list. (69 FR 66277) While the request included evidence of the general benefits of observation units, it did not include specific information demonstrating that the services described by these codes provided clinical benefit when furnished via telehealth, which is necessary for us to consider these codes on a category two basis. Therefore, we are not proposing to add these services to the list of approved telehealth services.

b. Emergency Department Visits: CPT Codes—

- 99281 (emergency department visit for the evaluation and management of a patient, which requires these three key components: A problem focused history; a problem focused examination; and straightforward medical decision making. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the presenting problem(s) are self-limited or minor);
- 99282 (emergency department visit for the evaluation and management of a patient, which requires these three key components: An expanded problem focused history; an expanded problem focused examination; and medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the presenting problem(s) are of low to moderate severity);
- 99283 (emergency department visit for the evaluation and management of a patient, which requires these three key components: An expanded problem focused history; an expanded problem focused examination; and medical decision making of moderate complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the presenting problem(s) are of moderate severity);
- 99284 (emergency department visit for the evaluation and management of a patient, which requires these three key components: A detailed history; a detailed examination; and medical decision making of moderate complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the presenting problem(s) are of high severity, and require urgent evaluation by the physician, or other qualified health care professionals but do not pose an immediate significant threat to life or physiologic function); and
- 99285 (emergency department visit for the evaluation and management of a patient, which requires these three key components within the constraints imposed by the urgency of the patient's clinical condition and mental status: A comprehensive history; a comprehensive examination; and medical decision making of high complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the presenting problem(s) are of high severity and pose an immediate significant threat to life or physiologic function).

In the CY 2005 PFS proposed rule (69 FR 47510), we considered a request but did not propose to add the emergency department visit CPT codes 99281–99285 to the list of Medicare telehealth services for the reasons described in that rule.

The current request to add the emergency department E/M services stated that the codes are similar to outpatient visit codes (CPT codes 99201–99215) that have been on the telehealth list since CY 2002. As we noted in the CY 2005 PFS final rule, while the acuity of some patients in the emergency department might be the same as in a physician's office; we believe that, in general, more acutely ill patients are more likely to be seen in the emergency department, and that difference is part of the reason there are separate codes describing evaluation and management visits in the Emergency Department setting. The practice of emergency medicine often requires frequent and fast-paced patient reassessments, rapid physician interventions, and sometimes the continuous physician interaction with ancillary staff and consultants. This work is distinctly different from the pace, intensity, and acuity associated with visits that occur in the office or outpatient setting. Therefore, we are not proposing to add these services to the list of approved telehealth services on a category one basis.

The requester did not provide any studies supporting the clinical benefit of managing emergency department patients with telehealth which is necessary for us to consider these codes on a category two basis. Therefore, we are not proposing to add these services to the list of approved telehealth services on a category two basis.

Many requesters of additions to the telehealth list urged us to consider the potential value of telehealth for providing beneficiaries access to needed expertise. We note that if clinical guidance or advice is needed in the emergency department setting, a consultation may be requested from an appropriate source, including consultations that are currently included on the list of telehealth services.

c. Critical Care Evaluation and Management: CPT Codes—

- 99291 (critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); and 99292 (critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (list separately in addition to code for primary service).

We previously considered and rejected adding these codes to the list of Medicare telehealth services in the CY 2009 PFS final rule (74 FR 69744) on a category 1 basis because, due to the acuity of critically ill patients, we did not believe critical care services are similar to any services on the current list of Medicare telehealth services. In that rule, we said that critical care services must be evaluated as category 2 services. Because we considered critical care services under category 2, we needed to evaluate whether these are services for which telehealth can be an adequate substitute for a face-to-face encounter, based on the category 2 criteria at the time of that request. We had no evidence suggesting that the use of telehealth could be a reasonable surrogate for the face-to-face delivery of this type of care.

The American Telemedicine Association (ATA) submitted a new request for CY 2016 that cited several studies to support adding these services on a category 2 basis. To qualify under category 2, we would need evidence that the service furnished via telehealth is still described accurately by the requested code and produces a clinical benefit for the patient via telehealth. However, in reviewing the information provided by the ATA and a study titled, ''Impact of an Intensive Care Unit Telemedicine Program on Patient Outcomes in an Integrated Health Care System,'' published July 2014 in *JAMA Internal Medicine,* which found no evidence that the implementation of ICU telemedicine significantly reduced mortality rates or hospital length of stay, which could be indicators of clinical benefit. Therefore, we stated that we do not believe that the submitted evidence demonstrates a clinical benefit to patients. Therefore, we did not propose to add these services on a category 2 basis to the list of Medicare telehealth services for CY 2016 (80 FR 71061).

This year, requesters cited additional studies to support adding critical care

services on a category 2 basis. Eight of the studies dealt with telestroke and one with teleneurology. Telestroke is an approach that allows a neurologist to provide remote treatment to vascular stroke victims. Teleneurology offers consultations for neurological problems from a remote location. It may be initiated by a physician or a patient, for conditions such as headaches, dementia, strokes, multiple sclerosis and epilepsy.

However, according to the literature, the management of stroke via telehealth requires more than a single practitioner and is distinct from the work described by the E/M codes. One additional study cited involved pediatric patients, while another noted that the Department of Defense has used telehealth to provide critical care services to hospitals in Guam for many years. Another reference study indicated that consulting intensivists thought that telemedicine consultations were superior to telephone consultations. In all of these cases, we believe the evidence demonstrates that interaction between these patients and distant site practitioners can have clinical benefit. However, we do not agree that the kinds of services described in the study are those that are included in the critical care E/M codes. We note that CPT guidance makes clear that a variety of other services are bundled into the payment rates for critical care, including gastric intubations and vascular access procedures among others We do not believe these kinds of services are furnished via telehealth. Public comments, included cited studies, can be viewed at *https://www.regulations.gov/#!documentDetail;D=CMS-2015-0081-0002*. Therefore, we are not proposing to add these services to the list of Medicare telehealth services for CY 2017.

However, we are persuaded by the requests that we recognize the potential benefit of critical care consultation services that are furnished remotely. We note that there are currently codes on the telehealth list that could be reported when consultation services are furnished to critically ill patients. But in consideration of these public requests, we recognize that there may be greater resource costs involved in furnishing these services relative to the existing telehealth consultation codes. We also agree with the requesters that there may be potential benefits of remote care by specialists for these patients. For these reasons, we think it would be advisable to create a coding distinction between telehealth consultations for critically ill patients relative to telehealth consultations for other hospital patients. Such a coding distinction would allow us to recognize the additional resource costs in terms of time and intensity involved in furnishing such services under the conditions where remote, intensive consultation is required to provide access to appropriate care for the critically ill patient. We recognize that the current set of codes may not adequately describe such services because current E/M coding presumes that the services are occurring in-person, in which case the expert care would be furnished in a manner described by the current codes for critical care.

Therefore, we are proposing to make payment through new codes, initial and subsequent, used to describe critical care consultations furnished via telehealth. This coding would provide a mechanism to report an intensive telehealth consultation service, initial or subsequent, for the critically ill patient under the circumstance when a qualified health care professional has in-person responsibility for the patient but the patient benefits from additional services from a distant-site consultant specially trained in providing critical care services. We propose limiting these services to once per day per patient. Like the other telehealth consultations, these services would be valued relative to existing E/M services (see Section II.L.2.b for proposed code valuations).

More details on the new coding (GTTT1 and GTTT2) and proposed valuation for these services are discussed in section II.L. of this proposed rule and the proposed RVUs for this service are included in Addendum B of this proposed rule. Like the other telehealth consultation codes, we are proposing that these services would be added to the telehealth list and would be subject to the geographic and other statutory restrictions that apply to telehealth services.

We request comment on this proposal, specifically as to whether the use of new coding would create a helpful distinction between telehealth consultations for critically ill patients relative to telehealth consultations for other hospital patients. We are also specifically interested in comments on how these services would be distinguished from existing critical care services and examples of different scenarios when each code would be appropriate. Such comments will help us to refine provider communication materials.

d. Psychological Testing: CPT Codes—

- 96101 (psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, *e.g.,* MMPI, Rorschach, WAIS), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report);
- 96102 psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, *e.g.,* MMPI and WAIS), with qualified health care professional interpretation and report, administered by technician, per hour of technician time, face-to-face);
- 96118 Neuropsychological testing (*e.g.,* Halstead-Reitan neuropsychological battery, Wechsler memory scales and Wisconsin card sorting test), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report); and,
- 96119 Neuropsychological testing (*e.g.,* Halstead-Reitan neuropsychological battery, Wechsler memory scales and Wisconsin card sorting test), with qualified health care professional interpretation and report, administered by technician, per hour of technician time, face-to-face).

Requesters indicated that there is nothing in the Minnesota Multiphasic Personality Inventory (MMPI), the Rorschach inkblot test, the Wechsler Adult Intelligence Scale (WAIS), the Halstead-Reitan Neuropsychological Battery and Allied Procedures, or the Wisconsin Card Sorting Test (WCST), that cannot be done via telehealth nor is different than neurological tests done for Parkinson's disease, seizure medication side effects, gait assessment, nor any of the many neurological examinations done via telehealth with the approved outpatient office visit and inpatient visit CPT codes currently on the telehealth list. As an example, requesters indicated that the MPPI is administered by a computer, which generates a report that is interpreted by the clinical psychologist, and that the test requires no interaction between the clinician and the patient.

We previously considered the request to add these codes to the Medicare telehealth list in the CY 2015 final rule (79 FR 67600). We decided not to add these codes, indicating that these services are not similar to other services on the telehealth list because they require close observation of how a patient responds. We noted that the requesters did not submit evidence supporting the clinical benefit of furnishing these services via telehealth so that we could evaluate them on a

category 2 basis. While we acknowledge that requesters believe that some of these tests require minimal, if any, interaction between the clinician and patient, we disagree. We continue to believe that successful completion of the tests listed as examples in these codes require the clinical psychologist to closely observe the patient's response, which cannot be performed via telehealth. Some patient responses, for example, sweating and fine tremors, may be missed when the patient and examiner are not in the same room. Therefore, we are not proposing to add these services to the list of Medicare telehealth services for CY 2017.

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

• 92507 (treatment of speech, language, voice, communication, and auditory processing disorder; individual); and, 92508 (treatment of speech, language, voice, communication, and auditory processing disorder; group, 2 or more individuals); 92521 (evaluation of speech fluency (*e.g.,* stuttering, cluttering)); 92522 (evaluation of speech sound production (*e.g.,* articulation, phonological process, apraxia, dysarthria)); 92523 (evaluation of speech sound production (*e.g.,* articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (*e.g.,* receptive and expressive language)); 92524 (behavioral and qualitative analysis of voice and resonance); (evaluation of oral and pharyngeal swallowing function); 92526 (treatment of swallowing dysfunction or oral function for feeding); 92610 (evaluation of oral and pharyngeal swallowing function); CPT codes 97001 (physical therapy evaluation); 97002 (physical therapy re-evaluation); 97003 (occupational therapy evaluation); 97004 (occupational therapy re-evaluation); 97110 (therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility); 97112 (therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, or proprioception for sitting or standing activities); 97116 (therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)); 97532 (development of cognitive skills to improve attention, memory, problem solving (includes compensatory training), direct (one-on-one) patient contact, each 15 minutes); 97533 (sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one-on-one) patient contact, each 15 minutes); 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); 97537 (community/work reintegration training (*e.g.,* shopping, transportation, money management, avocational activities or work environment/modification analysis, work task analysis, use of assistive technology device/adaptive equipment), direct one-on-one contact, each 15 minutes); 97542 (wheelchair management (*e.g.,* assessment, fitting, training), each 15 minutes); 97750 (physical performance test or measurement (*e.g.,* musculoskeletal, functional capacity), with written report, each 15 minutes); 97755 (assistive technology assessment (*e.g.,* to restore, augment or compensate for existing function, optimize functional tasks and maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes); 97760 Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(s), lower extremity(s) and/or trunk, each 15 minutes); 97761 (prosthetic training, upper and lower extremity(s), each 15 minutes); and 97762 (checkout for orthotic/prosthetic use, established patient, each 15 minutes).

The statute defines who is an authorized practitioner of telehealth services. Physical therapists, occupational therapists and speech-language pathologists are not authorized practitioners of telehealth under section 1834(m)(4)(E) of the Act, as defined in section 1842(b)(18)(C) of the Act. Because the above services are predominantly furnished by physical therapists, occupational therapists and speech-language pathologists, we do not believe it would be appropriate to add them to the list of telehealth services at this time. One requester suggested that we can add telehealth practitioners without legislation, as evidenced by the addition of nutritional professionals. However, we do not believe we have such authority and note that nutritional professionals are included as practitioners in the definition at section 1834(b)(18)(C)(vi) of the Act, and thus, are within the statutory definition of telehealth practitioners. Therefore, we are not proposing to add these services to the list of Medicare telehealth services for CY 2017.

In summary, we propose to add the following codes to the list of Medicare telehealth services beginning in CY 2017 on a category 1 basis:

• ESRD-related services 90967 through 90970. The required clinical examination of the catheter access site must be furnished face-to-face ''hands on'' (without the use of an interactive telecommunications system) by a physician, CNS, NP, or PA.

• Advance care planning (CPT codes 99497 and 99498).

• Telehealth Consultations for a Patient Requiring Critical Care Services (GTTT1 and GTTT2)

We remind all interested stakeholders that we are currently soliciting public requests to add services to the list of Medicare telehealth services. To be considered during PFS rulemaking for CY 2018, these requests must be submitted and received by December 31, 2016. 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. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, we refer readers to the CMS Web site at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

4. Place of Service (POS) Code for Telehealth Services

CMS has received multiple requests from various stakeholders to establish a POS code to identify services furnished via telehealth. These requests have come from other payers, but may also be related to confusion concerning whether to use the POS where the distant site physician is located or the POS where the patient is located. The process for establishing POS codes, is managed by the POS Workgroup within CMS, is available for use by all payers, and is not contingent upon Medicare PFS rulemaking. However, if such a POS code were to be created, in order to make it valid for use in Medicare, we would have to determine the appropriate payment rules associated with the code. Therefore, we are proposing how a POS code for telehealth would be used under the PFS with the expectation that, if such a code is available, it would be used as early as January 1, 2017. We propose that the physicians or practitioners furnishing telehealth services would be required to report the telehealth POS code to

indicate that the billed service is furnished as a telehealth service from a distant site.

Our proposed requirement for physicians and practitioners to use the telehealth POS code to report that telehealth services were furnished from a distant site would improve payment accuracy and consistency in telehealth claims submission. Currently, for services furnished via telehealth, we have instructed practitioners to report the POS code that would have been reported had the service been furnished in person. However, some practitioners use the POS where they are located when the service is furnished, while others use the POS corresponding to the patient's location.

Under the PFS, the POS code determines whether a service is paid using the facility or non-facility practice expense relative value units (PE RVUs). The facility rate is paid when a service is furnished in a location where Medicare is making a separate facility payment to an entity other than the physician or practitioner that is intended to reflect the facility costs associated with the service (clinical staff, supplies and equipment). We note that in accordance with section 1834(m)(2)(B) of the Act, the payment amount for the telehealth facility fee paid to the originating site is a national fee, paid without geographic or site of service adjustments that generally are made for payments to different kinds of Medicare providers and suppliers. In the case of telehealth services, we believe that facility costs (clinical staff, supplies, and equipment) associated with the provision of the service would generally be incurred by the originating site, where the patient is located, and not by the practitioner at the distant site. And, by statute, the Medicare pays a fee to the site that hosts the patient. This is analogous to the circumstances under which the facility PE RVUs are used to pay for services under the PFS. Therefore, we are proposing to use the facility PE RVUs to pay for telehealth services reported by physicians or practitioners with the telehealth POS code. We note that there are only three codes on the telehealth list with a difference greater than 1.0 PE RVUs between the facility PE RVUs and the non-facility PE RVUs. The remainder of the physician payments for telehealth services would be unchanged by this proposal. We do not anticipate that this proposal would result in a significant change in the total payment for the majority of services on the telehealth list. Moreover, many practitioners already use a facility POS when billing for telehealth services (those that report the POS of the originating site where the beneficiary is located). The proposed policy to use the telehealth POS code for telehealth services would not affect payment for telehealth services for these practitioners.

The POS code for telehealth would not apply to originating sites billing the facility fee. Originating sites are not furnishing a service via telehealth since the patient is physically present in the facility. Accordingly, the originating site would continue to use the POS code that applies to the type of facility where the patient is located.

We are also proposing a change to our regulation at § 414.22(b)(5)(i)(A) that addresses the PE RVUs used in different settings. These proposed revisions would improve clarity regarding our current and proposed policies. Specifically, we are proposing to amend this section to specify that the facility PE RVUs are paid for practitioner services furnished via telehealth under § 410.78. In addition, we are proposing a change to resolve any potential ambiguity and clarify that payment under the PFS is made at the facility rate (facility PE RVUs) when services are furnished in a hospital but for which the hospital is not being paid. Finally, to streamline the existing regulation, we are also proposing to delete § 414.32 of our regulation that refers to the calculating of payments for certain services prior to 2002.

This proposed change is aligned with regulatory changes being proposed in the ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Provider-Based Departments'' proposed rule to implement section 603 of the Bipartisan Budget Act of 2015. In that proposed rule, we discuss payment rates for services furnished to patients in off-campus provider-based departments.

D. 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.B. of this proposed 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 the 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 also 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/documents/reports/Mar06_EntireReport.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/documents/reports/march-2009-report-to-congress-medicare-payment-policy.pdf?sfvrsn=0*), 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 over 1,671 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, we finalized our policy to consolidate the review of physician work and PE at the same time (76 FR 73055 through 73958), 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, 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 (73 FR 38589). 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. 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.

3. Validating RVUs of Potentially Misvalued Codes

Section 1848(c)(2)(L) of the Act requires the Secretary to establish a formal process to validate RVUs under the PFS. The Act specifies that the validation process may include validation of work elements (such as time, mental effort and professional judgment, technical skill and physical effort, and stress due to risk) involved with furnishing a service and may include validation of the pre-, post-, and intra-service components of work. The Secretary is directed, as part of the validation, to validate a sampling of the work RVUs of codes identified through any of the 16 categories of potentially misvalued codes specified in section 1848(c)(2)(K)(ii) of the Act. Furthermore, the Secretary may conduct the validation using methods similar to those used to review potentially misvalued codes, including conducting surveys, other data collection activities, studies, or other analyses as the Secretary determines to be appropriate to facilitate the validation of RVUs of services.

In the CY 2011 PFS proposed rule (75 FR 40068) and CY 2012 PFS proposed rule (76 FR 42790), we solicited public comments on possible approaches, methodologies, and data sources that we should consider for a validation process. A summary of the comments along with our responses are included in the CY 2011 PFS final rule with comment period (75 FR 73217) and the CY 2012 PFS final rule with comment period (73054 through 73055).

We contracted with two outside entities to develop validation models for RVUs.

Given the central role of time in establishing work RVUs and the concerns that have been raised about the current 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. The Urban Institute collected data by directly observing the delivery of services and through the use of electronic health records for services selected by the contractor in consultation with CMS and is using this data to produce objective time estimates. We expect the final Urban Institute report will be made available on the CMS Web site later this summer.

The second contract is with the RAND Corporation, which used available data to build a validation model to predict work RVUs and the individual components of work RVUs, time and intensity. The model design was informed by the statistical methodologies and approach used to develop the initial work RVUs and to identify potentially misvalued procedures under current CMS and RUC processes. RAND consulted with a technical expert panel on model design issues and the test results. The RAND report is available under downloads on the Web site for the CY 2015 PFS Final Rule with Comment Period at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS–1612–FC.html*.

After posting RAND's report on the models and results on our Web site, we received comments indicating that the models did not adequately address global surgery services due to the lack of available data on included visits. Therefore, we modified the RAND contract to include the development of G-codes that could be used to collect data about post-surgical follow-up visits on Medicare claims to meet the requirements in section 1848(c)(8)(B) of the Act regarding collection of data on global services. Our proposals related to this data collection requirement are discussed in section II.D.6. Also, the data from this project would provide information that would allow the time for these services to be included in the model for validating RVUs.

4. CY 2017 Identification and Review of Potentially Misvalued Services

a. 0-day Global Services That Are Typically Billed With an Evaluation and Management (E/M) Service With Modifier 25

Because routine E/M is included in the valuation of codes with 0-, 10-, and 90-day global periods, Medicare only makes separate payment for E/M services that are provided in excess of those considered included in the global procedure. In such cases, the physician would report the additional E/M service with Modifier 25, which is defined as a significant, separately identifiable E/M service performed by the same physician on the day of a procedure above and beyond other services provided or beyond the usual preservice and postservice care associated with the procedure that was performed. Modifier 25 allows physicians to be paid for E/M services that would otherwise be denied as bundled.

In reviewing misvalued codes, both CMS and the RUC have often considered how frequently particular codes are reported with E/M codes to account for potential overlap in resources. Some stakeholders have expressed concern with this policy especially with regard to the valuation of 0-day global services that are typically billed with a separate E/M service with the use of Modifier 25. For example, when we established our valuation of the osteopathic manipulation services, described by CPT codes 98925–98929, we did so with the understanding that these codes are usually reported with E/M codes.

Medicare claims data for CY 2015 show that 19 percent of the codes that describe 0-day global services were billed over 50 percent of the time with an E/M with Modifier 25. Since routine E/M is included in the valuation of 0-day global services, we believe that the routine billing of separate E/M services may indicate a possible problem with the valuation of the bundle, which is intended to include all the routine care associated with the service.

We believe that reviewing the procedure codes typically billed with an E/M with Modifier 25 as potentially misvalued may be one avenue to improve valuation of these services. To develop the CY 2017 proposed list of potentially misvalued services in this category, we identified 0-day global codes billed with an E/M 50 percent of the time or more, on the same day of service, with the same physician and same beneficiary. To prioritize review of these potentially misvalued services, we are identifying the codes that have not been reviewed in the last 5 years, and with greater than 20,000 allowed services. Table 7 lists the 83 codes that meet these review criteria and we are proposing these as potentially misvalued for CY 2017. We request public input on additional ways to address appropriate valuations for all services that are typically billed with an E/M with Modifier 25.

TABLE 7—0-DAY GLOBAL SERVICES THAT ARE TYPICALLY BILLED WITH AN EVALUATION AND MANAGEMENT (E/M) SERVICE WITH MODIFIER 25

HCPCS	Long descriptor
11000	Removal of inflamed or infected skin, up to 10% of body surface.
11100	Biopsy of single growth of skin or tissue.
11300	Shaving of 0.5 centimeters or less skin growth of the trunk, arms, or legs.
11301	Shaving of 0.6 centimeters to 1.0 centimeters skin growth of the trunk, arms, or legs.
11302	Shaving of 1.1 to 2.0 centimeters skin growth of the trunk, arms, or legs.
11305	Shaving of 0.5 centimeters or less skin growth of scalp, neck, hands, feet, or genitals.
11306	Shaving of 0.6 centimeters to 1.0 centimeters skin growth of scalp, neck, hands, feet, or genitals.
11307	Shaving of 1.1 to 2.0 centimeters skin growth of scalp, neck, hands, feet, or genitals.
11310	Shaving of 0.5 centimeters or less skin growth of face, ears, eyelids, nose, lips, or mouth.
11311	Shaving of 0.6 centimeters to 1.0 centimeters skin growth of face, ears, eyelids, nose, lips, or mouth.
11312	Shaving of 1.1 to 2.0 centimeters skin growth of face, ears, eyelids, nose, lips, or mouth.
11740	Removal of blood accumulation between nail and nail bed.
11755	Biopsy of finger or toe nail.
11900	Injection of up to 7 skin growths.
11901	Injection of more than 7 skin growths.
12001	Repair of wound (2.5 centimeters or less) of the scalp, neck, underarms, trunk, arms or legs.
12002	Repair of wound (2.6 to 7.5 centimeters) of the scalp, neck, underarms, genitals, trunk, arms or legs.
12004	Repair of wound (7.6 to 12.5 centimeters) of the scalp, neck, underarms, genitals, trunk, arms or legs.
12011	Repair of wound (2.5 centimeters or less) of the face, ears, eyelids, nose, lips, or mucous membranes.
12013	Repair of wound (2.6 to 5.0 centimeters) of the face, ears, eyelids, nose, lips, or mucous membranes.
17250	Application of chemical agent to excessive wound tissue.
20526	Injection of carpal tunnel.
20550	Injections of tendon sheath, ligament, or muscle membrane.
20551	Injections of tendon attachment to bone.
20552	Injections of trigger points in 1 or 2 muscles.
20553	Injections of trigger points in 3 or more muscles.
20600	Aspiration or injection of small joint or joint capsule.
20604	Arthrocentesis, aspiration or injection, small joint or bursa (e.g., fingers, toes); with ultrasound guidance, with permanent recording and reporting.
20605	Aspiration or injection of medium joint or joint capsule.
20606	Arthrocentesis, aspiration or injection, intermediate joint or bursa (e.g., temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); with ultrasound guidance, with permanent recording and reporting.
20610	Aspiration or injection of large joint or joint capsule.
20611	Arthrocentesis, aspiration or injection, major joint or bursa (e.g., shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting.
20612	Aspiration or injection of cysts.
29105	Application of long arm splint (shoulder to hand).
29125	Application of non-moveable, short arm splint (forearm to hand).
29515	Application of short leg splint (calf to foot).
29540	Strapping of ankle or foot.
29550	Strapping of toes.
30901	Simple control of nose bleed.
30903	Complex control of nose bleed.
31231	Diagnostic examination of nasal passages using an endoscope.
31238	Control of nasal bleeding using an endoscope.
31500	Emergent insertion of breathing tube into windpipe cartilage using an endoscope.
31575	Diagnostic examination of voice box using flexible endoscope.
31579	Examination to assess movement of vocal cord flaps using an endoscope.
31645	Aspiration of lung secretions from lung airways using an endoscope.
32551	Removal of fluid from between lung and chest cavity, open procedure.
32554	Removal of fluid from chest cavity.
40490	Biopsy of lip.
43760	Change of stomach feeding, accessed through the skin.
45300	Diagnostic examination of rectum and large bowel using an endoscope.
46600	Diagnostic examination of the anus using an endoscope.
51701	Insertion of temporary bladder catheter.
51702	Insertion of indwelling bladder catheter.
51703	Insertion of indwelling bladder catheter.
56605	Biopsy of external female genitals.
57150	Irrigation of vagina or application of drug to treat infection.
57160	Fitting and insertion of vaginal support device.
58100	Biopsy of uterine lining.
64405	Injection of anesthetic agent, greater occipital nerve.
64418	Injection of anesthetic agent, collar bone nerve.
64455	Injections of anesthetic or steroid drug into nerve of foot.
65205	Removal of foreign body in external eye, conjunctiva.
65210	Removal of foreign body in external eye, conjunctiva or sclera.
65222	Removal of foreign body, external eye, cornea with slit lamp examination.
67515	Injection of medication or substance into membrane covering eyeball.
67810	Biopsy of eyelid.
67820	Removal of eyelashes by forceps.

TABLE 7—0-DAY GLOBAL SERVICES THAT ARE TYPICALLY BILLED WITH AN EVALUATION AND MANAGEMENT (E/M) SERVICE WITH MODIFIER 25—Continued

HCPCS	Long descriptor
68200	Injection into conjunctiva.
69100	Biopsy of ear.
69200	Removal of foreign body from ear canal.
69210	Removal of impact ear wax, one ear.
69220	Removal of skin debris and drainage of mastoid cavity.
92511	Examination of the nose and throat using an endoscope.
92941	Insertion of stent, removal of plaque or balloon dilation of coronary vessel during heart attack, accessed through the skin.
92950	Attempt to restart heart and lungs.
98925	Osteopathic manipulative treatment to 1–2 body regions.
98926	Osteopathic manipulative treatment to 3–4 body regions.
98927	Osteopathic manipulative treatment to 5–6 body regions.
98928	Osteopathic manipulative treatment to 7–8 body regions.
98929	Osteopathic manipulative treatment to 9–10 body regions.
G0168	Wound closure utilizing tissue adhesive(s) only.
G0268	Removal of impacted cerumen (one or both ears) by physician on same date of service as audiologic function testing.

b. End-Stage Renal Disease Home Dialysis Services (CPT Codes 90963 Through 90970)

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

The CPT Editorial Panel created new CPT codes to replace the G-codes for monthly ESRD-related services, and we accepted the new codes for use under the PFS in CY 2009. The CPT codes created were 90963–90966 for monthly ESRD-related services for home dialysis patient and CPT codes 90967–90970 for dialysis with less than a full month of services.

In a GAO report titled ''END-STAGE RENAL DISEASE Medicare Payment Refinements Could Promote Increased Use of Home Dialysis'' dated October 2015, *http://www.gao.gov/products/GAO-16-125,* the GAO stated that experts and stakeholders they interviewed indicated that home dialysis could be clinically appropriate for at least half of patients. Also, at a meeting in 2013, the chief medical officers of 14 dialysis facility chains jointly estimated that a realistic target for home dialysis would be 25 percent of dialysis patients. The GAO noted that CMS data showed that about 10 percent of adult Medicare dialysis patients use home dialysis as of March 2015.

In the report, the GAO noted that CMS intended for the existing payment structure to create an incentive for physicians to prescribe home dialysis, because the monthly payment rate for managing the dialysis care of home patients, which requires a single in-person visit, was approximately equal to the rate for managing and providing two to three visits to ESRD center-based patients. However, GAO found that, in 2013, the rate of $237 for managing home patients was lower than the average payment of $266 and maximum payment of $282 for managing ESRD center-based patients. The GAO stated that this difference in payment rates may discourage physicians from prescribing home dialysis.

Physician associations and other physicians GAO interviewed stated that the visits with home patients are often longer and more comprehensive than in-center visits; this is in part because physicians may conduct visits with individual home patients in a private setting, but they may be able to more easily visit multiple in-center patients on a single day as they receive dialysis. The physician associations GAO interviewed also said that they may spend a similar amount of time outside of visits to manage the care of home patients and that they are required to provide at least one visit per month to perform a complete assessment of the patient.

It is important to note that, as stated in the CY 2011 PFS final rule with comment period (75 FR 73296), we believe that furnishing monthly face-to-face visits is an important component of high quality medical care for ESRD patients being dialyzed at home and generally would be consistent with the current standards of medical practice. However, we also acknowledged that extenuating circumstances may arise that make it difficult for the MCP physician (or NPP) to furnish a visit to a home dialysis patient every month. Therefore, we allow Medicare contractors the discretion to waive the requirement for a monthly face-to-face visit for the home dialysis MCP service on a case-by-case basis, for example, when the MCP physician's (or NPP's) notes indicate that the MCP physician (or NPP) actively and adequately managed the care of the home dialysis patient throughout the month.

The GAO recommended, and we agreed, that CMS examine Medicare policies for monthly payments to physicians to manage the care of dialysis patients and revise them if necessary to ensure that these policies are consistent with our goal of encouraging the use of home dialysis among patients for whom it is appropriate. Therefore, we are proposing to identify CPT codes 90963 through 90970 as potentially misvalued codes based on the volume of claims submitted for these services relative to those submitted for facility ESRD services.

c. Direct PE Input Discrepancies

i. Appropriate Direct PE Inputs Involved in Procedures Involving Endoscopes

Stakeholders have raised concerns about potential inconsistencies with the inputs and the prices related to endoscopic procedures in the direct PE database. Upon review, we noted that there are 45 different pieces of endoscope related-equipment and 25 different pieces of endoscope related-supplies that are currently associated with these services. Relative to other kinds of equipment items in the direct PE input, these items are much more varied and used for many fewer services. Given the frequency with which individual codes can be reviewed and the importance of standardizing inputs for purposes of maintaining relativity across PFS services, we believe that this unusual degree of variation is likely to result in code misvaluation. To facilitate efficient review of this particular kind of misvaluation, and because we believe that stakeholders will prefer the opportunity to contribute to such standardization, we request that stakeholders like the RUC review and make recommendations on the appropriate endoscopic equipment and supplies typically provided in all endoscopic procedures for each anatomical body region, along with their appropriate prices.

ii. Appropriate Direct PE Inputs in the Facility Post-Service Period When Post-Operative Visits Are Excluded

We identified a potential inconsistency in instances where there are direct PE inputs included in the facility postservice period even though post-operative visit is not included in a service. We identified 13 codes that are affected by this issue and we are unclear if the discrepancy is caused by inaccurate direct PE inputs or inaccurate post-operative data in the work time file. We request that stakeholders including the RUC review these discrepancies and provide their recommendations on the appropriate direct PE inputs for the codes listed in Table 8.

TABLE 8—CODES THAT HAVE DIRECT PE INPUTS IN THE FACILITY POSTSERVICE PERIOD WHEN POST-OPERATIVE VISITS ARE EXCLUDED

CPT Code	Long descriptor
21077	Impression and preparation of eye socket prosthesis.
21079	Impression and custom preparation of temporary oral prosthesis.
21080	Impression and custom preparation of permanent oral prosthesis.
21081	Impression and custom preparation of lower jaw bone prosthesis.
21082	Impression and custom preparation of prosthesis for roof of mouth enlargement.
21083	Impression and custom preparation of roof of mouth prosthesis.
21084	Impression and custom preparation of speech aid prosthesis.
28636	Insertion of hardware to foot bone dislocation with manipulation, accessed through the skin.
28666	Insertion of hardware to toe joint dislocation with manipulation, accessed through the skin.
43652	Incision of vagus nerves of stomach using an endoscope.
46900	Chemical destruction of anal growths.
47570	Connection of gall bladder to bowel using an endoscope.
66986	Exchange of lens prosthesis.

d. Insertion and Removal of Drug Delivery Implants—CPT Codes 11981 and 11983

Stakeholders have urged CMS to create new coding describing the insertion and removal of drug delivery implants for buprenorphine hydrochloride, formulated as a 4 rod, 80 mg, long acting subdermal drug implant for the treatment of opioid addiction. These stakeholders have suggested that current coding that describes insertion and removal of drug delivery implants is too broad and that new coding is needed to account for specific additional resource costs associated with particular treatment. We are identifying existing CPT codes 11981 (Insertion, non-biodegradable drug delivery implant), 11982 (Removal, non-biodegradable drug delivery implant), and 11983 (Removal with reinsertion, non-biodegradable drug delivery implant) as potentially misvalued codes and are seeking comment and information regarding whether the current resource inputs in work and practice expense for these codes appropriately account for variations in the service relative to which devices and related drugs are inserted and removed.

5. Valuing Services That Include Moderate Sedation as an Inherent Part of Furnishing the Procedure

The CPT manual identifies more than 400 diagnostic and therapeutic procedures (listed in Appendix G) for which the CPT Editorial Committee has determined that moderate sedation is an inherent part of furnishing the procedure. In developing RVUs for these services, we include the resource costs associated with moderate sedation in the valuation since the CPT codes include moderate sedation as an inherent part of the procedure. Therefore, only the procedure code is currently reported when furnishing the service. Endoscopic procedures constitute a significant portion of the services identified in Appendix G. In the CY 2015 PFS proposed rule (79 FR 40349), we noted that it appeared that practice patterns for endoscopic procedures were changing, with anesthesia increasingly being separately reported for these procedures, meaning that the resource costs associated with sedation were no longer incurred by the practitioner reporting the Appendix G procedure. We indicated that, in order to reflect apparent changes in medical practice, we were considering establishing a uniform approach to the appropriate valuation of all Appendix G services for which moderate sedation is no longer inherent, rather than addressing the issue at the procedure level as individual codes are revalued. We solicited public comment on approaches to the appropriate valuation of these services.

In the CY 2016 PFS proposed rule (80 FR 41707), we again solicited public comment and recommendations on approaches to address the appropriate valuation of moderate sedation related to Appendix G services. In response to our comment solicitation, the CPT Editorial Panel created CPT codes for separately reporting moderate sedation services in association with the elimination of Appendix G from the CPT Manual for CY 2017. This coding change would provide for payment for

moderate sedation services only in cases where it is furnished. In addition to providing recommended values for the new codes used to separately report moderate sedation, the RUC has also provided a methodology for revaluing all services previously identified in Appendix G, without moderate sedation, in order to make appropriate corresponding adjustments for the procedural services. The RUC recommended this methodology to address moderate sedation valuation generally instead of recommending that it be addressed as individual codes are reviewed. The RUC's recommended methodology would remove work RVUs for moderate sedation from Appendix G codes based on a code-level assessment of whether the procedures are typically performed on straightforward patients or more difficult patients. Based on its recommended methodology, the RUC is recommending removal of fewer RVUs from each of the procedural services than it recommends for valuing the moderate sedation services. If we were to use the RUC-recommended values for both the moderate sedation codes and the Appendix G procedural codes without refinement, overall payments for these procedures, when moderate sedation is furnished, would increase relative to the current payment.

We direct readers to section II.L. of this proposed rule, which includes more details regarding our proposed valuation of the new moderate sedation codes and our proposed uniform methodology for revaluation of the procedural codes previously identified in Appendix G. We believe that the RVUs assigned under the PFS should reflect the overall resource costs of PFS services, regardless of how many codes are used to report the services. Therefore, our proposed methodology for valuation of Appendix G procedural services would maintain current resource assumptions for the procedures when furnished with moderate sedation and redistribute the RVUs associated with moderate sedation (previously included in Appendix G procedural codes) to other PFS services. We believe that our proposed uniform methodology for revaluation of Appendix G services without moderate sedation is consistent with our general principle that the overall resource costs for the procedures do not change based solely on changes in coding.

We also note that stakeholders presented information to CMS regarding specialty group survey data for physician work. The stakeholders shared survey results for physician work involved in furnishing moderate sedation that demonstrated a significant bimodal distribution between procedural services furnished by gastroenterologists (GI) and procedural services furnished by other specialties. Since we believe that gastroenterologists furnish the highest volume of services previously identified in Appendix G, and services primarily furnished by gastroenterologists prompted the concerns that led to our identification of changes in medical practice and potentially duplicative payment for these codes, we have addressed the variations between the GI and other specialties in our review of the new moderate sedation CPT codes and their recommended values. We again direct readers to section II.L. of this proposed rule where we discuss our proposal to augment the new CPT codes for moderate sedation with an endoscopy-specific moderate sedation code, as well as proposed valuations reflecting the differences in the physician survey data between GI and other specialties.

6. Collecting Data on Resources Used in Furnishing Global Services

a. Background

(1) Current Payment Policy for Global Packages

Under the PFS, certain services, such as surgery, are valued and paid for as part of global packages that include the procedure and the services typically furnished in the periods immediately before and after the procedure. For each of these global packages, we establish a single PFS payment that includes payment for particular services that we assume to be typically furnished during the established global period. There are three primary categories of global packages that are labeled based on the number of post-operative days included in the global period: 0-day; 10-day; and 90-day. The 0-day global packages include the surgical procedure and the pre-operative and post-operative services furnished by the physician on the day of the service. The 10-day global packages include these services and, in addition, visits related to the procedure during the 10 days following the day of the procedure. The 90-day global packages include the same services as the 0-day global codes plus the pre-operative services furnished one day prior to the procedure and post-operative services during the 90 days immediately following the day of the procedure. Section 40.1 of Chapter 12 of the Claims Processing Manual (Pub. 100–04) defines the global surgical package to include the following services related to the surgery when furnished during the global period by the same physician or another practitioner in the same group practice:

- *Pre-operative Visits:* Pre-operative visits after the decision is made to operate beginning with the day before the day of surgery for major procedures and the day of surgery for minor procedures;
- *Intra-operative Services:* Intra-operative services that are normally a usual and necessary part of a surgical procedure;
- *Complications Following Surgery:* All additional medical or surgical services required of the surgeon during the post-operative period of the surgery because of complications that do not require additional trips to the operating room;
- *Post-operative Visits:* Follow-up visits during the post-operative period of the surgery that are related to recovery from the surgery;
- *Post-surgical Pain Management:* By the surgeon;
- *Supplies:* Except for those identified as exclusions; and
- *Miscellaneous Services:* Items such as dressing changes; local incisional care; removal of operative pack; removal of cutaneous sutures and staples, lines, wires, tubes, drains, casts, and splints; insertion, irrigation and removal of urinary catheters, routine peripheral intravenous lines, nasogastric and rectal tubes; and changes and removal of tracheostomy tubes.

In the CY 2015 PFS proposed and final rules we extensively discussed the problems with accurate valuation of 10- and 90-day global packages. Our concerns included the fact that we do not use actual data on services furnished in order to update the rates, questions regarding the accuracy of our current assumptions about typical services, whether we will be able to adjust values on a regular basis to reflect changes in the practice of medicine and health care delivery, and how our global payment policies affect what services are actually furnished (79 FR 67582 through 67585). In finalizing a policy to transform all 10-day and 90-day global codes to 0-day global codes in CY 2017 and CY 2018, respectively, to improve the accuracy of valuation and payment for the various components of global packages, including pre- and post-operative visits and the procedure itself, we stated that we were adopting this policy because we believe it is critical that PFS payment rates be based upon RVUs that reflect the resource costs of furnishing the services. We also stated our belief that transforming all 10- and 90-day global codes to 0-day global packages would:

- Increase the accuracy of PFS payment by setting payment rates for individual services that more closely reflect the typical resources used in furnishing the procedures;
- Avoid potentially duplicative or unwarranted payments when a beneficiary receives post-operative care from a different practitioner during the global period;
- Eliminate disparities between the payment for E/M services in global periods and those furnished individually;
- Maintain the same-day packaging of pre- and post-operative physicians' services in the 0-day global packages; and
- Facilitate the availability of more accurate data for new payment models and quality research.

(2) Data Collection and Revaluation of Global Packages Required by MACRA

Section 523(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015) prohibits the Secretary from implementing the policy, described above, that would have transformed all 10-day and 90-day global surgery packages to 0-day global packages.

Section 1848(c)(8)(B) of the Act, which was also added by section 523(a) of the MACRA, requires us to collect data to value surgical services. Section 1848(c)(8)(B)(i) of the Act requires us to develop, through rulemaking, a process to gather information needed to value surgical services from a representative sample of physicians, and requires that the data collection begin no later than January 1, 2017. The collected information must include the number and level of medical visits furnished during the global period and other items and services related to the surgery and furnished during the global period, as appropriate. This information must be reported on claims at the end of the global period or in another manner specified by the Secretary. Section 1848(c)(8)(B)(ii) of the Act requires that, every 4 years, we reassess the value of this collected information; and allows us to discontinue the collection of this information if the Secretary determines that we have adequate information from other sources to accurately value global surgical services. Section 1848(c)(8)(B)(iii) of the Act specifies that the Inspector General shall audit a sample of the collected information to verify its accuracy. Section 1848(c)(9) of the Act (added by section 523(b) of the MACRA) authorizes the Secretary, through rulemaking, to delay up to 5 percent of the PFS payment for services for which a physician is required to report information under section 1848(c)(8)(B)(i) of the Act until the required information is reported.

Section 1848(c)(8)(C) of the Act, which was also added by section 523(a) of the MACRA, requires that, beginning in CY 2019, we must use the information collected as appropriate, along with other available data, to improve the accuracy of valuation of surgical services under the PFS.

(3) Public Input

As noted above, section 1848(c)(8)(C) of the Act mandates that we use the collected data to improve the accuracy of valuation of surgery services beginning in 2019. We described in the CY 2015 PFS final rule (79 FR 67582 through 67591) the limitations and difficulties involved in the appropriate valuation of the global packages, especially when the resources and the related values assigned to the component services are not defined. To gain input from stakeholders on implementation of this data collection, we sought comment on various aspects of this task in the CY 2016 proposed rule (80 FR 41707 through 41708). We solicited comments from the public regarding the kinds of auditable, objective data (including the number and type of visits and other services furnished during the post-operative period by the practitioner furnishing the procedure) needed to increase the accuracy of the values for surgical services. We also solicited comment on the most efficient means of acquiring these data as accurately and efficiently as possible. For example, we sought information on the extent to which individual practitioners or practices may currently maintain their own data on services, including those furnished during the post-operative period, and how we might collect and objectively evaluate those data for use in increasing the accuracy of the values beginning in CY 2019.

We received many comments regarding potential methods of valuing the individual components of the global surgical package. A large number of comments expressed strong support for our proposal to hold an open door forum or town hall meetings with the public. Toward this end, we held a national listening session on January 20, 2016. Prior to the listening session, the topics for which guidance was being sought were sent electronically to those who registered for the session and made available on our Web site. The topics were:

- Mechanisms for capturing the types of services typically furnished during the global period.
- Determining the representative sample for the claims-based data collection.
- Determining whether we should collect data on all surgical services or, if not, which services should be sampled.
- Potential for designing data collection elements to interface with existing infrastructure used to track follow-up visits within the global period.
- Consideration of use of 5 percent withhold until required information is furnished.

The 658 participants in the national listening session provided valuable information on this task. A written transcript and an audio recording of this session are available at *https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2016-01-20-MACRA.html*.

We considered both the comments submitted on the CY 2016 PFS proposed rule and the input provided at the listening session as we developed this proposal for data collection. When relevant, we discuss this stakeholder input below without distinguishing between comments on the proposed rule and input provided at the national listening session.

b. Data Collection Required To Accurately Value Global Packages

Resource-based valuation of individual physicians' services is a critical foundation for Medicare payment to physicians. It is essential that the RVUs under the PFS be based as closely and accurately as possible on the actual resources involved in furnishing the typical occurrence of specific services to make appropriate payment and preserve relativity among services. For global surgical packages, this requires using objective data on all of the resources used to furnish the services that are included in the package. Not having such data for some components may significantly skew relativity and create unwarranted payment disparities within the PFS.

The current valuations for many services valued as global packages are based upon the total package as a unit rather than by determining the resources used in furnishing the procedure and each additional service/visit and summing the results. As a result, we do not have the same level of information about the components of global packages as we do for other services. To value global packages accurately and

relative to other procedures, we need accurate information about the resources—work, PEs and malpractice—used in furnishing the procedure, similar to what is used to determine RVUs for all services. In addition we need the same information on the post-operative services furnished in the global period (and pre-operative services the day before for 90-day global packages). Public comments about our proposal to value all global services as 0-day global services and pay separately for additional post-operative services when furnished indicated that there were no reliable data available on the value of the underlying procedure that did not also incorporate the value of the post-operative services, reinforcing our view that more data are needed across the board.

While we believe that most of the services furnished in the global period are visits for follow-up care, we do not have accurate information on the number and level of visits typically furnished because those billing for global services are not required to submit claims for post-operative visits. A May 2012 Office of Inspector General (OIG) report, entitled Cardiovascular Global Surgery Fees Often Did Not Reflect the Number of Evaluation and Management Services Provided (*http://oig.hhs.gov/oas/reports/region5/50900054.pdf*) found that for 202 of the 300 sampled cardiovascular global surgeries, the Medicare payment rates were based on a number of visits that did not reflect the actual number of services provided. Specifically, physicians provided fewer services than the visits included in the payment calculation for 132 global surgery services and provided more services than were included in the payment calculations for 70 services. Similar results were found in OIG reports entitled ''Musculoskeletal Global Surgery Fees Often Did Not Reflect The Number Of Evaluation And Management Services Provided'' (*http://oig.hhs.gov/oas/reports/region5/50900053.asp*) and ''Review of Cataract Global Surgeries and Related Evaluation and Management Services, Wisconsin Physicians Service Insurance Corporation Calendar Year 2003, March 2007'' (*http://oig.hhs.gov/oas/reports/region5/50600040.pdf*).

Claims data plays a major role in PFS rate-setting. Specifically, Medicare claims data is a primary driver in the allocation of indirect PE RVUs and MP RVUs across the codes used by particular specialties, and in making overall budget neutrality and relativity adjustments. In most cases, a claim must be filed for all visits. Such claims provide information such as the place of service, the type and, if relevant, the level of the service, the date of the service, and the specialty of the practitioner furnishing the services. Because we have not required claims reporting of visits included in global surgical packages, we do not have any of this information for the services bundled in the package.

In addition to the lack of information about the number and level of visits actually furnished, the current global valuations rely on crosswalks to E/M visits, based upon the assumption that the resources, including work, used in furnishing pre- and post-operative visits are similar to those used in furnishing E/M visits. We are unaware of any studies or surveys that verify this assertion. Although we generally value global packages using the same direct PE inputs as are used for the E/M services, for services for which the RUC recommendations include specific PE inputs in addition to those typically included for E/M services, we generally use the additional inputs in the global package valuation. Of note, when a visit included in a global package would use fewer resources than a comparable E/M service, the RUC generally does not include recommendations to decrease the PE inputs of the visit included in the global package, and we have not generally made comparable reductions. Another inconsistency with our current global package valuation approach is that even though we effectively assume that the E/M codes are appropriate for valuing pre- and post-operative services, the indirect PE inputs used for calculating payments for global services are based upon the specialty mix furnishing the global service, not the specialty mix of the physicians furnishing the E/M services, resulting in a different valuation for the E/M services contained in global packages than for separately billable E/M services. There is a critical need to obtain complete information if we are to value global packages accurately and in a way that preserves relativity across the fee schedule.

To meet the requirement under section 1848(c)(8)(B)(i) of the Act, we develop, through rulemaking, a process to gather information needed to value surgical services. Therefore, we are proposing a rigorous data collection effort that we believe would provide us the data needed to accurately value the 4,200 codes with a 10- or 90-day global period. Using our authority under sections 1848(c)(2)(M) and (c)(8)(B)(i) of the Act, we propose to gather the data needed to determine how to best structure global packages with post-operative care that is typically delivered days, weeks or months after the procedure and whether there are some procedures for which accurate valuation for packaged post-operative care is not possible. Finally, we believe these data would provide useful information to assess the resources used in furnishing pre- and post-operative care. To accurately do so, we need to know the volume and costs of the resources typically used. Although it may not be possible to gather all the necessary data and to complete the analysis required to re-value all of the codes currently valued as 10- or 90-day global packages by January 1, 2019, we believe the proposed data collection would provide the foundation for such valuations and would allow us to re-value, as appropriate, the surgical services on a flow basis, starting in rulemaking for CY 2019.

We are proposing a three-pronged approach to collect timely and accurate data on the frequency of, and inputs involved in furnishing, global services including the procedure and the pre-operative visits, post-operative visits, and other services for which payment is included in the global surgical payment. By analyzing these data, we would not only have the most comprehensive information available on the resources used in furnishing these services, but also would be able to determine the appropriate packages for such services. Specifically, the effort would include:

- Comprehensive claims-based reporting about the number and level of pre- and post-operative visits furnished for 10- and 90-day global services.
- A survey of a representative sample of practitioners about the activities involved in and the resources used in providing a number of pre- and post-operative visits during a specified, recent period of time, such as two weeks.
- A more in-depth study, including direct observation of the pre- and post-operative care delivered in a small number of sites, including some ACOs.

This work is critical to understanding and characterizing the work and other resources involved in furnishing services throughout the current global periods assigned to specific surgical procedures. The information collected and analyzed through the activities would be the first comprehensive look at the volume and level of services in a global period, and the activities and inputs involved in furnishing global services. The data from these activities would ultimately inform our revaluation of global surgical packages.

(1) Statutory Authority for Data Collection

As described above, section 1848(c)(8)(B)(i) of the Act requires us to develop, through rulemaking, a process to gather information needed to value surgical services from a representative sample of physicians. The statute requires that the collected information include the number and level of medical visits furnished during the global period and other items and services related to the surgery and furnished during the global period, as appropriate.

In addition, section 1848(c)(2)(M) of the Act, which was added to the Act by section 220 of the PAMA, authorizes the Secretary to collect or obtain information on resources directly or indirectly related to furnishing services for which payment is made under the PFS. Such information may be collected or obtained from any eligible professional or any other source. Information may be collected or obtained from surveys of physicians, other suppliers, providers of services, manufacturers, and vendors. That section also authorizes the Secretary to collect information through any other mechanism determined appropriate. When using information gathered under this authority, the statute requires the Secretary to disclose the information source and discuss the use of such information in the determination of relative values through notice and comment rulemaking.

As described above, to gain all the information that is needed to determine the appropriate packages for global services and to revalue those services, we need to conduct a comprehensive study on the resources used in furnishing such services. Through such a study, we would have much more robust data to use in valuation than has been typically available. We anticipate that such efforts would inform how to more regularly collect data on the resources used in furnishing physicians' services. To the extent that such mechanisms prove valuable, they may be used to collect data for valuing other services. To achieve this significant data collection, we are proposing to collect data under the authority of both section 1848(c)(8)(B) and (c)(2)(M) of the Act.

(2) Claims-Based Data Collection

This section describes our proposal for claims-based data collection that would be applicable to 10- and 90-day global services furnished on or after January 1, 2017, including who would be required to report, what they would be required to report, and how reports would be submitted.

(a) Information To Be Reported

A key element of claims-based reporting is using codes that appropriately reflect the services furnished. In response to the comment solicitation in the CY 2016 PFS proposed rule and in the January 2016 listening session, we received numerous recommendations for the information to be reported on claims. The most frequently recommended approach was for practitioners to report the existing CPT code for follow-up visits included in the surgical package (CPT 99024—Postoperative follow-up visit, normally included in the surgical package, to indicate that an E/M service was performed during a postoperative period for a reason(s) related to the original procedure). Others suggested using this code for outpatient visits and using length of stay data for estimating the number of inpatient visits during the global period. In response to our concerns that CPT code 99024 would provide only the number of visits and not the level of visits as required by the statute, one commenter suggested using modifiers in conjunction with CPT code 99024 to indicate the level of the visit furnished. Others recommended using existing CPT codes for E/M visits to report post-operative care. One commenter suggested that CMS analyze data from a sample of large systems and practices that are using electronic health records that require entry of some CPT code for every visit to capture the number of post-operative visits. After noting that the documentation requirements and PEs required for post-operative visits differ from those of E/M visits outside the global period, one commenter encouraged us to develop a separate series of codes to capture the work of the post-operative services and to measure, not just estimate, the number and complexity of visits during the global period.

Other commenters opposed the use of a new set of codes or the use of modifiers to report post-operative visits. Commenters also noted several issues for us to consider in developing data collection mechanisms, including that many post-operative services do not have CPT codes to bill separately, that surgeons perform a wide range of collaborative care services, and that patient factors, including disease severity and comorbidities, influence what post-operative care is furnished.

To assist us in determining appropriate coding for claims-based reporting, we added a task to the RAND contract for developing a model to validate the RVUs in the PFS, which was awarded in response to a requirement in the Affordable Care Act. Comments that we received on RAND's report suggested the models did not adequately address global surgery services due to the lack of available data on included visits. Therefore, we modified the RAND contract to include the development of G-codes that could be used to collect data about post-surgical follow-up visits on Medicare claims for valuing global services under MACRA and so that this time could be included in the model for validating RVUs.

To inform its work, RAND conducted interviews with surgeons and other physicians/non-physician practitioners (NPP) who provide post-operative care. A technical expert panel (TEP), convened by RAND, reviewed the findings of the interviews and provided input on how to best capture care provided in the post-operative period on claims.

In summarizing the input from the interviews and the TEP, RAND indicated that several considerations were important in developing a claims-based method for capturing post-operative services. First, a simple system to facilitate reporting was needed. Since it was reported that a majority of post-operative visits are straightforward, RAND found that a key for any proposed system is identifying the smaller number of complex post-operative visits. Another consideration for RAND was not using the existing CPT E/M structure to capture postoperative care because of concerns that E/M codes are inadequately designed to capture the full scope of post-operative care and that using such codes might create confusion. Another consideration was that the TEP was most enthusiastic about a set of codes that used site of care, time, and complexity to report visits. RAND also believed it was important to distinguish—particularly in the inpatient setting—between circumstances where a surgeon is providing primary versus secondary management of a patient. Finally, a mechanism for reporting the postoperative care occurs outside of in-person visits and by clinical staff was needed. RAND noted that in the inpatient setting in particular, surgeons spend considerable time reviewing test results and coordinating care with other practitioners.

After reviewing various approaches, RAND recommended a set of time-based, post-operative visit codes that could be used for reporting care provided during the post-operative period.

The recommended codes are distinguished by the setting of care and whether they are furnished by a physician/NPP or by clinical staff. All codes are intended to be reported in 10-minute increments. A copy of the report is available available on the CMS Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/physicianfeesched/downloads/*.

Based upon the work done by RAND, we are proposing the following codes be used for reporting on claims the services actually furnished but not paid separately because they are part of global packages. No separate payment would be made for these codes.

TABLE 9—PROPOSED GLOBAL SERVICE CODES

Inpatient	GXXX1	Inpatient visit, typical, per 10 minutes, included in surgical package.
	GXXX2	Inpatient visit, complex, per 10 minutes, included in surgical package.
	GXXX3	Inpatient visit, critical illness, per 10 minutes, included in surgical package.
Office or Other Outpatient	GXXX4	Office or other outpatient visit, clinical staff, per 10 minutes, included in surgical package.
	GXXX5	Office or other outpatient visit, typical, per 10 minutes, included in surgical package.
	GXXX6	Office or other outpatient visit, complex, per 10 minutes, included in surgical package.
Via Phone or Internet	GXXX7	Patient interactions via electronic means by physician/NPP, per 10 minutes, included in surgical package.
	GXXX8	Patient interactions via electronic means by clinical staff, per 10 minutes, included in surgical package.

(i) Coding for Inpatient Global Service Visits

Our coding proposal includes three codes for reporting inpatient pre- and post-operative visits that distinguish the intensity involved in furnishing the services. The typical inpatient visit would be reported using HCPCS code GXXX1, Inpatient visit, typical, per 10 minutes, included in surgical package. The activities listed in Table 10 are those that RAND recommended to be reported as a typical visit. Under our proposal, visits that involve any combination or number of the services listed in Table 10 would be reported using GXXX1. Based on the findings from the interviews and the TEP, RAND reports that the vast majority of inpatient post-operative visits would be expected to be reported using GXXX1.

TABLE 10—ACTIVITIES INCLUDED IN TYPICAL VISIT (GXXX1 & GXXX5)

Review vitals, laboratory or pathology results, imaging, progress notes
Take interim patient history and evaluate post-operative progress
Assess bowel function
Conduct patient examination with a specific focus on incisions and wounds, post-surgical pain, complications, fluid and diet intake
Manage medications (for example, wean pain medications)
Remove stitches, sutures, and staples
Change dressings
Counsel patient and family in person or via phone
Write progress notes, post-operative orders, prescriptions, and discharge summary
Contact/coordinate care with referring physician or other clinical staff
Complete forms or other paperwork

Inpatient pre- and post-operative visits that are more complex than typical visits but do not qualify as critical illness visits would be coded using GXXX2 (Inpatient visit, complex, per 10 minutes, included in surgical package). To report this code, the practitioner would be required to furnish services beyond those included in a typical visit and have documentation that indicates what services were provided that exceeded those included in a typical visit. Some circumstances that might merit the use of the complex visit code are secondary management of a critically ill patient where another provider such as an intensivist is providing the primary management, primary management of a particularly complex patient such as a patient with numerous comorbidities or high likelihood of significant decline or death, management of a significant complication, or complex procedures outside of the operating room (For example, significant debridement at the bedside).

The highest level of inpatient pre- and post-operative visits, critical illness visits (GXXX3—Inpatient visit, critical illness, per 10 minutes, included in surgical package) would be reported when the physician is providing primary management of the patient at a level of care that would be reported using critical care codes if it occurred outside of the global period. This involves acute impairment of one or more vital organ systems such that there is a high probability of imminent or life threatening deterioration in the patient's condition.

Similar to how time is now counted for the existing CPT critical care codes, all time spent engaged in work directly related to the individual patient's care would count toward the time reported with the inpatient visit codes; this includes time spent at the immediate bedside or elsewhere on the floor or unit, such as time spent with the patient and family members, reviewing test results or imaging studies, discussing care with other staff, and documenting care.

(ii) Coding for Office and Other Outpatient Global Services Visits

Our proposal includes three codes that would be used for reporting post-operative visits in the office or other outpatient settings. For these three codes, time would be defined as the face-to-face time with patient, which reflects the current rules for time-based outpatient codes.

Under our proposal, GXXX4 (Office or other outpatient visit, clinical staff, per 10 minutes, included in surgical package) would be used for visits in which the clinical care is provided by clinical staff.

GXXX5 (Office or other outpatient visit, typical, per 10 minutes, included in surgical package) would be used for reporting any combination of activities in Table 10. Based on the findings from the interviews and the TEP, RAND reports that the vast majority of office or other outpatient visits would be expected to be reported using the GXXX5 code.

Accordingly, we would expect the office or other outpatient visit code, complex, GXXX6 (Office or other outpatient visit, complex, per 10 minutes, included in surgical package), to be used infrequently. Examples of when it might be used include management of a particularly complex patient such as a patient with numerous comorbidities or high likelihood of dying, management of a significant complication, or management or discussion of a complex diagnosis (For

example, new cancer diagnosis, high risk of mortality). Practitioners would include documentation in the medical record as to what services were provided that exceeded those included in a typical visit.

Only face-to-face time spent by the practitioner with the patient and their family members would count toward the time reported with the office visit codes. Therefore, even though the codes for both inpatient and outpatient settings use the same time increment, the services that are included differ by setting, consistent with the variation in existing coding conventions.

(iii) Coding for Services Furnished Via Electronic Means

Services that are provided via phone, the internet, or other electronic means outside the context of a face-to-face visit would be reported using GXXX7 when furnished by a practitioner and GXXX8 when furnished by clinical staff. We are proposing that practitioners would not report these services if they are furnished the day before, the day of, or the day after a visit as we believe these would be included in the pre- and post-service activities in the typical visit. However, we are proposing that these codes be used to report non-face-to-face services provided by clinical staff prior to the primary procedure since global surgery codes are typically valued with assumptions regarding pre-service clinical labor time. Given that some practitioners have indicated that services they furnish commonly include activities outside the face-to-face service, we believe it is important to capture information about those activities in both the pre- and post-service periods. We believe these requirements to report on clinical labor time are consistent with and no more burdensome than those used to report clinical labor time associated with chronic care management services, which similarly describe care that takes place over more than one patient encounter.

In addition, for services furnished via interactive telecommunications that meet the requirements of a Medicare telehealth service visit, the appropriate global service G-code for the services should be reported with the GT modifier to indicate that the service was furnished ''via interactive audio and video telecommunications systems.''

(iv) Benefits of G-Codes

One commenter indicated that the documentation requirements and PEs for post-operative visits differ from those of other E/M visits, and encouraged us to develop a separate series of codes to capture the work of the post-operative services and to measure, not just estimate, the number and complexity of visits during the global period. Others opposed the use of a new set of codes or the use of modifiers to collect information on post-operative visits. After considering the RAND report, the comments and other stakeholder input that we have received, and our needs for data to fulfill our statutory mandate and to value surgical services appropriately, we are proposing this new set of codes because we believe it provides us the most robust data upon which to determine the most appropriate way and amounts to pay for PFS surgical services. We believe that the codes being proposed would provide data of the kind that can reasonably collected through claims data and that reflect what we believe are key issues in the post-operative care where the service is provided, who furnishes the service, its relative complexity, and the time involved in the service.

We seek public comments about all aspects of these codes, including the nature of the services described, the time increment, and any other areas of interest to stakeholders. We are particularly interested in any pre- or post-operative services furnished that could not be appropriately captured by these codes. Although RAND developed this set of codes to collect data on post-operative services, we are proposing to also use such codes to collect data on pre-operative services. We are seeking comments on whether the codes discussed above are appropriate for collecting data on pre-operative services or whether additional codes should be added to distinguish in the data collected the resources used for pre-operative services from those used for post-operative services. We also seek comment on any activities that should be added to the list of activities in Table 10 to reflect typical pre-operative visit activities.

(v) Alternative Approach to Coding

As noted above, many stakeholders expressed strong support for the use of CPT code 99024 (Postoperative follow-up visit, normally included in the surgical package, to indicate that an evaluation and management service was performed during a postoperative period for a reason(s) related to the original procedure) to collect data on post-operative care. Stakeholders suggest that practitioners are familiar with this existing CPT code and the burden on practitioners would be minimized by only having to report that a visit occurred, not the level of the visit. We do not believe that this code alone would provide the information that we need for valuing surgical services nor do we believe it alone can meet the statutory requirement that we collect data on the number and level of visits because it does not provide any information beyond the number of visits. Although we are proposing to use the G-codes detailed above to measure pre- and post-operative visits, given the strong support that many stakeholders have for the use of CPT code 99024, we are soliciting comments specifically on how we could use this code to capture the statutorily required data on the number and level of visits and the data that we would need to value global services in the future.

Some have suggested using CPT code 99024 with modifiers to indicate to which of the existing levels of E/M codes the visit corresponds. As outlined in the RAND report, E/M visits may not accurately capture what drives greater complexity in post-operative visits. E/M billing requirements are built upon complexity in elements such as medical history, review of systems, family history, social history, and how many organ systems are examined. In the context of a post-operative visit, many of these elements may be irrelevant. RAND also noted that there was significant concern from interviewees and the expert panel about documentation that is required for reporting E/M codes. Specifically, they argued that documentation requirements for surgeons to support the relevant E/M visit code would place undue administrative burden on surgeons. RAND reported that many surgeons currently use minimal documentation when they provide a postoperative visit. Moreover, to value surgical packages accurately we need to understand the activities involved in furnishing post-operative care and as discussed above, we lack information that would demonstrate that activities involved in post-operative care are similar to those in E/M services. In addition, the use of modifiers to report levels of services is more difficult to operationalize than using unique HCPCS codes. However, we would be interested in whether, and if so, why, practitioners would find it easier to report CPT code 99024 with modifiers corresponding to the proposed G-code levels rather than the new G-codes, as proposed. We are also seeking comment on whether practitioners would find it difficult to use this for pre-operative visits since the CPT code descriptor specifically defines it as a ''post-operative follow-up'' service.

We are also seeking comment on whether time of visits could alone be a proxy for the level of visit. If pre- and post-operative care varies only by the time the practitioner spends care so that time could be a proxy for complexity of the service, then we could use the reporting of CPT code 99024 in 10-minute increments to meet the statutory requirement of collecting claims-based data on the number and level of visits. In addition to comments on whether time is an accurate proxy for level of visit, we are seeking comment on the feasibility and desirability of reporting CPT 99024 in 10-minute increments.

c. Reporting of Claims

We propose that the G-codes detailed above would be reported for services related to and within 10- and 90-day global periods for procedures furnished on or after January 1, 2017. Services related to the procedure furnished following recovery and otherwise within the relevant global period would be required to be reported. These codes would be included on claims filed through the usual process. Through this mechanism, we would collect all of the information reported on a claim for services, including information about the practitioner, service furnished, date of service, and the units of service. By not imposing special reporting requirements on the reporting of these codes, we intend to allow practitioners the flexibility to report the services on a rolling basis as they are furnished or to report all of the services on one claim once all have been furnished, as long as the filed claims meet the requirements for filing claims. As with all other claims, we would expect the patient's medical record to include documentation of the services furnished. Documentation that would be expected is an indication that a visit occurred or a service was furnished and sufficient information to determine that the appropriate G-code was reported.

We are not proposing any special requirements for inclusion of additional data on claims that could be used for linking the post-operative care furnished to a particular service. To use the data reported on post-operative visits for analysis and valuation, we will link the data reported on post-operative care to the related procedure using date of service, practitioner, beneficiary, and diagnosis. We believe this approach to matching will allow us to accurately link the preponderance of G-codes to the related procedure. However, we solicit comment on the extent to which post-operative care may not be appropriately linked to related procedures whether we should consider using additional variables to link these aspects of the care, and whether additional data should be required to be reported to enable a higher percentage of matching.

d. Special Provisions for Teaching Physicians

We are seeking comment on whether special provisions are needed to capture the pre- and post-operative services provided by residents in teaching settings. If the surgeon is present for the key portion of the visit, should the surgeon report the joint time spent by the resident and surgeon with the patient? If the surgeon is not present for the key portion of the visit, should the resident report the service? If we value services without accounting for services provided by residents that would otherwise be furnished by the surgeon in non-teaching settings, subsequent valuations based upon the data we collect may underestimate the resources used, particularly for the types of surgeries typically furnished in teaching facilities. However, there is also a risk of overvaluing services if the reporting includes services that are provided by residents when those services would otherwise be furnished by a physician other than the surgeon, such as a hospitalist or intensivist, and as such, should not be valued in the global package.

e. Who Reports

In both the comments on the CY 2016 proposed rule and in the national listening session, there was a great deal of discussion regarding the challenges that we are likely to encounter in obtaining adequate data to support appropriate valuation. Some indicated that a broad sample and significant cooperation from physicians would be necessary to understand what is happening as part of the global surgical package. One commenter suggested that determining a representative sample would be difficult and, due to the variability related to the patient characteristics, it would be easier to have all practitioners report. Many suggested that we conduct an extensive analysis across surgical specialties with a sample that is representative of the entire physician community and covers the broad spectrum of the various types of physician practice to avoid problems that biased or inadequate data collection would cause. Suggestions of factors to account for in selecting a sample include specialty, practice size (including solo practices), practice setting, volume of claims, urban, rural, type of surgery, and type of health care delivery systems. Another commenter pointed out that small sample sizes may lead to unreliable data. On the other hand, some commenters stated that requiring all practitioners to report this information is unreasonable and would be an insurmountable burden. A participant acknowledged that it would be difficult for practitioners to report on only certain procedures, while another stated that this would not be an administrative burden.

After considering the input of stakeholders, we are proposing that any practitioner who furnishes a procedure that is a 10- or 90-day global report the pre- and post-operative services furnished on a claim using the codes proposed above. We agree with stakeholders that it is necessary to obtain data from a broad, representative sample across specialties, geographic location, and practice size, practice model, patient acuity, and differing practice patterns. However, as we struggled to develop a sampling approach that would result in statistically reliable and valid data, it became apparent that we do not have adequate information about how post-operative care is delivered, how it varies and, more specifically, what drives variation in post-operative care. In its work to develop the coding used for its study, RAND found a range of opinions on what drives variation in post-operative care. (The report is available on the CMS Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/physicianfeesched/downloads/*.) Without information on what drives variation in pre- and post-operative care, we would have to speculate about the factors upon which to base a sample or assume that the variation in such care results from the same variables as are frequently identified for explaining variation in health care and clinical practice. In addition, we have concerns about whether a sample could provide sufficient volume to value accurately the global package, except in the case of a few high-volume procedures.

In addition to concerns about achieving an appropriate, sufficient, and unbiased representative sample of practitioners, we have significant operational concerns with collecting data from a limited sample of practitioners or on a limited sample of services. These include how to gain sufficient information on practitioners to sufficiently stratify the sample, how to identify the practitioners who must report, determining which services, and for those who practice in multiple settings and/or with multiple groups in which settings the practitioner would report. Establishing the rules to govern

which post-operative care should be reported for which procedures would be challenging for us to develop for a random sample and difficult for physicians to apply.

With the limited time between the issuance of the CY 2017 PFS final rule with comment period and the beginning of reporting on January 1st, it would be challenging to make sure that affected practitioners are aware of the requirement to report and have an ability to determine which post-operative care to report. If, instead, we require all practitioners to report, we can take a uniform approach to notifying practitioners. The national medical and coding organizations are routinely relied upon by practitioners for information on new coding and billing requirements and play a major role in the expeditious adoption of new coding or billing requirements. Similarly, adjustments to software used for medical records and coding are made by national organizations. We have concerns that if this requirement is only applied to a small segment of practitioners that these organizations will not be able to ensure that the affected practitioners are aware and easily able to comply with the requirements.

The more robust the reported data, the more accurate our ultimate valuations can be. Given the importance of data on visits in accurate valuations for global packages, we believe that collecting data on all pre- and post-operative visits in the global period is the best way to accurately value surgical procedures with global packages.

We recognize that reporting of all pre- and post-operative visits would require submission of additional claims by those practitioners furnishing global services, but we believe the benefits of accurate data for valuation of services merits the imposition of this requirement. By using the claims system to report the data, we believe the additional burden is minimized. Stakeholders have reported that many practitioners are already required by their practice or health care system to report a code for each visit for internal control purposes and some of these systems already submit claims for these services, which are denied. For these practices, the additional burden would be minimal. We believe that requiring only some physicians to report this information, or requiring reporting for only some services, could actually be more burdensome to physicians than requiring this information from all physicians on all services because of the additional steps necessary to determine whether a report is required for a particular service and adopting a mechanism to assure that data is collected and reported when required. Moreover, we believe the challenges with implementing a limited approach at the practice level as compared to a requirement for all global services would result in less reliable data being reported.

As we analyze the data collected and make decisions about valuations, we would reassess the data needed and what should be required from whom. Under section 1848(c)(8)(B)(ii) of the Act, we are required to reassess every 4 years whether continued collection of these data is needed. However, we can modify through rulemaking what data is collected at any time, as appropriate. By collecting data on all procedures with a 10- or 90-day global package, we would have the information to assess whether the post-operative care furnished varies by factors such as specialty, geography, practice setting, and practice size, and thus, the information needed for a selection of a representative sample. By initially collecting information from all practitioners that furnish surgical services, we believe we would be able to reduce required reporting in the future if we find that adequate information can be obtained by selective reporting. Without the broader set of data we would not be able to evaluate the variability of pre- and post-operative care in order to identify a useful targeted data collection.

While section 1848(c)(8)(B) of the Act requires us to collect data from a representative sample of physicians on the number and level of visits provided during the global period, it does not prohibit us from collecting data from a broad set of physicians. In addition, section 1848(c)(2)(M) of the Act authorizes the collection of data from a wide range of physicians. Given the benefits of more robust data, including avoiding sample bias, obtaining more accurate data, and facilitating operational simplicity, we believe collecting data on all post-operative care initially is the best way to undertake an accurate valuation of surgical services in the future.

(1) Survey of Practitioners

We agree with commenters that we need more information than is currently provided on claims and that we should utilize a number of different data sources and collection approaches to collect the data needed to assess and revalue global surgery services. In addition to the claims-based reporting, we are proposing to survey a large, representative sample of practitioners and their clinical staff in which respondents would report information about approximately 20 discrete pre-operative and post-operative visits and other global services like care coordination and patient training. The proposed survey would produce data on a large sample of pre-operative and post-operative visits and is being designed so that we could analyze the data collected in conjunction with the claims-based data that we would be collecting. We expect to obtain data from approximately 5,000 practitioners.

We have contracted with RAND to develop and, if our proposal is finalized, conduct this survey. RAND would also assist us in analyzing data collected under this survey and the claims-based data. While the primary data collection would be via a survey instrument, RAND would conduct semi-structured interviews and direct observations of data in a small number of pilot sites to inform survey design, validate survey results, and collect information that is not conducive to survey-based reporting.

Our proposed sampling approach would sample practitioners rather than for procedures or visits to streamline survey data collection and minimize respondent burden. Specifically, we propose to representative and random sample from a frame of providers who billed Medicare for more than a minimum threshold of surgical procedures with a 10- or 90-day global period (for example, 200 procedures) in the most recent available prior year of claims data. We expect to survey approximately 5,000 practitioners, stratified by specialty, geography, and practice type. Based upon preliminary analysis we believe this number of participants will allow us to collect information on post-operative care following the full range of CPT level-2 surgical procedure code groups. A smaller sample size would reduce the precision of estimates from the survey and more importantly risk missing important differences in post-operative care for specific specialties or following different types of surgical procedures. We expect a response rate in excess of 50 percent.

We are not proposing that respondents report on the entire period of post-operative care for individual patients, as a 90-day follow-up window (for surgeries currently with a 90-day global period) is too long to implement practically in this study setting and would be more burdensome to practitioners. Instead, we propose to collect information on a range of different post-operative services resulting from surgeries furnished by

the in-sample practitioner prior to or during a fixed reporting period.

Each sampled practitioner will be assigned to a specified and brief (for example, 2-week) reporting period. Given the proposed overall data collection period, the selected sample of providers will be randomly divided into 6 subsets within each specialty, each of which will be assigned to a specified reporting period. Practitioners will be asked to describe 20 post-operative visits furnished to Medicare beneficiaries or other patients during the reporting period. The information collected through the survey instrument, which will be developed based upon direct observation and discussions in a small number of pilot sites, will include contextual information to describe the background for the post-operative care, including, for example:

- Procedure codes(s) and date of service for procedure upon which the global period is based.
- Procedure place of service (type).
- Whether or not there were complications during or after the procedure.
- The number in sequence of the follow-up visit (for example, the first visit after the procedure).

The survey instrument will also collect information on the visit in question including, for example:

- Which level of visit using the finalized no-pay codes.
- Specific pre-service, face-to-face, and post-service activities furnished during the visit.
- Times for each activity.
- Identify who performed each activity (physician or other practitioner).
- PE components used during the visit, for example supplies like surgical dressings and clinical staff time.

Finally, the instrument will ask respondents to report other prior or anticipated care furnished to the patient by the practice outside of the context of a post-operative visit, for example non-face-to-face services.

The survey approach will complement the claims data collection by collecting detailed information on the activities, time, intensity, and resources involved in delivering global services. The resulting visit-level survey data would allow us to explore in detail the variation in activities, time, intensity, and resources associated with global services within and between physicians and procedures, and would help to validate the information gathered through claims. A summary of the work that RAND would be doing is available on the CMS Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/physicianfeesched/downloads/*.

(2) Required Participation in Data Collection

Using the authority we are provided under sections 1848(c)(8) and 1848(c)(2)(M) of the Act, we are proposing to require all practitioners who furnish a 10- or 90-day global service to submit a claim(s) providing information on all services furnished within the relevant global service period in the form and manner described below, beginning with surgical or procedural services furnished on or after January 1, 2017. We are also proposing to require participation by practitioners selected for the broad-based survey through which we are proposing to gather additional data needed to value surgical services, such as the clinical labor and equipment involved that cannot be efficiently collected on claim (see below).

Given the importance of the proposed survey effort, making sure that we get valid data is critical. By eliminating the bias that would be associated with using only data reported voluntarily, we believe we will get more accurate and representative data. In addition to the potential bias inherent in voluntary surveys, we are concerned that relying on voluntary data reporting would limit the adequacy of the volume of data we obtain, will require more effort to recruit participation, and may make it impossible to obtain data for valuation for CY 2019 as required by the statute.

Based on our previous experience with requesting voluntary cooperation in data collection activity, voluntary participation poses a significant challenge in data collection. Specifically, the Urban Institute's work (under contract with us) to validate work RVUs by conducting direct observation of the time it took to furnish certain elements of services paid under the physician fee schedule provides evidence of this challenge. (See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/RVUs-Validation-Urban-Interim-Report.pdf* for an interim report that describes challenges in securing participation in voluntary data collection.) Similarly, we routinely request invoices on equipment and supplies that are used in furnishing services and often receive no more than one invoice. These experiences support the idea that mandatory participation in data collection activities is essential if we are to collect valid and unbiased data.

Section 1848(a)(9) of the Act authorizes us, through rulemaking, to withhold payment of up to 5 percent of the payment for services on which the practitioner is required to report under section 1848(c)(8)(B)(i) of the Act until the practitioner has completed the required reporting. Some commenters opposed the imposition of this payment withhold, and others said it was too large of a penalty. While we believe this is a way to encourage practitioners to report on claims the information we propose to require on care that is furnished in the global period, we are not proposing to implement this option at this time. We believe that requiring physicians to report the information on claims, combined with the incentive to report complete information so that we can make appropriate revisions when we revalue payments for global surgical services, would result in compliance with the reporting requirements. However, we note that if we find that compliance with required claims-based reporting is not acceptable, we would consider in future rulemaking imposing up to a 5 percent payment withhold as authorized by the statute.

Consistent with the requirements of section 1848(c)(2)(M) of the Act, should the data collected under this requirement be used to determine RVUs, we will disclose the information source and discuss the use of such information in such determination of relative values through future notice and comment rulemaking.

(3) Data Collection From Accountable Care Organizations (ACOs)

We are particularly interested in knowing whether physicians and practices affiliated with ACOs expend greater time and effort in providing post-operative global services in keeping with their goal of improving care coordination for their assigned beneficiaries. ACOs are organizations in which practitioners and hospitals voluntarily come together to provide high-quality and coordinated care for their patients. Because such organizations share in the savings realized by Medicare, their incentive is to minimize post-operative visits while maintaining high quality post-operative care for patients. In addition, we believe that such organizations offer us the opportunity to gain more in-depth information about delivery of surgical services.

We propose to collect primary data on the activities and resources involved in delivering services in and around surgical events in the ACO context by surveying a small number of ACOs (Pioneer and Next Generation ACOs).

Similar to the approach of the more general practitioner survey, this effort would begin with an initial phase of primary data collection using a range of methodologies in a small number of ACOs; development, piloting, and validation of an additional survey module specific to ACOs. A survey of practitioners participating in approximately 4 to 6 ACOs using the survey instrument along with the additional ACO-specific module will be used to collect data from on pre- and post-operative visits.

(4) Conclusion

We recognize that the some of the data collection activity proposed here varies greatly from how the data is currently gathered to support PFS valuations for global surgery services. However, we believe the proposed claims-based data collection is generally consistent with how claims data is reported for other kinds of services paid under the PFS. We believe that the authority and requirements included in the statute through the MACRA and PAMA were intended to expand and enhance data that might be available to enhance the accuracy of PFS payments. Because these are new approaches to collecting data and in an area—global surgery—where very little data has previously been collected, we cannot describe exactly how this information would be used in valuing services. What is clear is that the claims-based data would provide information parallel to the kinds of claims-data used in developing RVUs for other PFS services and that by collecting these data, we would know far more than we do now about how post-operative care is delivered and gain insight to support appropriate packaging and valuation. We would include any revaluation proposals based on these data in subsequent notice and comment rulemaking.

E. Improving Payment Accuracy for Primary Care, Care Management, and Patient-Centered Services

1. Overview

In recent years, we have undertaken ongoing efforts to support primary care and patient-centered care management within the PFS as part of HHS' broader efforts to achieve better care, smarter spending and healthier people through delivery system reform. We have recognized the need to improve payment accuracy for primary care and patient-centered care management over several years, especially beginning in the CY 2012 PFS proposed rule (76 FR 42793) and continuing in each subsequent year of rulemaking. In the CY 2012 proposed rule, we acknowledged the limitations of the current code set that describes evaluation & management (E/M) services within the PFS. For example, E/M services represent a high proportion of PFS expenditures but have not been recently revalued to account for significant changes in the disease burden of the Medicare patient population and changes in health care practice that are underway, to meet the current population's health care needs. These trends in the Medicare population and health care practice have been widely recognized in the provider community and by health services researchers and policymakers alike.[1] We believe the focus of the health care system has shifted to delivery system reforms, such as patient-centered medical homes, clinical practice improvement, and increased investment in primary and comprehensive care management/coordination services for chronic and other conditions. This shift requires centralized management of patient needs and extensive care coordination among practitioners and providers (often on a non-face-to-face basis across an extended period of time). In contrast, the current CPT code set is designed with an overall orientation to pay for discrete services and procedural care as opposed to ongoing primary care, care management and coordination, and cognitive services. It includes thousands of separately paid, individual codes, most of which describe highly specialized procedures and diagnostic tests, while there are relatively few codes that describe care management and cognitive services. Further, in the past, we have not recognized as separately payable many existing CPT codes that describe care management and cognitive services, viewing them as bundled and paid as part of other services including the broadly drawn E/M codes that describe face-to-face visits billed by physicians and practitioners in all specialties.

This has resulted in minimal service variation for ongoing primary care, care management and coordination, and cognitive services relative to other PFS services, and in potential misvaluation of E/M services under the PFS (76 FR 42793). Some stakeholders believe that there is substantial misvaluation of physician work within the PFS, and that the current service codes fail to capture the range and intensity of nonprocedural physician activities (E/M services) and the ''cognitive'' work of certain specialties (*http://www.nejm.org/doi/full/10.1056/NEJMp1600999#t=article*).

Recognizing the inverse for specialties that furnish other kinds of services, MedPAC has noted that the PFS allows some specialties to more easily increase the volume of services they provide (and therefore their revenue from Medicare) relative to other specialties, particularly those that spend most of their time providing E/M services. (MedPAC March 2015 Report to the Congress, available at *http://www.medpac.gov/-documents-/reports*). We agree with this analysis, and we recognize that the current set of E/M codes limits Medicare's ability under the PFS to appropriately recognize the relative resource costs of primary care, care management/coordination and cognitive services relative to specialized procedures and diagnostic tests.

In recent years, we have been engaged in an ongoing incremental effort to update and improve the relative value of primary care, care management/coordination, and cognitive services within the PFS by identifying gaps in appropriate payment and coding. These efforts include changes in payment and coding for a broad range of PFS services. This effort is particularly vital in the context of the forthcoming transition to the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) incentives under The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015), since MIPS and many APMs will adopt and build on PFS coding, RVUs and PFS payment as their foundation.

In CY 2013, we began by focusing on post-discharge care management and transition of beneficiaries back into the community, establishing new codes to pay separately for transitional care management (TCM) services. Next we finalized new coding and separate payment beginning in CY 2015 for chronic care management (CCM) services provided by clinical staff. Most recently, in the CY 2016 PFS proposed rule (80 FR 41708 through 41711), we solicited public comments on three additional policy areas of consideration: (1) Improving payment for the professional work of care management

[1] See, for example, *http://content.healthaffairs.org/content/25/5/w378.full*; *http://www.commonwealthfund.org/publications/issue-briefs/2008/feb/how-disease-burden-influences-medication-patterns-for-medicare-beneficiaries—implications-for-polic*; *http://www.hhs.gov/ash/about-ash/multiple-chronic-conditions/index.html*; *http://www.nejm.org/doi/full/10.1056/NEJMp1600999#t=article*; *https://www.pcpcc.org/about*; *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html*.

services through coding that would more accurately describe and value the work of primary care and other cognitive specialties for complex patients (for example, monthly timed services including care coordination, patient/caregiver education, medication management, assessment and integration of data, care planning); (2) establishing separate payment for collaborative care, particularly, how we might better value and pay for robust inter-professional consultation, between primary care physicians and psychiatrists (developing codes to describe and provide payment for the evidence-based psychiatric collaborative care model (CoCM), and between primary care physicians and other (non-mental health) specialists; and (3) assessing whether current PFS payment for CCM services is adequate and whether we should reduce the administrative burden associated with furnishing and billing these services.

In the CY 2016 PFS final rule with comment period (80 FR 70919 through 70921), we summarized the many public comments we received in response to last year's comment solicitation. Instead of the specific policies we sought comment on, several commenters recommended an overhaul and complete revaluation of the E/M codes through a major research initiative akin to that undertaken when the PFS was first established. Many other commenters recommended that, until a major research initiative could be conducted to fully address the deficiencies in the current E/M code set, CMS should make separate payment under Medicare for a number of existing CPT codes to improve payment in the areas in which we solicited comments, including the codes used to describe complex CCM services (CPT codes 99487 and 99489). Other commenters also suggested that care management services may be beneficial to a number of other patient populations in addition to those transitioning into the community from an inpatient setting and those with multiple chronic conditions.

Also in response to our CY 2016 comment solicitation, the AMA restructured its existing CPT/RUC workgroup on these issues and convened the relevant individual specialty societies to develop new CPT coding that would address these issues. We understand that these efforts are ongoing, and that at this time, two sets of new codes are scheduled to be included in the CY 2018 CPT code set in response to our 2016 comment solicitation. One is a set of new codes describing services furnished under the psychiatric CoCM and the other is a code for assessment and care planning services for patients with cognitive impairment. Several stakeholders have urged us to facilitate Medicare payment for these and other new primary care, care management, and cognitive services sooner than CY 2018 by proposing payment using G-codes for CY 2017.

In response to our comment solicitation in the CY 2016 proposed rule, MedPAC commented that the PFS is an ill-suited payment mechanism for primary care and cognitive care generally. MedPAC recommended that Congress replace the expired Primary Care Incentive Payment (PCIP) with a capitated payment mechanism and expressed preference for codes like CCM that are beneficiary-centered and do not pay for each distinct care coordination activity.

Finally, many public commenters recommended a number of modifications to the current CCM payment rules. According to many commenters, current payment does not cover the cost of furnishing these services, and therefore, the codes are underutilized. As referenced in section II.E.3 on improving access and payment for CCM services, our assessment of claims data for CY 2015 for CPT code 99490 suggests that CCM services may be underutilized relative to the intended eligible patient population.

After considering the commenters' perspective and recommendations, as well as monitoring the ongoing efforts at the AMA/RUC and CPT to respond with new/revised coding, for CY 2017 we are proposing a number of changes to coding and payment policies under the PFS. These proposals are intended to accomplish the following:

- Improve payment for care management services provided in the care of beneficiaries with behavioral health conditions (including services for substance use disorder treatment) through new coding, including three codes used to describe services furnished as part of the psychiatric CoCM and one to address behavioral health integration more broadly.
- Improve payment for cognition and functional assessment, and care planning for beneficiaries with cognitive impairment.
- Adjust payment for routine visits furnished to beneficiaries whose care requires additional resources due to their mobility-related disabilities.
- Recognize for Medicare payment the additional CPT codes within the Chronic Care Management family (for Complex CCM services) and adjust payment for the visit during which CCM services are initiated (the initiating CCM visit) to reflect resources associated with the assessment for, and development of, a new care plan.
- Recognize for Medicare payment CPT codes for non-face-to-face Prolonged E/M services by the physician (or other billing practitioner) that are currently bundled, and increase payment rates for face-to-face prolonged E/M services by the physician (or other billing practitioner) based on existing RUC recommended values.

We are aware that CPT has approved a code to describe assessment and care planning for patients with cognitive impairment; however, it will not be ready in time for valuation in CY 2017. Therefore, we are proposing to make payment using a G-code (GPPP6—see below) for this service in 2017. We are also aware that CPT has approved three codes that describe services furnished consistent with the psychiatric CoCM, but that they will also not be ready in time for valuation in CY 2017. We discuss these services in more detail in the next section of this proposed rule. To facilitate separate payment for these services furnished to Medicare beneficiaries during CY 2017, we are proposing to make payment through the use of three G-codes (GPPP1, GPPP2, and GPPP3—see below) that parallel the new CPT codes, as well as a fourth G-code (GPPPX—see below) to describe services furnished using a broader application of behavioral health integration in the primary care setting. We intend for these to be temporary codes (for perhaps only one year) and will consider whether to adopt and establish values for the new CPT codes under our standard process, presumably for CY 2018. While we recognize that there may be overlap in the patient populations for the proposed new G-codes, we note that time spent by a practitioner or clinical staff cannot be counted more than once for any code (or assigned to more than one patient), consistent with PFS coding conventions.

Proposed payment for services described by new coding are as follows (please note that the descriptions included for GPPP1, GPPP2, and GPPP3 are from *Current Procedural Terminology* (CPT®) Copyright 2016 American Medical Association (and will be effective as part of CPT codes January 1, 2018). All rights reserved):

- GPPP1: Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified

health care professional, with the following required elements:

++ Outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional;

++ Initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan;

++ Review by the psychiatric consultant with modifications of the plan if recommended;

++ Entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant; and

++ Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies.

• GPPP2: Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements:

++ Tracking patient follow-up and progress using the registry, with appropriate documentation;

++ Participation in weekly caseload consultation with the psychiatric consultant;

++ Ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers;

++ Additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant;

++ Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies;

++ Monitoring of patient outcomes using validated rating scales; and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment.

• GPPP3: 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 (List separately in addition to code for primary procedure) (Use GPPP3 in conjunction with GPPP1, GPPP2).

• GPPPX: 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 time, per calendar month.

• GPPP6: Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history obtained from patient and/or caregiver, by the physician or other qualified health care professional in office or other outpatient setting or home or domiciliary or rest home.

• GPPP7: Comprehensive assessment of and care planning by the physician or other qualified health care professional for patients requiring chronic care management services, including assessment during the provision of a face-to-face service (billed separately from monthly care management services) (Add-on code, list separately in addition to primary service).

• GDDD1: Resource-intensive services for patients for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient lifts, and adjustable padded leg supports) is medically necessary and used during the provision of an office/outpatient evaluation and management visit (Add-on code, list separately in addition to primary procedure).

Additionally, we are aware that other codes are being developed through the CPT process. We have noted with interest that the CPT Editorial Panel and AMA/RUC restructured the former Chronic Care Coordination Workgroup to establish a new Emerging CPT and RUC Issues Workgroup that we hope will continue to consider the issues raised in this section of our CY 2017 proposed rule. We are continuing to consider possible additional codes for CCM services that would describe the time of the physician or other billing practitioner. We also remain interested in whether there should be changes under the PFS to reflect additional models of inter-professional collaboration for health conditions, in addition to those we are proposing for behavioral health integration.

For additional details on the coding and proposed valuation related to these proposals, see section II.L of this proposed rule for Valuation of Specific Codes. We note that the development of coding for these and other kinds of services across the PFS is typically an iterative process that responds to changes in medical practice and may be best refined over several years, with PFS rulemaking and the development of CPT codes as important parts of that process. Thus, we anticipate continuing the multi-year process of implementing initiatives designed to improve payment for, and recognize long-term investment in, primary care, care management and cognitive services, and patient-centered services.

2. Non-Face-To-Face Prolonged Evaluation & Management (E/M) Services

In public comments to the CY 2016 PFS proposed rule, many commenters recommended that CMS should establish separate payment for non-face-to-face prolonged E/M service codes that we currently consider to be ''bundled'' under the PFS (CPT codes 99358, 99359). The CPT descriptors are:

• CPT code 99358 (Prolonged evaluation and management service before and/or after direct patient care, first hour); and

• CPT code 99359 (Prolonged evaluation and management service before and/or after direct patient care, each additional 30 minutes (List separately in addition to code for prolonged service).

Commenters believed that separate payment for these existing CPT codes would provide a means for physicians and other billing practitioners to receive payment that more appropriately accounts for time that they spend providing non-face-to-face care. We agree that these codes would provide a means to recognize the additional resource costs of physicians and other practitioners when they spend an extraordinary amount of time outside the in-person office visit caring for the individual needs of their patients. And we believe that doing so in the context of the ongoing changes in health care practice to meet the current population's health care needs would be beneficial for Medicare beneficiaries and consistent with our overarching goals related to patient-centered care.

These non-face-to-face prolonged service codes are broadly described (although they include only time spent personally by the physician or other billing practitioner) and have a relatively high time threshold (the time counted must be beyond the usual service time for the primary or companion E/M code that is also billed). We believe this makes them sufficiently distinct from the other codes we propose to pay in CY 2017 as part of our

primary care/care management/cognitive care initiative described in this section of our proposed rule. Accordingly, beginning in CY 2017 we propose to recognize CPT codes 99358 and 99359 for separate payment under the PFS. We note that time could not be counted more than once towards the provision of CPT codes 99358 or 99359 and any other PFS service. See section II.L for a discussion of our proposed valuation of CPT codes 99358 and 99359.

We propose to require the services to be furnished on the same day by the same physician or other billing practitioner as the companion E/M code. However, in reviewing the CPT guidance for CPT codes 99358 and 99359, we noted that CPT codes 99358 and 99359 should not be reported during the same service period as complex CCM services (CPT codes 99487, 99489) or TCM services (CPT codes 99495, 99496). One reason for excluding TCM and complex CCM services from concurrent billing would be that, like prolonged services, TCM and complex CCM services include substantial non-face-to-face work by the billing physician or other practitioner (an E/M visit and/or medical decision-making of moderate or high complexity). However, the CPT prolonged service with patient contact codes are billable on the same day an E/M service is furnished, and the CPT prolonged service codes without direct patient contact are services furnished during a single day that are directly related to a discrete face-to-face service. In contrast, TCM and CCM codes are billed monthly and focused on a broader episode of patient care. We are seeking public input on the intersection of the prolonged service codes with CCM and TCM services. We are also seeking public comment on the potential intersection of the prolonged service CPT codes 99358 and 99359 with proposed code GPPP7 (Comprehensive assessment of and care planning for patients requiring CCM services). Specifically, we are seeking comment regarding how distinctions among these services can be clearly delineated, including how the prolonged time can be clearly distinguished from typical pre- and post-service time, which is continued to be bundled with other codes. For all of these services, we have concerns that there may potentially be program integrity risks as the same non-face-to-face activities could be undertaken to meet the billing requirements for any of the above. We are seeking public comment to help us identify the full extent of program integrity considerations, as well as options for mitigating program integrity risks associated with these and other potentially overlapping codes.

3. Establishing Separate Payment for Behavioral Health Integration (BHI)

a. Psychiatric Collaborative Care Model (CoCM)

In the CY 2016 PFS final rule with comment period (80 FR 70920), we stated that we believed the care and management for Medicare beneficiaries with behavioral health conditions may include extensive discussion, information sharing and planning between a primary care physician and a specialist. We refer to this practice broadly as ''Behavioral Health Integration'' (BHI). In CY 2016 rulemaking, we described that in recent years, many randomized controlled trials have established an evidence base for an approach to caring for patients with behavioral health conditions called the psychiatric Collaborative Care Model (CoCM). A specific model for BHI, CoCM typically is provided by a primary care team, consisting of a primary care provider and a care manager who works in collaboration with a psychiatric consultant, such as a psychiatrist. Care is directed by the primary care team and includes structured care management with regular assessments of clinical status using validated tools and modification of treatment as appropriate. The psychiatric consultant provides regular consultations to the primary care team to review the clinical status and care of patients and to make recommendations. As we previously noted, several resources have been published that describe the psychiatric CoCM in greater detail and assess the impact of the model, including pieces from the University of Washington (*http://aims.uw.edu/*), the Institute for Clinical and Economic Review (*http://icer-review.org/announcements/icer-report-presents-evidence-based-guidance-to-support-integration-of-behavioral-health-into-primary-care/*), and the Cochrane Collaboration (*http://www.cochrane.org/CD006525/DEPRESSN_collaborative-care-forpeople-with-depression-and-anxiety*). Because this particular kind of collaborative care model has been tested and documented in medical literature, we expressed that we were particularly interested in comments on how coding under the PFS might facilitate appropriate valuation of the services furnished under the model. We also solicited comments to assist us in considering refinements to coding and payment to address this model in particular relative to current coding and payment policies, as well as information related to various requirements and aspects of these services.

After consideration of the comments, we are proposing to begin making separate payment for services furnished using the psychiatric CoCM beginning January 1, 2017. We are aware that CPT, recognizing the need for new coding for services under this model of care, has approved three codes to describe psychiatric collaborative care that is consistent with this model, but the codes will not be ready in time for valuation in CY 2017. Current CPT coding does not accurately describe or facilitate appropriate payment for the treatment of Medicare beneficiaries under this model of care. For example, under current Medicare payment policy, there is no payment made specifically for regular monitoring of patients using validated clinical rating scales or for regular psychiatric caseload review and consultation that does not involve face-to-face contact with the patient. We believe that these resources are directly involved in furnishing ongoing care management services to specific patients with specific needs, but they are not appropriately recognized under current coding and payment mechanisms. Because PFS valuation is based on the relative resource costs of the PFS services furnished to Medicare beneficiaries, we believe that appropriate coding for these services for CY 2017 will facilitate accurate payment for these and other PFS services. Therefore, we are proposing separate payment for services under the psychiatric CoCM using three new G-codes, as detailed above: GPPP1, GPPP2, and GPPP3, which would parallel the CPT codes that are being created to report these services. We intend for these to be temporary codes (for perhaps only one year) and will consider whether to adopt and establish values for the new CPT codes under our standard process, presumably for CY 2018.

Services in the psychiatric CoCM are provided under the direction of a treating physician or other qualified health care professional during a calendar month. These services are provided when a patient has a diagnosed psychiatric disorder that requires a behavioral health care assessment; establishing, implementing, revising, or monitoring a care plan; and provision of brief interventions. The diagnosis may be either pre-existing or made by the billing practitioner. These services are reported by the treating physician or other qualified health care

professional and include the services of the treating physician or other qualified health care professional, the behavioral health care manager (see description below) who furnishes services incident to services of the treating physician or other qualified health care professional, and the psychiatric consultant (see description below) whose consultative services are furnished incident to services of the treating physician or other qualified health care professional. Patients who are appropriate candidates to participate in the psychiatric CoCM may have newly diagnosed conditions, need help in engaging in treatment, have not responded to standard care delivered in a non-psychiatric setting, or require further assessment and engagement prior to consideration of referral to a psychiatric care setting. Patients are treated under this model for an episode of care, defined as beginning when the behavioral health care manager engages in care of the patient under the appropriate supervision of the treating physician and ending with:

- The attainment of targeted treatment goals, which typically results in the discontinuation of care management services and continuation of usual follow-up with the treating physician or other qualified healthcare professional; or
- Failure to attain targeted treatment goals culminating in referral to a psychiatric care provider for ongoing treatment; or
- Lack of continued engagement with no psychiatric collaborative care management services provided over a consecutive six month calendar period (break in episode).

A new episode of care starts after a break in episode of six calendar months or more.

The treating physician or other qualified health care professional directs the behavioral health care manager and continues to oversee the patient's care, including prescribing medications, providing treatments for medical conditions, and making referrals to specialty care when needed. Medically necessary E/M and other services may be reported separately by the treating physician or other qualified health care professional, or other physicians or practitioners, during the same calendar month. Time spent by the treating physician or other qualified health care professional on activities for services reported separately may not be included in the services reported using GPPP1, GPPP2, and GPPP3. The behavioral health care manager under this model of care is a member of the treating physician or other qualified health care professional's clinical staff with formal education or specialized training in behavioral health (which could include a range of disciplines, for example, social work, nursing, and psychology) who provides care management services, as well as an assessment of needs, including the administration of validated rating scales,[2] the development of a care plan, provision of brief interventions, ongoing collaboration with the treating physician or other qualified health care professional, maintenance of a registry,[3] all in consultation with a psychiatric consultant. The behavioral health care manager furnishes these services both face-to-face and non-face-to-face, and consults with the psychiatric consultant minimally on a weekly basis. We would expect that the behavioral health care manager would be on-site at the location where the treating physician or other qualified health care professional furnishes services to the beneficiary.

The behavioral health care manager may or may not be a professional who meets all the requirements to independently furnish and report services to Medicare. If otherwise eligible, then that individual may report separate services furnished a beneficiary receiving the services described by GPPP1, GPPP2, GPPP3, and GPPPX in the same calendar month. These could include: psychiatric evaluation (90791, 90792), psychotherapy (90832, 90833, 90834, 90836, 90837, 90838), psychotherapy for crisis (90839, 90840), family psychotherapy (90846, 90847), multiple family group psychotherapy (90849), group psychotherapy (90853), smoking and tobacco use cessation counseling (99406, 90407), and alcohol or substance abuse structured screening and brief intervention services (99408, 99409). Time spent by the behavioral health care manager on activities for services reported separately may not be included in the services reported using time applied to GPPP1, GPPP2, and GPPP3.

The psychiatric consultant involved in the ''incident to'' care furnished under this model is a medical professional trained in psychiatry and qualified to prescribe the full range of medications. The psychiatric consultant advises and makes recommendations, as needed, for psychiatric and other medical care, including psychiatric and other medical diagnoses, treatment strategies including appropriate therapies, medication management, medical management of complications associated with treatment of psychiatric disorders, and referral for specialty services, that are communicated to the treating physician or other qualified health care professional, typically through the behavioral health care manager. The psychiatric consultant does not typically see the patient or prescribe medications, except in rare circumstances, but can and should facilitate a referral to a psychiatric care provider when clinically indicated.

In the event that the psychiatric consultant furnishes services to the beneficiary directly in the calendar month described by other codes, such as E/M services or psychiatric evaluation (90791, 90792), the services may be reported separately by the psychiatric consultant. Time spent by the psychiatric consultant on activities for services reported separately may not be included in the services reported using GPPP1, GPPP2, and GPPP3.

We also note that, although the psychiatric CoCM has been studied extensively in the setting of specific behavioral health conditions (for example, depression), we received persuasive comments last year recommending that we not specify particular diagnoses required for use of the codes for several reasons, including that: there may be overlap in behavioral health conditions; there are concerns that there could be modification of diagnoses to fit within payment rules which could skew the accuracy of submitted diagnosis code data; and for many patients for whom specialty care is not available, or who choose for other reasons to remain in primary care, primary care treatment will be more effective if it is provided within a model of integrated care that includes care management and psychiatric consultation.

(1) General Behavioral Health Integration (BHI)

We recognize that the psychiatric CoCM is prescriptive and that much of its demonstrated success may be attributable to adherence to a set of elements and guidelines of care as described in the preceding paragraphs. Therefore, we are proposing the use of these codes to pay accurately for this specific model of care for the benefit of Medicare beneficiaries, given its wide-spread adoption and recognized effectiveness. However, we note that PFS coding, in general, does not dictate how physicians practice medicine and believe that it should, instead, reflect the practice of medicine. We also recognize that there are primary care practices that are incurring, or may

[2] For example, see *https://aims.uw.edu/resource-library/measurement-based-treatment-target.*

[3] For example, see *https://aims.uw.edu/collaborative-care/implementation-guide/plan-clinical-practice-change/identify-population-based.*

incur, resource costs inherent to treatment of patients with similar conditions based on other models of BHI that may benefit beneficiaries with behavioral health conditions (see, for example, the approach described at *http://www.integration.samhsa.gov/integrated-care-models*.) These models of care include resource costs associated with care managers and consultants that are not accurately characterized by the descriptions in the preceding paragraphs. However, these costs are also not included as direct PE inputs in other PFS services, such as E/M codes. In its comment regarding the psychiatric CoCM, MedPAC noted its preference for beneficiary-centered treatment that would allow for flexibility in addressing patient needs, rather than approaches that are tied to a particular model of care. MedPAC also urged CMS not to make separate payment for each care management activity.

Therefore, to recognize the resource costs associated with furnishing behavioral health care management services to Medicare beneficiaries under related but different models of care without paying for each activity separately, we are also proposing to make payment using a new G-code that describes care management for beneficiaries with diagnosed behavioral health conditions under a broader application of integration in the primary care setting. We believe that for this subset of Medicare beneficiaries, the resources associated with medically necessary care management services are not otherwise adequately reflected under the PFS. The proposed code is GPPPX (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 time, per calendar month). We note that we expect this coding to be refined over time as we receive more information about other behavioral health care models being used and how they are implemented.

We are seeking stakeholder input on whether we should consider requiring a longer duration of time for this code or an add-on to the code that would allow, for example, additional 20 minute increments. In addition, while we recognize that services inherent to models of BHI provided under this code may range in resource costs, we hope that appropriate payment for these services will lead to appropriate use of BHI models of care, which, in turn, will inform further refinement of the valuation in the future. For additional information on proposed valuation of these codes, see section II.L of this proposed rule.

(2) Initiating Visit for Proposed BHI Codes (GPPP1, GPPP2, GPPP3, and GPPPX)

Similar to CCM services (see section II.E.4), we propose to require an initiating visit for the BHI codes (both the psychiatric CoCM model and the general BHI code), that would be billable separately from the services themselves. We propose that the same services that can serve as the initiating visit for CCM services (see section II.E.3 of this proposed rule) can serve as the initiating visit for the proposed BHI codes. The initiating visit would establish the beneficiary's relationship with the billing practitioner (most aspects of the BHI services would be furnished incident to the billing practitioner's professional services), ensure the billing treating physician or other qualified health care professional assesses the patient prior to initiating other care management processes, and provides an opportunity to obtain beneficiary consent (discussed below). We welcome public comment on the types of services that are appropriate for an initiating visit for the BHI codes, and within what timeframe the initiating visit should be conducted prior to furnishing BHI services.

(3) Beneficiary Consent

Commenters to the CY 2016 PFS proposed rule indicated that they did not believe a specific patient consent for BHI services is necessary and, in fact, that requiring special informed consent for these services may reduce access due to stigma associated with behavioral health conditions. Instead, the commenters recommended requiring a more general consent prior to initiating these services whereby the beneficiary gives the initiating physician or practitioner permission to consult with relevant specialists, which would include conferring with a psychiatric consultant. Accordingly, we propose to require a general beneficiary consent to consult with relevant specialists prior to initiating these services, recognizing that applicable rules continue to apply regarding privacy. The proposed general consent would encompass conferring with a psychiatric consultant when furnishing the psychiatric CoCM codes (GPPP1, GPPP2, and GPPP3) or the broader BHI code (GPPPX). Similar to the proposed beneficiary consent process for CCM services (see section II.E.4 of this proposed rule), we propose that the billing practitioner must document in the beneficiary's medical record that the beneficiary's consent was obtained to consult with relevant specialists including a psychiatric consultant, and that, as part of the consent, the beneficiary is informed that there is beneficiary cost-sharing, including potential deductible and coinsurance amounts, for both in-person and non-face-to-face services that are provided. We welcome stakeholder comments on this proposal.

We recognize that special informed consent can also be helpful in cases when a particular service is limited to being billed by a single practitioner for a particular beneficiary. We do not believe that there are circumstances where it would reasonable for multiple practitioners to be reporting these codes during the same month. However, we are not proposing a formal limit at this time. We are seeking comment on whether such a limitation would be beneficial or whether there are circumstances under which a beneficiary might reasonably receive BHI services from more than one practitioner during a given month.

In recent months, many stakeholders have advised that we should waive the applicable Part B coinsurance for services such as those included in our proposed BHI codes. However, we currently lack statutory authority to waive the coinsurance for services such as these.

4. Reducing Administrative Burden and Improving Payment Accuracy for Chronic Care Management (CCM) Services

Beginning in CY 2015, we implemented separate payment for chronic care management (CCM) services under CPT code 99490 (Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health professional, per calendar month, with the following required elements:

- Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient;
- Chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;
- Comprehensive care plan established, implemented, revised, or monitored.

We finalized a proposal to make separate payment for CCM services as one initiative in a series of initiatives designed to improve payment for, and encourage long-term investment in, care management services (79 FR 67715). In particular, we sought to address an issue raised to us by the physician community, which asserted that the care management included in many of the existing E/M services, such as office visits, does not adequately describe the

typical non-face-to-face care management work required by certain categories of beneficiaries (78 FR 43337). We began to re-examine how Medicare should pay under the PFS for non-face-to-face care management services that were bundled into the PFS payment for face-to-face E/M visits, being included in the pre- and post-encounter work (78 FR 43337). In proposing separate payment for CCM, we acknowledged that, even though we had previously considered non-face-to-face care management services as bundled into the payment for face-to-face E/M visits, the E/M office/outpatient visit CPT codes may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries. We stated that we believed that the resources required to furnish complex chronic care management services to beneficiaries with multiple (that is, two or more) chronic conditions were not adequately reflected in the existing E/M codes. Medical practice and patient complexity required physicians, other practitioners and their clinical staff to spend increasing amounts of time and effort managing the care of comorbid beneficiaries outside of face-to-face E/M visits, for example complex and multidisciplinary care modalities that involve regular physician development and/or revision of care plans; subsequent report of patient status; review of laboratory and other studies; communication with other health care professionals not employed in the same practice who are involved in the patient's care; integration of new information into the care plan; and/or adjustments of medical therapy.

Therefore, in the CY 2014 PFS final rule with comment period, we established a separate payment under the PFS for CPT code 99490 (78 FR 43341 through 43342). We sought to include a relatively broad eligible patient population within the code descriptor, established a moderate payment amount, and established bundled payment for concurrently new CPT codes that were reserved for beneficiaries requiring ''complex'' CCM services (base CPT code 99487 and its add-on code 99489) (79 FR 67716 through 67719). We stated that we would evaluate the services reported under CPT code 99490 to assess whether the service is targeted to the right population and whether the payment amount is appropriate (79 FR 67719). We remind stakeholders that CMS did not limit the eligible population to any particular list of chronic conditions other than the language in the CPT code descriptor. Accordingly, one or more of the chronic conditions being managed through CCM services could be chronic mental health or behavioral health conditions or chronic cognitive disorders, as long as the chronic conditions meet the eligibility language in the CPT code descriptor for CCM services and the billing practitioner meets all of Medicare's requirements to bill the code including comprehensive, patient-centered care planning for all health conditions (see Table 11).

In finalizing separate payment for CPT code 99490, we considered whether we should develop standards to ensure that physicians and other practitioners billing the service would have the capability to fully furnish the service (79 FR 67721). We sought to make certain that the new PFS code(s) would provide beneficiary access to appropriate care management services that are characteristic of advanced primary care, such as patient support for chronic diseases to achieve health goals; 24/7 patient access to care and health information; receipt of preventive care; patient, family and caregiver engagement; and timely coordination of care through electronic health information exchange. Accordingly, we established a set of scope of service elements and payment rules in addition to or in lieu of those established in CPT guidance (in the CPT code descriptor and CPT prefatory language), that the physician or nonphysician practitioner must satisfy to fully furnish CCM services and report CPT code 99490 (78 FR 74414 through 74427, 79 FR 67715 through 67730, and 80 FR 14854). We established requirements to furnish a preceding qualifying visit, obtain advance written beneficiary consent, use certified electronic health record (EHR) technology to furnish certain elements of the service, share the care plan and clinical summaries electronically, document specified activities, and other items summarized in Table 11. For the CCM service elements for which we required use of a certified EHR, the billing practitioner must use, at a minimum, technology meeting the edition(s) of certification criteria that is acceptable for purposes of the EHR Incentive Programs as of December 31st of the calendar year preceding each PFS payment year. (For the CY 2017 PFS payment year, this would mean technology meeting the 2014 edition of certification criteria). These elements and requirements for separately payable CCM services are extensive and generally exceed those required for payment of codes describing procedures, diagnostic tests, or other E/M services under the PFS. In addition, both CPT guidance and our rules specify that only a single practitioner who assumes the care management role for a given beneficiary can bill CPT code 99490 per service period (calendar month). Because the new CCM service closely overlapped with several Medicare demonstration models of advanced primary care (the Multi-Payer Advanced Primary Care Practice (MAPCP) demonstration and the Comprehensive Primary Care Initiative (CPCI)), we provided that practitioners participating in one of these two initiatives could not be paid for CCM services furnished to a beneficiary attributed by the initiative to their practice (79 FR 67729).

Given the non-face-to-face nature of CCM services, we also sought to ensure that beneficiaries would receive advance notice that Part B cost sharing applies since we currently have no legislative authority to ''waive'' cost sharing for this service. Also since only one practitioner can bill for CCM each service period, we believed the beneficiary notice requirement would help prevent duplicate payment to multiple practitioners.

Since the establishment of CPT code 99490 for separate payment of CCM services, in a number of forums and in public comments to the CY 2016 PFS final rule (80 FR 70921), many practitioners have stated that the service elements and billing requirements are burdensome, redundant and prevent them from being able to provide the services to beneficiaries who could benefit from them. Stakeholders have stated that CPT 99490 is underutilized because it is underpaid relative to the resources involved in furnishing the services, especially given the extensive Medicare rules for payment, and they have suggested a number of potential changes to our current payment rules. Stakeholders continue to believe that many of the CCM payment rules are duplicative of other statutory and regulatory provisions, and to recommend that we reduce the rules and expand CCM coding and payment to distinguish among different levels of patient complexity. We also note that section 103 of the MACRA requires CMS to assess and report to Congress (no later than December 31, 2017) on access to CCM services by underserved rural and racial and ethnic minority populations and to conduct an outreach/education campaign that is underway.

Our assessment of claims data for CY 2015 for CPT code 99490 suggests that

CCM services may indeed be underutilized considering the number of eligible Medicare beneficiaries. Our analysis of Medicare claims data indicates that for CY 2015, approximately 275,000 unique Medicare beneficiaries received the service an average of 3 times each, totaling $37 million in allowed charges. Since CPT code 99490 describes a minimum of 20 minutes of clinical staff time spent furnishing CCM services during a month and does not have a time limit, and since we currently do not separately pay the other codes in the CCM family of CPT codes (which would provide us with utilization data on the number of patients requiring longer service times during a billing period), we do not know how often patients required more than 20 minutes of CCM services per month. We also do not know their relative complexity, other than meeting the acuity criteria in the CPT code descriptor. We also have no way to know the relative complexity of the CCM services furnished to beneficiaries.

In light of this stakeholder feedback and our mandate under MACRA section 103 to encourage and report on access to CCM services, we are proposing several changes in the payment rules for CCM services. Our primary goal and statutory mandate is to pay as accurately as possible for services furnished to Medicare beneficiaries based on the relative resources required to furnish PFS services, including CCM services. In so doing, we also expect to facilitate beneficiaries' access to reasonable and necessary CCM services that improve health outcomes. First, for CY 2017 we are proposing to more appropriately recognize and pay for the other codes in the CPT family of CCM services (CPT codes 99487 and 99489 describing complex CCM), consistent with our general practice to price services according to their relative ranking within a given family of services. We direct the reader to section II.L of this proposed rule for a discussion of proposed valuation for base CPT code 99487 and its add-on CPT code 99489. The CPT code descriptors are:

- CPT code 99487—Complex chronic care management services, with the following required elements:

++ Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient;

++ Chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;

++ Establishment or substantial revision of a comprehensive care plan;

++ Moderate or high complexity medical decision making;

++ 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.

- CPT code 99489—Each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure).

As CPT provides, less than 60 minutes of clinical staff time in the service period could not be reported separately, and similarly, less than 30 minutes in addition to the first 60 minutes of complex CCM in a service period could not be reported. We would require 60 minutes of services for reporting CPT code 99487 and 30 additional minutes for each unit of CPT code 99489.

We propose to adopt the CPT provision that CPT codes 99487, 99489, 99490 may only be reported once per service period (calendar month) and only by the single practitioner who assumes the care management role with a particular beneficiary for the service period. That is, a given beneficiary would be classified as eligible to receive either complex or non-complex CCM during a given service period (calendar month), not both, and only one professional claim could be submitted to the PFS for CCM for that service period by one practitioner.

Except for differences in the CPT code descriptors, we propose to require the same CCM service elements for CPT codes 99487, 99489 and 99490. In other words, all the requirements in Table 11 would apply whether the code being billed for the service period is CPT code 99487 (plus 99489 if applicable) or CPT code 99490. These three codes would differ in the amount of clinical staff service time provided; the complexity of medical decision-making as defined in the E/M 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). Billing practitioners could consider identifying beneficiaries who require complex CCM services using criteria suggested in CPT guidance (such as number of illnesses, number of medications or repeat admissions or emergency department visits) or the profile of typical patients in the CPT prefatory language, but these would not comprise Medicare conditions of eligibility for complex CCM.

We are proposing several changes to our current scope of service elements for CCM, and are proposing that the same scope of service elements, as amended, would apply to all codes used to report CCM services beginning in 2017 (*i.e.,* CPT codes 99487, 99489 and 99490). In particular, we are proposing changes in the requirements for the initiating visit, 24/7 access to care and continuity of care, format and sharing of the care plan and clinical summaries, beneficiary receipt of the care plan, beneficiary consent, and documentation. In Table 11, we summarize the current scope of service elements and payment rules for CCM and indicate whether we are proposing to retain, remove or revise each element.

a. Initiating Visit

As provided in the CY 2014 PFS final rule with comment period (78 FR 74425) and subregulatory guidance (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Payment_for_CCM_Services_FAQ.pdf*), CCM must be initiated by the billing practitioner during a ''comprehensive'' E/M visit, annual wellness visit (AWV) or initial preventive physical exam (IPPE). This face-to-face, initiating visit is not part of the CCM service and can be separately billed to the PFS, but is required before CCM services can be provided directly or under other arrangements. The billing practitioner must discuss CCM with the patient at this visit. While informed patient consent does not have to be obtained during this visit, the visit is an opportunity to obtain the required consent. The face-to-face visit included in transitional care management (TCM) services (CPT 99495 and 99496) qualifies as a ''comprehensive'' visit for CCM initiation. Levels 2 through 5 E/M visits (CPT 99212 through 99215) also qualify; CMS does not require the practice to initiate CCM during a level 4 or 5 E/M visit. However CPT codes that do not involve a face-to-face visit by the billing practitioner or are not separately payable by Medicare (such as CPT 99211, anticoagulant management, online services, telephone and other E/M services) do not qualify as initiating visits. If the practitioner furnishes a ''comprehensive'' E/M, AWV, or IPPE and does not discuss CCM with the patient at that visit, that visit cannot count as the initiating visit for CCM.

We continue to believe that we should require an initiating visit in advance of furnishing CCM services, separate from the services themselves, because a face-to-face visit establishes the beneficiary's relationship with the billing practitioner

(most aspects of the CCM services are furnished incident to the billing practitioner's professional services). The initiating visit also ensures collection of comprehensive health information to inform the care plan. We continue to believe that the types of face-to-face services that qualify as an initiating visit for CCM are appropriate. We are not proposing to change the kinds of visits that can qualify as initiating CCM visits. However we are proposing to require the initiating visit only for new patients or patients not seen within one year instead of for all beneficiaries receiving CCM services. We believe this will allow practitioners with existing relationships with patients who have been seen relatively recently to initiate CCM services without furnishing a potentially unnecessary E/M visit. We are seeking public comment on whether a period of time shorter than one year would be more appropriate.

We are also proposing for CY 2017 to create a new add-on G-code that would improve payment for visits that qualify as initiating visits for CCM services. The code would be billable for beneficiaries who require extensive face-to-face assessment and care planning by the billing practitioner (as opposed to clinical staff), through an add-on code to the initiating visit, GPPP7 (Comprehensive assessment of and care planning by the physician or other qualified health care professional for patients requiring chronic care management services (billed separately from monthly care management services) (Add-on code, list separately in addition to primary service). We propose that when the billing practitioner initiating CCM personally performs extensive assessment and care planning outside of the usual effort described by the billed E/M code (or AWV or IPPE code), the practitioner could bill GPPP7 in addition to the E/M code for the initiating visit (or in addition to the AWV or IPPE), and in addition to the CCM CPT code 99490 (or proposed 99487 and 99489) if all requirements to bill for CCM services are also met. See section II.L for proposed valuation of GPPP7.

The code GPPP7 would account specifically for additional work of the billing practitioner in personally performing a face-to-face assessment of a beneficiary requiring CCM services, and personally performing CCM care planning (the care planning could be face-to-face and/or non-face-to-face) that is not already reflected in the initiating visit itself (nor in the monthly CCM service code). We believe GPPP7 might be particularly appropriate to bill when the initiating visit is a less complex visit (such as a level 2 or 3 E/M visit), although GPPP7 could be billed along with higher level visits if the billing practitioner's effort and time exceeded the usual effort described by the initiating visit code. It could also be appropriate to bill GPPP7 when the initiating visit addresses problems unrelated to CCM, and the billing practitioner does not consider the CCM-related work he or she performs in determining what level of initiating visit to bill. We believe that this proposal will more appropriately recognize the relative resource costs for the work of the billing practitioner in initiating CCM services, specifically for extensive work assessing the beneficiary and establishing the CCM care plan that is reasonable and necessary, and that is not accounted for in the billed initiating visit or in the unit of the CCM service itself that is billed for a given service period. In addition, we believe this proposal will help ensure that the billing practitioner personally performs and meaningfully contributes to the establishment of the CCM care plan when the patient's complexity warrants it.

Consistent with general coding guidance, the work that is reported under GPPP7 (including time) could not also be reported under or counted towards the reporting of any other billed code, including any of the monthly CCM services codes. The care plan that the practitioner must create in order to bill GPPP7 would be subject to the same requirements as the care plan included in the monthly CCM services, namely it must be an electronic patient-centered 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. This would distinguish it from the more limited care plan included in the BHI codes GPPP1, GPPP2, GPPP3 or GPPPX which focus on behavioral health issues, or the care plan included in GPPP6 which focuses on cognitive status. We are seeking public input on potential overlap among these codes and further clinical input as to how the assessments and care planning that is included in them would differ.

Finally, although not part of our proposals for 2017, we have noted with interest a recent CPT coding proposal for a code that would potentially identify and separately pay for monthly CCM work that is personally performed by the billing physician or other practitioner. We will continue to follow any CPT developments in this area.

b. 24/7 Access to Care and Continuity of Care

We propose several revisions to the scope of service elements of 24/7 Access to care and Continuity of Care. We continue to believe these elements are important aspects of CCM services, but that it would be appropriate to improve alignment with CPT provisions and remove the requirement for the care plan to be available remotely to individuals providing CCM services after hours. Studies have shown that after-hours care is best implemented as part of a larger practice approach to access and continuity (see for example, the peer-review article available at *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3475839/*). There is substantial local variation in how 24/7 access and continuity of care are achieved, depending on the contractual relationships among practitioners and providers in a particular geographic area and other factors. Care models include various contractual relationships between physician practices and after-hours clinics, urgent care centers and emergency departments; extended primary care office hours; physician call-sharing; telephone triage systems; and health information technology such as shared EHRs and systematic notification procedures (*http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3475839/*). Some or all of these may be used to provide access to urgent care on a 24/7 basis while maintaining information continuity between providers.

We recognize that some models of care require more significant investment in practice infrastructure than others, for example resources in staffing or health information technology. In addition, we believe there is room to reduce the administrative complexity of our current payment rules for CCM services to accommodate a range of potential care models. In re-examining what should be included in the CCM scope of service elements for 24/7 Access to Care and Continuity of Care, we believe the CPT language adequately and more appropriately describes the services that should, at a minimum, be included in these service elements. Therefore, we propose to adopt the CPT language for these two elements. For 24/7 Access to Care, the scope of service element would be to provide 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. We believe

the CPT language more accurately reflects the potential role of clinical staff or call-sharing services in addressing after-hours care needs than our current language does. In addition, the 24/7 access would be for ''urgent'' needs rather than ''urgent chronic care needs,'' because we believe after-hours services typically would and should address any urgent needs and not only those explicitly related to the beneficiary's chronic conditions.

We recognize that health information systems that include remote access to the care plan or the full EHR after hours, or a feedback loop that communicates back to the primary care physician and others involved in the beneficiary's care regarding after-hours care or advice provided, are extremely helpful (*http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3475839/#CR25*). They help ensure that the beneficiary receives necessary follow up, particularly if he or she is referred to the emergency department, and follow up after an emergency department visit is required under the CCM element of Management of Care Transitions. Accordingly, we continue to support and encourage the use of interoperable EHRs or remote access to the care plan in providing the CCM service elements of 24/7 Access to Care, Continuity of Care, and Management of Care Transitions. However, adoption of such technology would be optimal not only for CCM services, but also for a number of other PFS services and procedures (including various other care management services), and we have not required adoption of any certified or non-certified health information technology as a condition of payment for any other PFS service. We note that there are incentives under other Medicare programs to adopt such information technology, and are concerned that imposing EHR-related requirements at the service level as a condition of PFS payment could create disparities between these services and others under the fee schedule. Lastly, we recognize that not all after-hours care warrants follow-up or a feedback loop with the practitioner managing the beneficiary's care overall, and that under particular circumstances feedback loops can be achieved through oral, telephone or other less sophisticated communication methods. Therefore at this time, we propose to remove the requirement that the individuals providing CCM after hours must have access to the electronic care plan. This proposal reflects our understanding that flexibility in how practices can provide the requisite 24/7 access to care, as well as continuity of care and management of care transitions, for their CCM patients can facilitate appropriate access to these services for Medicare beneficiaries. This proposal is not intended to undermine the significance of standardized communication methods as part of effective care. Instead, we recognize that other CMS initiatives may be better mechanisms to incentivize increased interoperability of health information systems than conditions of payment assigned to particular services under the PFS. We also anticipate that improved accuracy of payment for care management services and reduced administrative burden associated with billing for them will contribute to practitioners' capacity to invest in the best tools for managing the care of Medicare beneficiaries.

For Continuity of Care, we currently require the ability to obtain successive routine appointments ''with the practitioner or a designated member of the care team,'' while CPT only references successive routine appointments ''with a designated member of the care team.'' We do not believe there is any practical difference between these two phrases and therefore are proposing to omit the words ''practitioner or'' from our requirement. The billing practitioner is a member of the CCM care team, so the CPT language already allows for successive routine appointments either with the billing practitioner or another appropriate member of the CCM care team.

c. Electronic Care Plan

Based on review of extensive public comment and stakeholder feedback, we have come to believe that we should not require individuals providing the beneficiary with the required 24/7 access to care for urgent needs to have access to the care plan as a condition of CCM payment. As discussed above, we believe that in general, provision of effective after-hours care of the beneficiary would require access to the care plan, if not the full EHR. However, we have heard from rural and other practices that remote access to the care plan is not always necessary or possible because urgent care needs after-hours are often referred to a practitioner or care team member who established the care plan or is familiar with the beneficiary. In some instances, the care plan does not need to be available in order to address urgent patient needs after business hours. In addition, we have not required the use of any certified or non-certified health information technology in the provision of any other PFS services (including various other care management services). We are concerned that imposing EHR-related requirements at the service level as a condition of PFS payment could distort the relative valuation of services priced under the fee schedule. Therefore, we propose to change the CCM service element to require timely electronic sharing of care plan information within and outside the billing practice, but not necessarily on a 24/7 basis, and to allow transmission of the care plan by fax.

We acknowledge that it is best for practitioners and providers to have access to care plan information any time they are providing services to beneficiaries who require CCM services. This proposal is not intended to undermine the significance of electronic communication methods other than fax transmission in providing effective, continuous care. On the contrary, we believe that fax transmission, while commonly used, is much less efficient and secure than other methods of communicating patient health information, and we encourage practitioners to adopt and use electronic technologies other than fax for transmission and exchange of the CCM care plan. We continue to believe the best means of exchange of all relevant patient health information is through standardized electronic means. However, we recognize that other CMS initiatives may be better mechanisms to incentivize increased interoperability of health information systems than conditions of payment assigned to particular services under the PFS. We believe our proposal would still allow timely availability of health information within and outside the practice for purposes of providing CCM, and would simplify the rules governing provision of the service and improve access to the service. These proposed revisions would better align the service with appropriate CPT prefatory language, which may reduce unnecessary administrative complexity for practitioners in navigating the differences between CPT guidance and Medicare rules.

d. Clinical Summaries

The CCM scope of service element Management of Care Transitions includes a requirement for the creation and electronic transmission and exchange of continuity of care documents referred to as ''clinical summaries'' (see Table 11). We patterned our requirements regarding clinical summaries after the EHR Incentive Program requirement that an eligible professional who transitions their patient to another setting of care or provider of care, or refers their patient to another provider of care, should

provide a summary care record for each transition of care or referral. This clinical summary includes demographics, the medication list, medication allergy list, problem list, and a number of other data elements if the practitioner knows them. As a condition of CCM payment, we required standardized content for clinical summaries (that they must be created/formatted according to certified EHR technology). For the exchange/transport function, we did not require the use of a specific tool or service to exchange/transmit clinical summaries, as long as they are transmitted electronically (this can include fax only when the receiving practitioner or provider can only receive by fax).

Based on review of extensive public comment and stakeholder feedback, we have come to believe that we should not require the use of any specific electronic technology in managing a beneficiary's care transitions as a condition of payment for CCM services. Instead we are proposing more simply to require the billing practitioner to create and exchange/transmit continuity of care document(s) timely with other practitioners and providers. To avoid confusion with the requirements of the EHR Incentive Programs, and since we would no longer require standardized content for the CCM continuity of care document(s), we would refer to them as continuity of care documents instead of clinical summaries. We would no longer specify how the billing practitioner must transport or exchange these document(s), as long as it is done timely and consistent with the Care Transitions Management scope of service element. We welcome public input on how we should refer to these document(s), noting that CPT does not provide model language specific to CCM services. The proposed term ''continuity of care document(s)'' draws on CPT prefatory language for TCM services, which CPT provides may include ''obtaining and reviewing the discharge information (for example, discharge summary, as available, or continuity of care document).''

Again, this proposal is not intended to undermine the significance of a standardized, electronic format and means of exchange (other than fax) of all relevant patient health information, for achieving timely, seamless care across settings especially after discharge from a facility. On the contrary, we believe that fax transmission, while commonly used, is much less efficient and secure than other methods of communicating patient health information, and we encourage practitioners to adopt and use electronic technologies other than fax for transmission and exchange of continuity of care documents in providing CCM services. We continue to believe the best means of exchange of all relevant patient health information is through standardized electronic means. However, as we discussed above regarding the CCM care plan, we have not applied similar requirements to other PFS services specifically (including various other care management services) and have concerns about how doing so may create disparities between these services and others under the PFS. We also recognize that other CMS initiatives may be better mechanisms to incentivize increased interoperability of health information systems than conditions of payment assigned to particular services under the PFS. However, we also anticipate that our proposals will contribute to practitioners' capacity to invest in the best tools for managing the care of Medicare beneficiaries.

e. Beneficiary Receipt of Care Plan

We propose to simplify the current requirement to provide the beneficiary with a written or electronic copy of the care plan, by instead adopting the CPT language specifying more simply that a copy of the care plan must be given to the patient or caregiver. While we believe beneficiaries should and must be provided a copy of the care plan, and that practitioners may choose to provide the care plan in hard copy or electronic form in accordance with patient preferences, we do not believe it is necessary to specify the format of the care plan that must be provided as a condition of CCM payment. Additionally, we recognize that there may be times that sharing the care plan with the caregiver (in a manner consistent with applicable privacy and security rules and regulations) may be appropriate.

f. Beneficiary Consent

We continue to believe that obtaining advance beneficiary consent to receive CCM services is important to ensure the beneficiary is informed, educated about CCM services, and is aware of applicable cost sharing. We also believe that querying the beneficiary about whether another practitioner is already providing CCM services helps to reduce the potential for duplicate provision or billing of the services. However, we believe the consent process could be simplified, and that it should be left to the practitioner and the beneficiary to decide the best way to establish consent. Therefore, we propose to continue to require billing practitioners to inform the beneficiary of the currently required information (that is, inform the beneficiary of the availability of CCM services; inform the beneficiary that only one practitioner can furnish and be paid for these services during a calendar month; and inform the beneficiary of the right to stop the CCM services at any time (effective at the end of the calendar month)). However, we propose to specify that the practitioner could document in the beneficiary's medical record that this information was explained and note whether the beneficiary accepted or declined CCM services instead of obtaining a written agreement.

We also propose to remove the language requiring beneficiary authorization for the electronic communication of his or her medical information with other treating providers as a condition of payment for CCM services, because under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CFR 164.506), a covered entity is permitted to use or disclose protected health information for purposes of treatment without patient authorization. Moreover, if such disclosure is electronic, the HIPAA Security Rule requires secure transmission (45 CFR 164.312(e)). In previous regulations we have reminded practitioners that for all electronic sharing of beneficiary information in the provision of CCM services, HIPAA Privacy and Security Rule standards apply in the usual manner (79 FR 67728).

g. Documentation

We have heard from practitioners that the requirements to document certain information in a certified EHR format are redundant because the CCM billing rules already require documentation of core clinical information in a certified EHR format. Specifically, we already require structured recording of demographics, problems, medications and medication allergies, and the creation of a clinical summary record, using a qualifying certified EHR; and that a full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care. Therefore, we propose to no longer require the use of a qualifying certified EHR to document communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits and to document beneficiary consent. We would continue to require documentation in the medical record of beneficiary consent (discussed above) and of communication to and from home- and community-based providers

regarding the patient's psychosocial needs and functional deficits.

In summary, we believe our proposed changes would retain elements of the CCM service that are most characteristic of the changes in medical practice toward advanced primary care, while eliminating redundancy, simplifying provision of the services, and improving access without compromising quality of care and beneficiary privacy or advance notice and consent. We also anticipate that improved accuracy of payment for care management services and reduced administrative burden associated with billing for these services will contribute to practitioners' capacity to invest in the best tools for managing the care of Medicare beneficiaries.

g. CCM Requirements for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

RHCs and FQHCs have been authorized to bill for CCM services since January 1, 2016, and are paid based on the Medicare PFS national average non-facility payment rate when CPT code 99490 is billed alone or with other payable services on a RHC or FQHC claim. The RHC and FQHC requirements for billing CCM services have generally followed the requirements for practitioners billing under the PFS, with some adaptations based on the RHC and FQHC payment methodologies.

To assure that CCM requirements for RHCs and FQHCs are not more burdensome than those for practitioners billing under the PFS, we are proposing revisions for CCM services furnished by RHCs and FQHCs similar to the revisions proposed under the section above entitled, ''Reducing Administrative Burden and Improving Payment Accuracy for Chronic Care Management (CCM) Services'' for RHCs and FQHCs. Specifically, we propose to:

- Require that CCM be initiated during an AWV, IPPE, or comprehensive E/M visit only for new patients or patients not seen within one year. This would replace the requirement that CCM could only be initiated during an AWV, IPPE, or comprehensive E/M visit where CCM services were discussed.
- Require 24/7 access to a RHC or FQHC practitioner or auxiliary staff with a means to make contact with a RHC or FQHC practitioner to address urgent health care needs regardless of the time of day or day of week. This would replace the requirement that CCM services be available 24/7 with health care practitioners in the RHC or FQHC who have access to the patient's electronic care plan to address his or her urgent chronic care needs, regardless of the time of day or day of the week.
- Require timely electronic sharing of care plan information within and outside the RHC or FQHC, but not necessarily on a 24/7 basis, and allow transmission of the care plan by fax. This would replace the requirement that the electronic care plan be available on a 24/7 basis to all practitioners within the RHC or FQHC whose time counts towards the time requirement for the practice to bill the CCM code, and removes the restriction on allowing the care plan to be faxed.
- Require that in managing care transitions, the RHC or FQHC creates, exchanges, and transmits continuity of care document(s) in a timely manner with other practitioners and providers. This would replace the requirements that clinical summaries must be created and formatted according to certified EHR technology, and the requirement for electronic exchange of clinical summaries by a means other than fax.
- Require that a copy of the care plan be given to the patient or caregiver. This would remove the description of the format (written or electronic) and allows the care plan to be provided to the caregiver when appropriate (and in a manner consistent with applicable privacy and security rules and regulations).
- Require that the RHC or FQHC practitioner documents in the beneficiary's medical record that all the elements of beneficiary consent (for example, that the beneficiary was informed of the availability of CCM services; only one practitioner can furnish and be paid for these services during a calendar month; the beneficiary may stop the CCM services at any time, effective at the end of the calendar month, etc.) were provided, and whether the beneficiary accepted or declined CCM services. This would replace the requirement that RHCs and FQHCs obtain a written agreement that these elements were discussed, and removes the requirement that the beneficiary provide authorization for the electronic communication of his or her medical information with other treating providers as a condition of payment for CCM services.
- Require that communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits be documented in the patient's medical record. This would replace the requirement to document this patient health information in a certified EHR format.

We note that we are not proposing an additional payment adjustment for patients who require extensive assessment and care planning as part of the initiating visit, as payments for RHC and FQHC services are not adjusted for length or complexity of the visit.

We believe these proposed changes would keep the CCM requirements for RHCs and FQHCs consistent with the CCM requirements for practitioners billing under the PFS, simplify the provision of CCM services by RHCs and FQHCs, and improve access to these services without compromising quality of care, beneficiary privacy, or advance notice and consent.

TABLE 11—CHRONIC CARE MANAGEMENT (CCM) SCOPE OF SERVICE ELEMENTS AND BILLING REQUIREMENTS

CCM Scope of service element/billing requirement	Propose to retain	Propose to remove	Proposed revision
Initiating Visit—Initiation during an AWV, IPPE, or face-to-face E/M visit for all patients (Level 4 or 5 visit not required).	.....	.....	Initiation during an AWV, IPPE, or face-to-face E/M visit (Level 4 or 5 visit not required) for new patients or patients not seen within 1 year.
Structured Recording of Patient Information Using Certified EHR Technology—Structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary record, using certified EHR technology. A full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care.	.....	.....	*Structured Recording of Patient Information Using Certified EHR Technology*—Structured recording of demographics, problems, medications and medication allergies using certified EHR technology. A full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care.

TABLE 11—CHRONIC CARE MANAGEMENT (CCM) SCOPE OF SERVICE ELEMENTS AND BILLING REQUIREMENTS—Continued

CCM Scope of service element/billing requirement	Propose to retain	Propose to remove	Proposed revision
24/7 Access to Care—Access to care management services 24/7 (providing the beneficiary with a means to make timely contact with health care practitioners in the practice who have access to the patient's electronic care plan to address his or her urgent chronic care needs regardless of the time of day or day of the week).	.....	.....	Provide 24/7 access to physicians or other qualified health 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.
Continuity of Care—Continuity of care with a designated practitioner or member of the care team with whom the beneficiary is able to get successive routine appointments.	.....	.....	Continuity of care with a designated member of the care team with whom the beneficiary is able to schedule successive routine appointments.
Comprehensive Care Management—Care management for chronic conditions including systematic assessment of the beneficiary'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 beneficiary self-management of medications.	X	.....	
Electronic Comprehensive Care Plan—Creation of an electronic patient-centered 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.	X	.....	
Electronic Sharing of Care Plan—Must at least electronically capture care plan information; make this information available on a 24/7 basis to all practitioners within the practice whose time counts towards the time requirement for the practice to bill the CCM code; and share care plan information electronically (by fax in extenuating circumstance) as appropriate with other practitioners and providers.	.....	.....	Must at least electronically capture care plan information, and make this information available timely within and outside the billing practice as appropriate. Share care plan information electronically (can include fax) and timely within and outside the billing practice to individuals involved in the beneficiary's care.
Beneficiary Receipt of Care Plan—Provide the beneficiary with a written or electronic copy of the care plan.	.....	.....	A copy of the plan of care must be given to the patient or caregiver.
Documentation of care plan provision to beneficiary—Document provision of the care plan as required to the beneficiary using certified EHR technology.	.....	X	
Management of Care Transitions ..... • 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. • Format clinical summaries according to certified EHR technology (content standard). • Not required to use a specific tool or service to exchange/transmit clinical summaries, as long as they are transmitted electronically (by fax in extenuating circumstance).	.....	.....	*Management of Care Transitions* • 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. • Create and exchange/transmit continuity of care document(s) timely with other practitioners and providers.
Home- and Community-Based Care Coordination—Coordination with home and community based clinical service providers.	X	.....	
Documentation of Home- and Community-Based Care Coordination—Communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits must be documented in the patient's medical record using certified EHR technology.	.....	.....	Communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits must be documented in the patient's medical record.

TABLE 11—CHRONIC CARE MANAGEMENT (CCM) SCOPE OF SERVICE ELEMENTS AND BILLING REQUIREMENTS—Continued

CCM Scope of service element/billing requirement	Propose to retain	Propose to remove	Proposed revision
Enhanced Communication Opportunities—Enhanced opportunities for the beneficiary and any caregiver to communicate with the practitioner regarding the beneficiary'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.	X	.....	
Beneficiary Consent— • Inform the beneficiary of the availability of CCM services and obtain his or her written agreement to have the services provided, including authorization for the electronic communication of his or her medical information with other treating providers. • Inform the beneficiary of the right to stop the CCM services at any time (effective at the end of the calendar month) and the effect of a revocation of the agreement on CCM services. • Inform the beneficiary that only one practitioner can furnish and be paid for these services during a calendar month. • Document the beneficiary's written consent and authorization using certified EHR technology.	.....	.....	• Inform the beneficiary of the availability of CCM services. • Inform the beneficiary that only one practitioner can furnish and be paid for these services during a calendar month. • Inform the beneficiary of the right to stop the CCM services at any time (effective at the end of the calendar month). • Document in the beneficiary's medical record that the required information was explained and whether the beneficiary accepted or declined the services.

5. Assessment and Care Planning for Patients With Cognitive Impairment

For CY 2017 we are proposing a G-code that would provide separate payment to recognize the work of a physician (or other appropriate billing practitioner) in assessing and creating a care plan for beneficiaries with cognitive impairment, GPPP6 (Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history obtained from patient and/or caregiver, in office or other outpatient setting or home or domiciliary or rest home). We understand that a similar code was recently approved by the CPT Editorial Panel and is scheduled to be included in the CY 2018 CPT code set. We intend for GPPP6 to be a temporary code (perhaps for only one-year) and will consider whether to adopt and establish relative value units for the new CPT code under our standard process, presumably for CY 2018.

We reviewed the list of service elements that were proposed at CPT, and are proposing the following as required service elements of GPPP6:

- Cognition-focused evaluation including a pertinent history and examination.
- Medical decision making of moderate or high complexity (defined by the E/M guidelines).
- Functional assessment (for example, Basic and Instrumental Activities of Daily Living), including decision-making capacity.
- Use of standardized instruments to stage dementia.
- Medication reconciliation and review for high-risk medications, if applicable.
- Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized instrument(s).
- Evaluation of safety (for example, home), including motor vehicle operation, if applicable.
- Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks.
- Advance care planning and addressing palliative care needs, if applicable and consistent with beneficiary preference.
- Creation of a care plan, including initial plans to address any neuropsychiatric symptoms and referral to community resources as needed (for example, adult day programs, support groups); care plan shared with the patient and/or caregiver with initial education and support.

The proposed valuation of GPPP6 (discussed in section II.E.1) assumes that this code would include services that are personally performed by the physician (or other appropriate billing practitioner) and would significantly overlap with services described by certain E/M visit codes, advance care planning services, and certain psychological or psychiatric service codes that are currently separately payable under the PFS. Accordingly, we propose that GPPP6 must be furnished by the physician (or other appropriate billing practitioner) and could not be billed on the same date of service as CPT codes 90785 (Psytx complex interactive), 90791 (Psych diagnostic evaluation), 90792 (Psych diag eval w/ med srvcs), 96103 (Psycho testing admin by comp), 96120 (Neuropsych tst admin w/comp), 96127 (Brief emotional/behav assmt), 99201–99215 (Office/outpatient visits new), 99324–99337 (Domicil/r-home visits new pat), 99341–99350 (Home visits new patient), 99366–99368 (Team conf w/pat by hc prof), 99497 (Advncd care plan 30 min), 99498 (Advncd care plan addl 30 min)), since these codes all reflect face-to-face services provided by the physician or other billing practitioner for related services that are separately payable. In addition, we are proposing to prohibit billing of GPPP6 with other care planning services, such as care plan oversight services (CPT code 99374), home health care and hospice supervision (G0181, G0182), or our proposed add-on code for comprehensive assessment and care planning by the billing practitioner for patients requiring CCM services (GPPP7). We are seeking comment on whether there are circumstances where multiple care planning codes could be furnished without significant overlap. We propose to specify that GPPP6 may serve as a companion or primary E/M code to the prolonged service codes (those that are currently separately paid, and those we propose to separately pay beginning in 2017), but are interested in

public input on whether there is any overlap among these services. We are seeking comment on how to best delineate the post-service work for GPPP6 from the work necessary to provide the prolonged services code.

We do not believe the services described by GPPP6 would significantly overlap with proposed or current medically necessary CCM services (CPT codes 99487, 99489, 99490); TCM services (99495, 99496); or the proposed behavioral health integration service codes (GPPP1, GPPP2, GPPP3, GPPPX). Therefore we propose that GPPP6 could be billed on the same date-of-service or within the same service period as these codes (CPT codes 99487, 99489, 99490, 99495, 99496, GPPP1, GPPP2, GPPP3, GPPPX). There may be overlap in the patient population eligible to receive these services and the population eligible to receive the services described by GPPP6, but we believe there would be sufficient differences in the nature and extent of the assessments, interventions and care planning, as well as the qualifications of individuals providing the services, to allow concurrent billing for services that are medically reasonable and necessary. We welcome public comment on potential overlap between GPPP6 and existing PFS billing codes, as well as the other primary care/cognitive services addressed in this section of the proposed rule.

6. Improving Payment Accuracy for Care of People With Disabilities

a. Background

People with disabilities face significant challenges accessing the health care system. Medicare beneficiaries who are under age 65 with disabilities are three times more likely to report having difficulties finding a doctor who accepts Medicare than beneficiaries age 65 and older.[4] When able to find a Medicare participating physician, people with disabilities report worse experiences than people without disabilities on many quality measures, including those related to patient-centered care and patient safety based on data from the National Healthcare Disparities Report, produced by the Agency for Healthcare Research and Quality (AHRQ).[5] The reasons for these access and quality disparities are multifaceted and may include a range of payment challenges, accessibility issues with equipment and facilities, communication obstacles, and sometimes lack of practitioner understanding of how to assess and fully address the needs and preferences of people with disabilities. The Equity Plan for Improving Quality in Medicare, released last fall by CMS, highlights many challenges in achieving better outcomes for people with disabilities.

One way to help improve access to high-quality physicians' services for people with disabilities is to ensure Medicare Physician Fee Schedule payments are based on the accurate relative resource costs of services furnished to people with disabilities.

As described in section I.B. of this proposed rule, PFS payments are required to be based on the relative resources involved in furnishing a service. To determine the relative resources required to furnish a service described by a specific HCPCS code, CMS considers the ''typical'' Medicare service described by that code, and identifies the resources involved in that scenario. This approach assumes that while practitioners might incur greater or fewer costs in furnishing any specific service to any particular beneficiary, RVUs are allocated appropriately based on a ''typical'' Medicare case-mix.

For HCPCS codes that describe narrowly-defined procedures and tests, PFS payment rates based on the typical resources may be accurate for most kinds of practitioners and many beneficiaries, because the granularity of coding corresponds with practitioners' use of resources based on the specific medical needs of their patients. However, the HCPCS codes that describe the office/outpatient E/M services are broadly defined, so the typical service billed using one of those HCPCS codes matches a much smaller percentage of all the services billed using that HCPCS code. Medicare payment rates for these kinds of services under the PFS do not vary by the population being served, or by the particular practitioner furnishing the services. Payment for these kinds of service vary only based on the delineations among the level of visits, despite the reality that adequately serving certain patients requires much greater resources in ways that are generally not reflected in the described differentiation between visit levels.

For example, the same codes and rates are used to pay for routine care of all patients, including furnishing care to patients with disabilities that often require greater resources relating to equipment, clinical staff, and physician time relative to the resource costs associated with providing the same kind of care to other Medicare beneficiaries. Thus, the payment rate for the code may not accurately reflect the resources involved in providing the service to certain categories of beneficiaries. For these reasons, the resources involved in furnishing care, including and especially routine care of both acute and chronic illness, to beneficiaries with disabilities may be routinely and systematically underestimated under PFS payment made on the basis of the broadly described visit codes. This effectively reduces overall payment relative to resource needs for practitioners who more frequently serve such patients, which could negatively impact access or quality of care for beneficiaries with disabilities.

b. Establishing a HCPCS G-Code To Improve Payment Accuracy for Care of People With Mobility-Related Disabilities

We estimate that about 7 percent of all Medicare beneficiaries have a potentially disabling mobility-related diagnosis (the Medicare-only prevalence is 5.5 percent and the prevalence for Medicare-Medicaid dual eligible beneficiaries is 11 percent), using 2010 Medicare (and for dual eligible beneficiaries, Medicaid) claims data.

When a beneficiary with a mobility-related disability goes to a physician or other practitioner's office for an E/M visit, the resources associated with providing the visit can exceed the resources required for the typical E/M visit. An E/M visit for a patient with a mobility-related disability can require more physician and clinical staff time to provide appropriate care because the patient may require skilled assistance throughout the visit to carefully move and adjust his/her body. Furthermore, an E/M visit for a patient with a mobility-related disability commonly requires specialized equipment such as a wheel chair accessible scale, floor and overhead lifts, a movable exam table, padded leg supports, a stretcher and transfer board. The current E/M visit payment rates, based on an assumption of ''typical'' resources involved in furnishing an E/M visit to a ''typical'' patient, do not accurately reflect these additional resources associated with furnishing appropriate care to many beneficiaries with mobility-related disabilities.

When furnishing E/M services to beneficiaries with mobility-related

[4] The Henry J Kaiser Family Foundation. 2010. ''Medicare and Nonelderly People with Disabilities.''

[5] National Healthcare Disparities Report, 2013. May 2014. Agency for Healthcare Research and Quality, Rockville, MD. The National Healthcare Disparities Report summarizes health care quality and access among various racial, ethnic, and income groups and other priority populations, such as residents of rural areas and people with disabilities.

disabilities, practitioners face difficult choices in deciding whether to take the extra time necessary and invest in the required specialized equipment for these visits even though the payment rate for the service does not account for either expense; potentially providing less than optimal care for a beneficiary whose needs exceed the standard appointment block of time in the standard equipped exam room reflected in the current E/M visit payment rate; or declining to accept appointments altogether for beneficiaries who require additional time and specialized equipment.

Each of these scenarios is potentially problematic. The first two scenarios suggest that the quality of care for this beneficiary population might be compromised by assumptions under the PFS regarding relative resource costs in furnishing services to this population. The third scenario reflects an obvious access problem for these beneficiaries. To improve payment accuracy and help ameliorate potential disparity in access and quality for beneficiaries with mobility-related disabilities, we propose to create a new add-on G-code, effective for CY 2017, to describe the additional services furnished in conjunction with E/M services to beneficiaries with disabilities that impair their mobility:

- GDDD1: Resource-intensive services for patients for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient lifts, and adjustable padded leg supports) is medically necessary and used during the provision of an office/outpatient evaluation and management service visit (Add-on code, list separately in addition to primary procedure).

Effective January 1, 2017, we propose that this add-on code could be billed with new and established patient office/outpatient E/M codes (CPT codes 99201 through 99205, and 99212 through 99215), as well as transitional care management codes (CPT codes 99495 and 99496), when the additional resources described by the code are medically necessary and used in the provision of care. In addition to seeking comment on this proposal, we are also seeking comment on other HCPCS codes that may be appropriate base codes for this proposed add-on code, including those describing preventive visits and services. We remind potential commenters that the rationale for this proposal is based in large part on the broad use and lack of granularity in coding for E/M services relative to other PFS services in conjunction with the additional resources used.

The proposed inputs and valuation for this code are detailed in section II.L of this proposed rule.

c. Soliciting Comment on Other Coding Changes To Improve Payment Accuracy for Care of People With Disabilities

When furnishing care to a beneficiary with a mobility-related disability, the current E/M visit payment rates may not fully reflect the associated resource costs that are being incurred by practitioners. We recognize that there are other populations for which payment adjustment may be appropriate. Our proposal regarding beneficiaries with mobility-related disabilities reflects the discrete nature of the additional resource costs for this population, the clear lack of differentiation in resource costs regarding particular kinds of frequently-furnished services, and the broad recognition of access problems. We recognize that some physician practices may frequently furnish services to particular populations for which the relative resource costs are similarly systemically undervalued and we seek comment regarding other circumstances where these dynamics can be discretely observed.

7. Supervision for Requirements for Non-Face-to-Face Care Management Services

Our current regulations in § 410.26(b) provide for an exception to allow general supervision of CCM services (and similarly, for the non-face-to-face portion of TCM services), because these are non-face-to-face care management/care coordination services that would commonly be provided by clinical staff when the billing practitioner, and hence, the supervising physician, is not physically present; and the CPT codes are comprised solely (or largely) of non-face-to-face services provided by clinical staff. A number of codes that we are proposing to establish for separate payment in CY 2017 under our initiative to improve payment accuracy for primary care and care management are similar to CCM services in that a critical element of the services is non-face-to-face care management/care coordination services provided by clinical staff when the billing practitioner may not be physically present. Accordingly, we are proposing to amend § 410.26(a)(3) and § 410.26 (b) to better define general supervision and to allow general supervision not only for CCM services and the non-face-to-face portion of TCM services, but also for proposed codes GPPP1, GPPP2, GPPP3, GPPPX, CPT code 99487, and CPT code 99489. Instead of adding each of these proposed codes requiring general supervision to the regulation text on an individual basis, we propose to revise our regulation under paragraph (b)(1) of § 410.26 to allow general supervision of the non-face-to-face portion of designated care management services, and we would designate the applicable services through notice and comment rulemaking.

F. Improving Payment Accuracy for Services: Diabetes Self-Management Training (DSMT)

Section 1861(s)(2)(S) of the Act specifies that medical and other health services include DSMT services as defined in section 1861(qq) of the Act. DSMT services are intended to educate beneficiaries in the successful self-management of diabetes. DSMT includes, as applicable, instructions in self-monitoring of blood glucose; education about diet and exercise; an insulin treatment plan developed specifically for the patient who is insulin-dependent; and motivation for patients to use the new skills for self-management (see § 410.144(a)(5)). DSMT services are reported under HCPCS codes G0108 (Diabetes outpatient self-management training services, individual, per 30 minutes) and G0109 (Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes). The benefit, as specified at § 410.141, consists of 1 hour of individual and 9 hours of group training unless special circumstances warrant more individual training or no group session is available within 2 months of the date the training is ordered.

Section 1861(qq) of the Act specifies that DMST services are furnished by a certified provider, defined as a physician or other individual or entity that also provides, in addition to DSMT, other items or services for which payment may be made under Medicare. The physician, individual or entity that furnishes the training also must meet certain quality standards. The physician, individual or entity can meet standards established by us or standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who participated in their establishment, or can be recognized by an organization that represents individuals with diabetes as meeting standards for furnishing the services.

We require that all those who furnish DSMT services be accredited as meeting quality standards by a CMS-approved national accreditation organization (NAO). In accordance with § 410.144, a CMS-approved NAO may accredit an

individual, physician or entity to meet one of three sets of DSMT quality standards: CMS quality standards; the National Standards for Diabetes Self-Management Education Programs (National Standards); or the standards of an NAO that represents individuals with diabetes that meet or exceed our quality standards. Currently, we recognize the American Diabetes Association and the American Association of Diabetes Educators as approved NAOs, both of whom follow National Standards. Medicare payment for outpatient DSMT services is made in accordance with § 414.63.

An article titled ''Use of Medicare's Diabetes Self-Management Training Benefit'' was published in the *Health Education Behavior* on January 23, 2015. The article noted that only 5 percent of Medicare beneficiaries with newly diagnosed diabetes used DSMT services. The article recommended that future research identify barriers to DSMT access.

We understand there are a number of issues that may contribute to the low utilization of these services. Some of the issues that have been brought to our attention by the DSMT community and NAOs are:

- Concerns that claims have been rejected or denied because of confusion about the credentials of the individuals who furnish DSMT services. In entities following the National Standards, the credentials of the educators actually providing the training are determined by the NAO and are not to be determined by the Medicare Administrative Contractor. Many individuals who actually furnish DSMT services, such as registered nurses and pharmacists, do not qualify to enroll in Medicare as certified providers, as that term is defined at section 1861(qq)(2)(A) of the Act, and codified in our regulations at § 410.140 as approved entit(ies).
- Questions about when individual (rather than group) DSMT services are available. As noted above, the benefit consists of 1 hour of individual and 9 hours of group training unless special circumstances warrant more individual training or no group session is available within 2 months of the date the training is ordered. The special circumstances are when the beneficiary's physician or qualified NPP documents in the beneficiary's medical record that the beneficiary has special needs resulting from conditions such as severe vision, hearing, or language limitations that would hinder effective participation in a group training session. In all cases, however, the physician or NPP must order individual training.
- Concerns that the Medicare Benefit Policy Manual, Chapter 15, section 300 does not clarify the settings and locations in which DSMT services may be provided. As a result, some providers (and perhaps some Medicare contractors) are confused. In regard to this issue, we note that a forthcoming manual update will reiterate the guidance we provided to the DSMT community, including the NAOs, in a response to their letter requesting clarification regarding the settings and locations in which DSMT services can be provided. The manual update will clarify that: (a) In the case of DSMT services furnished by an entity that submits professional claims to the A/B Medicare Administrative Contractor (MAC), such as a physician's office or an RD's practice, DSMT services may be furnished at alternate locations used by the entity as a practice location; and (b) when the DSMT services are furnished by an entity that is a hospital outpatient department (HOPD), these DSMT services must be furnished in the hospital (including a provider-based department) and cannot be furnished at alternate non-hospital locations. We plan to address and clarify the above issues through Medicare program instructions as appropriate. We also recognize the possibility that Medicare payment for these services may not fully reflect the resources required to provide them and this may be contributing to relatively low utilization. There may also be other barriers to access of which we are not aware. We are seeking public comment on such barriers to help us identify and address them. We also seek comment and information on whether Medicare payment for these services is accurate. In particular, we would appreciate information on the time and intensity of services provided, and on the services and supplies that should be included in the calculation of practice expenses. We will consider this information to determine whether to propose an update to resource inputs used to develop payment rates for these services in future rulemaking.

G. Target for Relative Value Adjustments for Misvalued Services

Section 1848(c)(2)(O) of the Act establishes 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 estimated net reduction in expenditures for a year as a result of adjustments to the relative values for misvalued codes is equal to or greater than the target for that 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. The provision also specifies that the amount by which such reduced expenditures exceeds the target for a given year shall be treated as a net reduction in expenditures for the succeeding year, for purposes of determining whether the target has been met for that subsequent year. Section 1848(c)(2)(O)(iv) of the Act defines a target recapture amount as the difference between the target for the year and the estimated net reduction in expenditures under the PFS resulting from adjustments to RVUs for misvalued codes. 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. Under section 1848(c)(2)(O)(v) of the Act, the target that applies to calendar years (CYs) 2017 and 2018 is calculated as 0.5 percent of the estimated amount of expenditures under the PFS for the year.

In CY 2016 PFS rulemaking, we proposed and finalized a methodology to implement this statutory provision.

Because the annual target is calculated by measuring changes from one year to the next, for CY 2016, we considered how to account for changes in values that are best measured over 3 years, instead of 2 years. As we described in the CY 2016 final rule with comment period (80 FR 70932), our general valuation process for potentially misvalued, new, and revised codes was to establish values on an interim final basis for a year in the PFS final rule with comment period. Then, during the 60-day period following the publication of the final rule with comment period, we would accept public comment about those valuations. In the final rule with comment period for the subsequent year, we would consider and respond to public comments received on the interim final values, and make any appropriate adjustments to values based on those comments. Under that process for revaluing new, revised, and misvalued codes, we believe the overall change in valuation for many codes would best measured across values for 3 years: Between the original value in the first year; the interim final value in the second year; and the finalized value in the third year. However, the target calculation for a year would only be comparing changes in RVUs between 2 years and not among 3 years, so the

contribution of a particular change towards the target for any single year would be measured against only the preceding year without regard to the overall change that takes place over 3 years.

For recent years, interim final values for misvalued codes (year 2) have generally reflected reductions relative to original values (year 1), and for most codes, the interim final values (year 2) are maintained and finalized (year 3). However, when values for particular codes have changed between the interim final (year 2) and final values (year 3) based on public comment, the general tendency has been that codes increase in the final value (year 3) relative to the interim final value (year 2), even in cases where the final value (year 3) represents a decrease from the original value (year 1). Therefore, for these codes, the year 2 changes compared to year 1 would risk over-representing the overall reduction, while the year 3 to year 2 changes would represent an increase in value. We noted that if there were similar targets in every PFS year, and a similar number of misvalued code changes made on an interim final basis, the incongruence in measuring what is really a 3-year change in 2-year increments might not be particularly problematic since each year's calculation would presumably include a similar number of codes measured between years 1 and 2 and years 2 and 3.

However, including changes that take place over 3 years generated challenges in calculating the target for CY 2016. Because there was no target for CY 2015, any reductions that occurred on an interim final basis for CY 2015 were not counted toward achievement of a target. If we had then included any upward adjustments made to these codes based on public comment as ''misvalued code'' changes for CY 2016, we would effectively be counting the service-level increases for 2016 (year 3) relative to 2015 (year 2) against achievement of the target without any consideration to the service-level changes relative to 2014 (year 1), even in cases where the overall change in valuation was negative.

Therefore, we proposed and finalized the decision to exclude code-level input changes for CY 2015 interim final values from the calculation of the CY 2016 misvalued code target since the misvalued change occurred over multiple years, including years not applicable to the misvalued code target provision.

For the CY 2017 final rule with comment period, we will be finalizing values (year 3) for codes that were interim final in CY 2016 (year 2). Unlike codes that were interim final for CY 2015, the codes that are interim final for CY 2016 were included as misvalued codes and will fall within the range of years for which the misvalued code target provision applies. Thus, overall changes in values for these codes would be measured in the target across 3 full years: The original value in the first year (CY 2015); the interim final value in the second year (CY 2016); and the finalized value in the third year (CY 2017). The changes in valuation for these CY 2016 interim final codes were previously measured and counted towards the target during their initial change in valuation between years 1 and 2.

As such, we are proposing to include changes in values of the CY 2016 interim final codes toward the CY 2017 misvalued code target. We believe that this is consistent with the approach that we finalized in last year's final rule with comment period. The changes in values of CY 2015 interim final codes were not counted towards the misvalued code target in CY 2016 since the valuation change occurred over multiple years, including years not applicable to the misvalued code target provision. However, both of the changes in valuation for the CY 2016 interim final codes, from year 1 to year 2 (CY 2015 to CY 2016) and from year 2 to year 3 (CY 2016 to CY 2017), have taken place during years that occur within the misvalued code target provision. We therefore believe that any adjustments made to these codes based on public comment should be considered towards the achievement of the target for CY 2017, just as any changes in valuation for these same CY 2016 interim final codes previously counted towards the achievement of the target for CY 2016.

We seek public comments regarding this proposal. We also remind commenters that we have revised our process for revaluing new, revised and misvalued codes so that we will be proposing and finalizing values for most of the misvalued codes during a single calendar year. After this year, there will be far fewer instances of interim final codes and changes that are best measured over 3 years far.

We refer readers to the regulatory impact analysis section of this proposed rule for our estimate of the proposed net reduction in expenditures relative to the 0.5 percent target for CY 2017, and the resulting adjustment required to be made to the conversion factor. Additionally, we refer readers to the public use file that provides a comprehensive description of how the target is calculated as well as the estimated impact by code family on the CMS Web site under the supporting data files for the CY 2017 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

H. Phase-In of Significant RVU Reductions

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 the CY 2016 PFS rulemaking, we proposed and finalized a methodology to implement this statutory provision. To determine which services are described by new or revised codes for purposes of the phase-in provision, we apply the phase-in to all services that are described by the same, unrevised code in both the current and update year, and exclude codes that describe different services in the current and update year.

Because the phase-in of significant reductions in RVUs falls within the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act, we estimate the total RVUs for a service prior to the budget-neutrality redistributions that result from implementing phase-in values. 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.

The statute provides that the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period when the RVU reduction for a code for a year is estimated to be equal to or greater than 20 percent. Since CY 2016 was the first year in which we applied the phase-in transition, CY 2017 will be the first year in which a single code could be subject to RVU reductions greater than 20 percent for 2 consecutive years.

Under our finalized policy, the only codes that are not subject to the phase-in are those that are new or revised, which we defined as those services that are not described by the same, unrevised code in both the current and update year, or by the same codes that describe different services in the current and update year. Since CY 2016 was the first year for which the phase-in provision applied, we did not address how we would handle codes with

values that had been partially phased in during the first year, but that have a remaining phase-in reduction of 20 percent or greater.

The significant majority of codes with reductions in RVUs that are greater than 20 percent in year one would not be likely to meet the 20 percent threshold in a consecutive year. However, in a few cases, significant changes (for example, in the input costs included in the valuation of a service) could produce reductions of 20 percent or greater in consecutive years.

We believe that a consistent methodology regarding the phase-in transition should be applied to these cases. We propose to reconsider in each year, for all codes that are not new or revised codes and including codes that were assigned a phase-in value in the previous year, whether the total RVUs for the service would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year. Under this proposed policy, the 19 percent reduction in total RVUs would continue to be the maximum one-year reduction for all codes (except those considered new and revised), including those codes with phase-in values in the previous year. In other words, for purposes of the 20 percent threshold, every service is evaluated anew each year, and any applicable phase-in is limited to a decrease of 19 percent. For example, if we were to adopt a 50 percent reduction in total RVUs for an individual service, the reduction in any particular year would be limited to a decrease of 19 percent in total RVUs. Because we do not set rates 2 years in advance, the phase-in transition continues to apply until the year-to-year reduction for a given code does not meet the 20 percent threshold.

We are soliciting comments regarding this proposal.

The list of codes proposed to be subject to the phase-in and the associated proposed RVUs that result from this methodology are available on the CMS Web site under downloads for the CY 2017 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

I. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, PE, and malpractice (MP)). The PFS localities are discussed in section II.E.3. of this proposed rule. Although the statute requires that the PE and MP GPCIs reflect the full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the work GPCIs reflect only one-quarter of the relative cost differences compared to the national average. In addition, section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for services furnished in Alaska beginning January 1, 2009, and section 1848(e)(1)(I) of the Act sets a permanent 1.0 PE GPCI floor for services furnished in frontier states (as defined in section 1848(e)(1)(I) of the Act) beginning January 1, 2011. Additionally, section 1848(e)(1)(E) of the Act provided for a 1.0 floor for the work GPCIs, which was set to expire on March 31, 2015. Section 201 of the MACRA amended the statute to extend the 1.0 floor for the work GPCIs through CY 2017 (that is, for services furnished no later than December 31, 2017).

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years. Section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be half of the adjustment that otherwise would be made. Therefore, since the previous GPCI update was implemented in CY 2014 and CY 2015, we are proposing to phase in 1/2 of the latest GPCI adjustment in CY 2017.

We have completed a review of the GPCIs and are proposing new GPCIs in this proposed rule. We also calculate a geographic adjustment factor (GAF) for each PFS locality. The GAFs are a weighted composite of each area's work, PE and malpractice expense GPCIs using the national GPCI cost share weights. While we do not actually use GAFs in computing the fee schedule payment for a specific service, they are useful in comparing overall areas costs and payments. The actual effect on payment for any actual service would deviate from the GAF to the extent that the proportions of work, PE and MP RVUs for the service differ from those of the GAF.

As noted above, section 201 of the MACRA extended the 1.0 work GPCI floor for services furnished through December 31, 2017. Therefore, the proposed CY 2017 work GPCIs and summarized GAFs reflect the 1.0 work floor. Additionally, as required by sections 1848(e)(1)(G) and 1848(e)(1)(I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for frontier states are permanent, and therefore, applicable in CY 2017. See Addenda D and E to this proposed rule for the proposed CY 2017 GPCIs and summarized GAFs available on the CMS Web site under the supporting documents section of the CY 2017 PFS proposed rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

2. GPCI Update

The proposed updated GPCI values were calculated by a contractor. There are three GPCIs (work, PE, and MP), and all GPCIs are calculated through comparison to a national average for each. Additionally, each of the three GPCIs relies on its own data source(s) and methodology for calculating its value as described below. Additional information on the CY 2017 GPCI update may be found in our contractor's draft report, ''Draft Report on the CY 2017 Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule,'' which is available on our Web site. It is located under the supporting documents section for the CY 2017 PFS proposed rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

a. Work GPCIs

The work GPCIs are designed to reflect the relative costs of physician labor by Medicare PFS locality. As required by statute, the work GPCI reflects one quarter of the relative wage differences for each locality compared to the national average.

To calculate the work GPCIs, we use wage data for seven professional specialty occupation categories, adjusted to reflect one-quarter of the relative cost differences for each locality compared to the national average, as a proxy for physicians' wages. Physicians' wages are not included in the occupation categories used in calculating the work GPCI because Medicare payments are a key determinant of physicians' earnings. Including physician wage data in calculating the work GPCIs would potentially introduce some circularity to the adjustment since Medicare payments typically contribute to or influence physician wages. That is, including physicians' wages in the physician work GPCIs would, in effect, make the indices, to some extent, dependent upon Medicare payments.

The work GPCI updates in CYs 2001, 2003, 2005, and 2008 were based on professional earnings data from the 2000 Census. However, for the CY 2011 GPCI update (75 FR 73252), the 2000 data were outdated and wage and earnings data were not available from the more recent Census because the ''long form'' was discontinued. Therefore, we used the median hourly earnings from the 2006 through 2008 Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) wage data as a replacement for the 2000 Census data. The BLS OES data meet several criteria that we consider to be important for selecting a data source for purposes of calculating the GPCIs. For example, the BLS OES wage and employment data are derived from a large sample size of approximately 200,000 establishments of varying sizes nationwide from every metropolitan area and can be easily accessible to the public at no cost. Additionally, the BLS OES is updated regularly, and includes a comprehensive set of occupations and industries (for example, 800 occupations in 450 industries). For the CY 2014 GPCI update, we used updated BLS OES data (2009 through 2011) as a replacement for the 2006 through 2008 data to compute the work GPCIs.

Because of its reliability, public availability, level of detail, and national scope, we believe the BLS OES continues to be the most appropriate source of wage and employment data for use in calculating the work GPCIs (and as discussed in section II.E.2.b the employee wage component and purchased services component of the PE GPCI). Therefore, for the proposed CY 2017 GPCI update, we used updated BLS OES data (2011 through 2014) as a replacement for the 2009 through 2011 data to compute the work GPCIs.

b. Practice Expense GPCIs

The PE GPCIs are designed to measure the relative cost difference in the mix of goods and services comprising practice expenses (not including malpractice expenses) among the PFS localities as compared to the national average of these costs. Whereas the physician work GPCIs (and as discussed later in this section, the MP GPCIs) are comprised of a single index, the PE GPCIs are comprised of four component indices (employee wages; purchased services; office rent; and equipment, supplies and other miscellaneous expenses). The employee wage index component measures geographic variation in the cost of the kinds of skilled and unskilled labor that would be directly employed by a physician practice. Although the employee wage index adjusts for geographic variation in the cost of labor employed directly by physician practices, it does not account for geographic variation in the cost of services that typically would be purchased from other entities, such as law firms, accounting firms, information technology consultants, building service managers, or any other third-party vendor. The purchased services index component of the PE GPCI (which is a separate index from employee wages) measures geographic variation in the cost of contracted services that physician practices would typically buy. (For more information on the development of the purchased service index, we refer readers to the CY 2012 PFS final rule with comment period (76 FR 73084 through 73085)). The office rent index component of the PE GPCI measures relative geographic variation in the cost of typical physician office rents. For the medical equipment, supplies, and miscellaneous expenses component, we believe there is a national market for these items such that there is not significant geographic variation in costs. Therefore, the equipment, supplies and other miscellaneous expense cost index component of the PE GPCI is given a value of 1.000 for each PFS locality.

For the previous update to the GPCIs (implemented in CY 2014) we used 2009 through 2011 BLS OES data to calculate the employee wage and purchased services indices for the PE GPCI. As discussed in section II.E.2.a., because of its reliability, public availability, level of detail, and national scope, we continue to believe the BLS OES is the most appropriate data source for collecting wage and employment data. Therefore, in calculating the proposed CY 2017 GPCI update, we used updated BLS OES data (2011 through 2014) as a replacement for the 2009 through 2011 data for purposes of calculating the employee wage component and purchased service index of the PE GPCI.

c. Malpractice Expense (MP) GPCIs

The MP GPCIs measure the relative cost differences among PFS localities for the purchase of professional liability insurance (PLI). The MP GPCIs are calculated based on insurer rate filings of premium data for $1 million to $3 million mature claims-made policies (policies for claims made rather than services furnished during the policy term). For the CY 2014 GPCI update (seventh update) we used 2011 and 2012 malpractice premium data (78 FR 74382). The proposed CY 2017 MP GPCI update reflects 2014 and 2015 premium data. Additionally, the proposed CY 2017 MP GPCI update reflects several proposed technical refinements to the MP GPCI methodology as discussed later in section 5.

d. GPCI Cost Share Weights

For the proposed CY 2017 GPCIs, we are continuing to use the current cost share weights for determining the PE GPCI values and locality GAFs. We refer readers to the CY 2014 PFS final rule with comment period (78 FR 74382 through 74383), for further discussion regarding the 2006-based MEI cost share weights revised in CY 2014 that were also finalized for use in the CY 2014 (seventh) GPCI update.

The proposed GPCI cost share weights for CY 2017 are displayed in Table 12.

TABLE 12—PROPOSED COST SHARE WEIGHTS FOR CY 2017 GPCI UPDATE

Expense category	Current cost share weight (%)	Proposed CY 2017 cost share weight (%)
Work	50.866	50.866
Practice Expense	44.839	44.839
—Employee Compensation	16.553	16.553
—Office Rent	10.223	10.223
—Purchased Services	8.095	8.095
—Equipment, Supplies, Other	9.968	9.968
Malpractice Insurance	4.295	4.295
Total	100.000	100.000

e. PE GPCI Floor for Frontier States

Section 10324(c) of the Affordable Care Act added a new subparagraph (I) under section 1848(e)(1) of the Act to establish a 1.0 PE GPCI floor for physicians' services furnished in frontier states effective January 1, 2011. In accordance with section 1848(e)(1)(I) of the Act, beginning in CY 2011, we applied a 1.0 PE GPCI floor for physicians' services furnished in states determined to be frontier states. In general, a frontier state is one in which at least 50 percent of the counties are ''frontier counties,'' which are those that have a population per square mile of less than 6. For more information on the criteria used to define a frontier state, we refer readers to the FY 2011 Inpatient Prospective Payment System (IPPS) final rule (75 FR 50160 through 50161). There are no changes in the states identified as Frontier States for the CY 2017 proposed rule. The qualifying states are: Montana, Wyoming, North Dakota, South Dakota, and Nevada. In accordance with statute, we would apply a 1.0 PE GPCI floor for these states in CY 2017.

f. Proposed GPCI Update

As explained above in the background section, the periodic review and adjustment of GPCIs is mandated by section 1848(e)(1)(C) of the Act. At each update, the proposed GPCIs are published in the PFS proposed rule to provide an opportunity for public comment and further revisions in response to comments prior to implementation. The proposed CY 2017 updated GPCIs for the first and second year of the 2-year transition, along with the GAFs, are displayed in Addenda D and E to this proposed rule available on our Web site under the supporting documents section of the CY 2017 PFS proposed rule Web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

3. Payment Locality Discussion

a. Background

The current PFS locality structure was developed and implemented in 1997. There are currently 89 total PFS localities; 34 localities are statewide areas (that is, only one locality for the entire state). There are 52 localities in the other 16 states, with 10 states having 2 localities, 2 states having 3 localities, 1 state having 4 localities, and 3 states having 5 or more localities. The combined District of Columbia, Maryland, and Virginia suburbs; Puerto Rico; and the Virgin Islands are the remaining three localities of the total of 89 localities. The development of the current locality structure is described in detail in the CY 1997 PFS proposed rule (61 FR 34615) and the subsequent final rule with comment period (61 FR 59494). We note that the localities generally represent a grouping of one or more constituent counties.

Prior to 1992, Medicare payments for physicians' services were made under the reasonable charge system. Payments were based on the charging patterns of physicians. This resulted in large differences in payment for physicians' services among types of services, geographic payment areas, and physician specialties. Recognizing this, the Congress replaced the reasonable charge system with the Medicare PFS in the Omnibus Budget Reconciliation Act (OBRA) of 1989, and the PFS went into effect January 1, 1992. Payments under the PFS are based on the relative resources involved with furnishing services, and are adjusted to account for geographic variations in resource costs as measured by the GPCIs.

Payment localities originally were established under the reasonable charge system by local Medicare carriers based on their knowledge of local physician charging patterns and economic conditions. These localities changed little between the inception of Medicare in 1967 and the beginning of the PFS in 1992. Shortly after the PFS took effect, we undertook a study in 1994 that culminated in a comprehensive locality revision that was implemented in 1997 (61 FR 59494).

The revised locality structure reduced the number of localities from 210 to the current 89, and the number of statewide localities increased from 22 to 34. The revised localities were based on locality resource cost differences as reflected by the GPCIs. For a full discussion of the methodology, see the CY 1997 PFS final rule with comment period (61 FR 59494). The current 89 fee schedule areas are defined alternatively by state boundaries (for example, Wisconsin), metropolitan areas (for example, Metropolitan St. Louis, MO), portions of a metropolitan area (for example, Manhattan), or rest-of-state areas that exclude metropolitan areas (for example, Rest of Missouri). This locality configuration is used to calculate the GPCIs that are in turn used to calculate payments for physicians' services under the PFS.

As stated in the CY 2011 PFS final rule with comment period (75 FR 73261), changes to the PFS locality structure would generally result in changes that are budget neutral within a state. For many years, before making any locality changes, we have sought consensus from among the professionals whose payments would be affected. In recent years, we have also considered more comprehensive changes to locality configuration. In 2008, we issued a draft comprehensive report detailing four different locality configuration options (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/downloads/ReviewOfAltGPCIs.pdf*). We refer readers to the CY 2014 PFS final rule with comment period for further discussion regarding that report, as well as a discussion about the Institute of Medicine's empirical study of the Medicare GAFs established under sections 1848(e) (PFS GPCI) and 1886(d)(3)(E) (IPPS wage index) of the Act.

b. California Locality Update to the Fee Schedule Areas Used for Payment Under Section 220(h) of the Protecting Access to Medicare Act

(1) General Discussion and Legislative Change

Section 220(h) of the PAMA added a new section 1848(e)(6) to the Act, that modifies the fee schedule areas used for payment purposes in California beginning in CY 2017.

Currently, the fee schedule areas used for payment in California are based on the revised locality structure that was implemented in 1997 as previously discussed. Beginning in CY 2017, section 1848(e)(6)(A)(i) of the Act requires that the fee schedule areas used for payment in California must be Metropolitan Statistical Areas (MSAs) as defined by the Office of Management and Budget (OMB) as of December 31 of the previous year; and section 1848(e)(6)(A)(ii) of the Act requires that all areas not located in an MSA must be treated as a single rest-of-state fee schedule area. The resulting modifications to California's locality structure would increase its number of localities from 9 under the current locality structure to 27 under the MSA-based locality structure.

However, section 1848(e)(6)(D) of the Act defines transition areas as the fee schedule areas for 2013 that were the rest-of-state locality, and locality 3, which was comprised of Marin county, Napa county, and Solano county. Section 1848(e)(6)(B) specifies that the GPCI values used for payment in a transition area are to be phased in over 6 years, from 2017 through 2021, using a weighted sum of the GPCIs calculated under the new MSA-based locality structure and the GPCIs calculated under the current PFS locality structure. That is, the GPCI values applicable for

these areas during this transition period are a blend of what the GPCI values would have been under the current locality structure, and what the GPCI values would be under the MSA-based locality structure. For example, in the first year, CY 2017, the applicable GPCI values for counties that were previously in rest-of-state or locality 3 and are now in MSAs are a blend of 1/6 of the GPCI value calculated for the year under the MSA-based locality structure, and 5/6 of the GPCI value calculated for the year under the current locality structure. The proportions shift by 1/6 in each subsequent year so that, by CY 2021, the applicable GPCI values for counties within transition areas are a blend of 5/6 of the GPCI value for the year under the MSA-based locality structure, and 1/6 of the GPCI value for the year under the current locality structure. Beginning in CY 2022, the applicable GPCI values for counties in transition areas are the values calculated under the new MSA-based locality structure. For the sake of clarity, we reiterate that this incremental phase-in is only applicable to those counties that are in transition areas that are now in MSAs, which are only some of the counties in the 2013 California rest-of state locality and locality 3.

Additionally, section 1848(e)(6)(C) of the Act establishes a hold harmless for transition areas beginning with CY 2017 whereby the applicable GPCI values for a year under the new MSA-based locality structure may not be less than what they would have been for the year under the current locality structure. There are a total of 58 counties in California, 50 of which are in transition areas as defined in section 1848(e)(6)(D) of the Act. Therefore, 50 counties in California are subject to the hold harmless provision. The other 8 counties, which are metropolitan counties that are not defined as transition areas, are not held harmless for the impact of the new MSA-based locality structure, and may therefore potentially experience slight decreases in their GPCI values as a result of the provisions in section 1848(e)(6) of the Act, insofar as the locality in which they are located now newly includes data from adjacent counties that decreases their GPCI values relative to those that would have applied had the new data not been incorporated. Therefore, the GPCIs for these eight counties under the MSA-based locality structure may be less than they would have been under the current GPCI structure. The eight counties that are not within transition areas are: Orange; Los Angeles; Alameda; Contra Costa; San Francisco; San Mateo; Santa Clara; and Ventura counties.

We emphasize that while transition areas are held harmless from the impact of the GPCI changes using the new MSA-based locality structure, because we are proposing other updates for CY 2017 as part of the eighth GPCI update, including the use of updated data, transition areas would still be subject to impacts resulting from those other updates. Table 13 illustrates using GAFs, for CY 2017, the isolated impact of the MSA-based locality changes and hold-harmless for transition areas required by section 1848(e)(6) of the Act, the impact of the proposed use of updated data for GPCIs, and the combined impact of both of these proposed changes.

TABLE 13—IMPACT ON CALIFORNIA GAFS AS A RESULT OF SECTION 1848(e)(6) OF THE ACT AND PROPOSED UPDATED DATA BY FEE SCHEDULE AREA

[Sorted alphabetically by locality name]

Medicare fee schedule area	Transition area	2016 GAF	2017 GAF w/o 1848(e)(6)	% Change due to new GPCI data	2017 GAF w/ 1848(e)(6)	% Change due to 1848(e)(6)	Combined impact of PAMA and new GPCI data (%)
Bakersfield	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Chico	1	1.04	1.031	−0.50	1.031	0.00	−0.50
El Centro	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Fresno	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Hanford-Corcoran	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Los Angeles-Long Beach-Anaheim (Los Angeles County)	0	1.09	1.09	−0.20	1.091	0.10	−0.10
Los Angeles-Long Beach-Anaheim (Orange County)	0	1.09	1.104	1.10	1.101	−0.30	0.80
Madera	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Merced	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Modesto	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Napa	1	1.14	1.128	−0.80	1.128	0.00	−0.80
Oxnard-Thousand Oaks-Ventura	0	1.09	1.083	−0.60	1.083	0.00	−0.60
Redding	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Rest Of California	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Riverside-San Bernardino-Ontario	1	1.04	1.031	−0.50	1.032	0.10	−0.40
Sacramento-Roseville-Arden-Arcade	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Salinas	1	1.04	1.031	−0.50	1.033	0.20	−0.30
San Diego-Carlsbad	1	1.04	1.031	−0.50	1.035	0.40	−0.10
San Francisco-Oakland-Hayward (Alameda/Contra Costa County)	0	1.18	1.125	−4.80	1.142	1.50	−3.40
San Francisco-Oakland-Hayward (Marin County)	1	1.14	1.128	−0.80	1.129	0.10	−0.70
San Francisco-Oakland-Hayward (San Francisco County)	0	1.18	1.194	1.00	1.175	−1.60	−0.60
San Francisco-Oakland-Hayward (San Mateo County)	0	1.18	1.187	0.40	1.171	−1.30	−0.90
San Jose-Sunnyvale-Santa Clara (San Benito County)	1	1.04	1.031	−0.50	1.053	2.10	1.60
San Jose-Sunnyvale-Santa Clara (Santa Clara County)	0	1.18	1.176	0.10	1.175	−0.10	0.00

TABLE 13—IMPACT ON CALIFORNIA GAFS AS A RESULT OF SECTION 1848(e)(6) OF THE ACT AND PROPOSED UPDATED DATA BY FEE SCHEDULE AREA—Continued

[Sorted alphabetically by locality name]

Medicare fee schedule area	Transition area	2016 GAF	2017 GAF w/o 1848(e)(6)	% Change due to new GPCI data	2017 GAF w/ 1848(e)(6)	% Change due to 1848(e)(6)	Combined impact of PAMA and new GPCI data (%)
San Luis Obispo-Paso Robles-Arroyo Grande	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Santa Cruz-Watsonville	1	1.04	1.031	−0.50	1.042	1.10	0.60
Santa Maria-Santa Barbara	1	1.04	1.031	−0.50	1.036	0.50	0.00
Santa Rosa	1	1.04	1.031	−0.50	1.037	0.60	0.10
Stockton-Lodi	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Vallejo-Fairfield	1	1.14	1.128	−0.80	1.128	0.00	−0.80
Visalia-Porterville	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Yuba City	1	1.04	1.031	−0.50	1.031	0.00	−0.50

Additionally, for the purposes of calculating budget neutrality and consistent with the PFS budget neutrality requirements as specified under section 1848(c)(2)(B)(ii)(II) of the Act, we are proposing to start by calculating the national GPCIs as if the current localities are still applicable nationwide; then for the purposes of payment in California, we will override the GPCI values with the values that are applicable for California consistent with the requirements of section 1848(e)(6) of the Act. This approach is consistent with the implementation of the GPCI floor provisions that have previously been implemented—that is, as an after-the-fact adjustment that is implemented for purposes of payment after both the GPCIs and PFS budget neutrality have already been calculated.

(2) Proposed Operational Considerations

As discussed above, under section 1848(e)(6) of the Act, counties that were previously in the rest-of-state locality or locality 3 and are now in MSAs would have their GPCI values under the new MSA-based locality structure phased in gradually, in increments of one-sixth over 6 years. Section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be 1/2 of the adjustment that otherwise would be made. While section 1848(e)(6)(B) of the Act establishes a blended phase-in for the MSA-based GPCI values, it does not explicitly state whether or how that provision is to be reconciled with the requirement at section 1848(e)(1)(C) of the Act. We believe that since section 1848(e)(6)(A) of the Act requires that we must make the change to MSA-based fee schedule areas for California GPCIs notwithstanding the preceding provisions of section 1848(e) of the Act, and subject to the succeeding provisions of section 1848(e)(6) of the Act, that applying the two-year phase-in specified by the preceding provisions simultaneously with the six-year phase-in would undermine the incremental 6-year phase-in specified in section 1848(e)(6)(B) of the Act. Therefore, we are proposing that the requirement at section 1848(e)(1)(C) of the Act to phase in ½ of the adjustment in year 1 of the GPCI update would not apply to counties that were previously in the rest-of-state or locality 3 and are now in MSAs, and therefore, are subject to the blended phase-in as described above. Since section 1848(e)(6)(B) of the Act provides for a gradual phase in of the GPCI values under the new MSA-based locality structure, specifically in one-sixth increments over 6 years, if we were to also apply the requirement to phase in 1/2 of the adjustment in year 1 of the GPCI update then the first year increment would effectively be one-twelfth. We note that this issue is only of concern if more than 1 year has elapsed since the previous GPCI update, and would only be applicable through CY 2021 since, beginning in CY 2022, the GPCI values for such areas in an MSA would be fully based on the values calculated under the new MSA-based locality structure for California.

As previously stated, the resulting modifications to California's locality structure increase its number of localities from 9 under the current locality structure to 27 under the MSA-based locality structure. However, both the current localities and the MSA-based localities are comprised of various component counties, and in some localities only some of the component counties are subject to the blended phase-in and hold harmless provisions required by section 1848(e)(6)(B) and (C) of the Act. Therefore, the application of these provisions may produce differing GPCI values among counties within the same fee schedule area under the MSA-based locality structure. For example, the MSA-based San Jose-Sunnyvale-Santa Clara locality, is comprised of 2 constituent counties—San Benito county, and Santa Clara county. San Benito County is in a transition area (2013 rest-of-state), while Santa Clara county is not. Hence, although the counties are in the same MSA, the requirements of section 1848(e)(6)(B) and (C) of the Act may produce differing GPCI values for each county. To address this issue, we propose to assign a unique locality number to the counties that would be impacted in the aforementioned manner. As a result, although the modifications to California's locality structure increase the number of localities from 9 under the current locality structure to 27 under the MSA-based locality structure, for purposes of payment, the actual number of localities under the MSA-based locality structure would be 32 to account for instances where unique locality numbers are needed as described above. Additionally, while the fee schedule area names are consistent with the MSAs designated by OMB, we are proposing to maintain 2-digit locality numbers to correspond to the existing fee schedule areas. Pursuant to the implementation of the new MSA-based locality structure for California, the total number of PFS localities would increase from 89 to 112. Table 14 displays the current fee schedule areas in California, and Table 15 displays the MSA-based fee schedule areas in California required by section 1848(e)(6) of the Act. Additional information on the California locality update may be found in our contractor's draft report, ''Draft Report on the CY 2017 Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule,'' which is available on the CMS Web site.

It is located under the supporting documents section of the CY 2017 PFS proposed rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

TABLE 14—CURRENT FEE SCHEDULE AREAS IN CALIFORNIA

[Sorted alphabetically by locality name]

Locality number	Fee schedule area	Counties
26	Anaheim/Santa Ana.	Orange
18	Los Angeles	Los Angeles
03	Marin/Napa/Solano.	Marin, Napa, And Solano
07	Oakland/Berkley.	Alameda And Contra Costa
05	San Francisco	San Francisco
06	San Mateo	San Mateo
09	Santa Clara	Santa Clara
17	Ventura	Ventura
99	Rest Of State	All Other Counties

TABLE 15—MSA-BASED FEE SCHEDULE AREAS IN CALIFORNIA

[Sorted alphabetically by locality name]

Current locality number	Proposed new locality number	Fee schedule area (MSA name)	Counties	Transition area
99	54	Bakersfield, CA	Kern	YES.
99	55	Chico, CA	Butte	YES.
99	71	El Centro, CA	Imperial	YES.
99	56	Fresno, CA	Fresno	YES.
99	57	Hanford-Corcoran, CA	Kings	YES.
18	18	Los Angeles-Long Beach-Anaheim, CA *(Los Angeles County)*.	Los Angeles	NO.
26	26	Los Angeles-Long Beach-Anaheim, CA *(Orange County)*	Orange	NO.
99	58	Madera, CA	Madera	YES.
99	59	Merced, CA	Merced	YES.
99	60	Modesto, CA	Stanislaus	YES.
3	51	Napa, CA	Napa	YES.
17	17	Oxnard-Thousand Oaks-Ventura, CA	Ventura	NO.
99	61	Redding, CA	Shasta	YES.
99	75	REST OF STATE	All Other Counties	YES.
99	62	Riverside-San Bernardino-Ontario, CA	Riverside, and San Bernardino	YES.
99	63	Sacramento—Roseville—Arden-Arcade, CA	El Dorado, Placer, Sacramento, and Yolo.	YES.
99	64	Salinas, CA	Monterey	YES.
99	72	San Diego-Carlsbad, CA	San Diego	YES.
7	7	San Francisco-Oakland-Hayward, CA *(Alameda County/Contra Costa County)*.	Alameda, Contra Costa	NO.
3	52	San Francisco-Oakland-Hayward, CA *(Marin County)*	Marin	YES.
5	5	San Francisco-Oakland-Hayward, CA *(San Francisco County)*.	San Francisco	NO.
6	6	San Francisco-Oakland-Hayward, CA *(San Mateo County)*	San Mateo	NO.
99	65	San Jose-Sunnyvale-Santa Clara, CA *(San Benito County)*	San Benito	YES.
9	9	San Jose-Sunnyvale-Santa Clara, CA *(Santa Clara County)*.	Santa Clara	NO.
99	73	San Luis Obispo-Paso Robles-Arroyo Grande, CA	San Luis Obispo	YES.
99	66	Santa Cruz-Watsonville, CA	Santa Cruz	YES.
99	74	Santa Maria-Santa Barbara, CA	Santa Barbara	YES.
99	67	Santa Rosa, CA	Sonoma	YES.
99	73	Stockton-Lodi, CA	San Joaquin	YES.
3	53	Vallejo-Fairfield, CA	Solano	YES.
99	69	Visalia-Porterville, CA	Tulare	YES.
99	70	Yuba City, CA	Sutter, and Yuba	YES.

4. Proposed Update to the Methodology for Calculating GPCIs in the U.S. Territories

In calculating GPCIs within U.S. states, we use county-level wage data from the Bureau of Labor Statistics (BLS) Occupational Employment Statistics Survey (OES), county-level residential rent data from the American Community Survey (ACS), and malpractice insurance premium data from state departments of insurance. In calculating GPCIs for the U.S. territories, we currently use three distinct methodologies—one for Puerto Rico, another for the Virgin Islands, and a third for the Pacific Islands (Guam, American Samoa, and Northern Marianas Islands). These three methodologies were adopted at different times based primarily on the data that were available at the time they were adopted. At present, because Puerto Rico is the only territory where county-level BLS OES, county-level ACS, and malpractice premium data are available, it is the only territory for which we use territory-specific data to calculate GPCIs. For the Virgin Islands, because county-level wage and rent data are not available, and insufficient malpractice premium data are available, CMS has set the work, PE, and MP GPCI values for the Virgin Islands payment locality at the national average of 1.0 even though,

like Puerto Rico, the Virgin Islands is its own locality and county-level BLS OES data are available for the Virgin Islands. For the U.S. territories in the Pacific Ocean, we currently crosswalk GPCIs from the Hawaii locality for each of the three GPCIs, and incorporate no local data from these territories into the GPCI calculations even though county-level BLS OES data does exist for Guam, but not for American Samoa or the Northern Mariana Islands.

As noted above, currently Puerto Rico is the only territory for which we calculate GPCIs using the territory-specific information relative to data from the U.S. States. For several years stakeholders in Puerto Rico have raised concerns regarding the applicability of the proxy data in Puerto Rico relative to their applicability in the U.S. states. We believe that these concerns may be consistent across island territories, but lack of available, appropriate data has made it difficult to quantify such variation in costs. For example, some stakeholders previously indicated that shipping and transportation expenses increase the cost of acquiring medical equipment and supplies in islands and territories relative to the mainland. While we have previously attempted to locate data sources specific to geographic variation in such shipping costs, we found no comprehensive national data source for this information (we refer readers to 78 FR 74387 through 74388 for the detailed discussion of this issue). Therefore, we have not been able to quantify variation in costs specific to island territories in the calculation of the GPCIs.

For all the island territories other than Puerto Rico, the lack of comprehensive data about unique costs for island territories has had minimal impact on GPCIs because we have used either the Hawaii GPCIs (for the Pacific territories) or used the unadjusted national averages (for the Virgin Islands). In an effort to provide greater consistency in the calculation of GPCIs given the lack of comprehensive data regarding the validity of applying the proxy data used in the States in accurately accounting for variability of costs for these island territories, we are proposing to treat the Caribbean Island territories (the Virgin Islands and Puerto Rico) in a consistent manner. We propose to do so by assigning the national average of 1.0 to each GPCI index for both Puerto Rico and the Virgin Islands. We are not proposing any changes to the GPCI methodology for the Pacific Island territories (Guam, American Samoa, and Northern Marianas Islands) where we already consistently assign the Hawaii GPCI values for each of the three GPCIs. Additional information on the Proposed Update to the Methodology for Calculating GPCIs in the U.S. Territories may be found in our contractor's draft report, ''Draft Report on the CY 2017 Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule,'' which is available on our Web site. It is located under the supporting documents section of the CY 2017 PFS proposed rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

5. Proposed Refinement to the MP GPCI Methodology

In the process of calculating MP GPCIs for the purposes of this proposed rule, we identified several technical refinements to the methodology that yield improvements over the current method. We are also proposing refinements that conform to our proposed methodology for calculating the GPCIs for the U.S. Territories described above. Specifically, we are proposing modifications to the methodology to account for missing data used in the calculation of the MP GPCI. Under the methodology used in the CY 2014 GPCI update (78 FR 74380 through 74391), we first calculated the average premiums by insurer and specialty, then imputed premium values for specialties for which we did not have specific data, before adjusting the specialty-specific premium data by market share weights. We are proposing to revise our methodology to instead calculate the average premiums for each specialty using issuer market share for only available companies. This proposed methodological improvement would reduce potential bias resulting from large amounts of imputation, an issue that is prevalent for insurers that only write policies for ancillary specialties for which premiums tend to be low. The current method would impute the low premiums for ancillary specialties across the remaining specialties, and generally greater imputation leads to less accuracy. Additional information on the MP GPCI methodology, and the proposed refinement to the MP GPCI methodology may be found in our contractor's draft report, ''Draft Report on the CY 2017 Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule,'' which is available on our Web site. It is located under the supporting documents section of the CY 2017 PFS proposed rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

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

Section 502(a)(1) of the Consolidated Appropriations Act of 2016 (H.R. 2029) amended section 1848(b) of the Act by establishing new paragraph (b)(9). Effective for services furnished beginning January 1, 2017, section 1848(b)(9)(A) of the Act reduces by 20 percent the payment amounts under the PFS for the technical component (TC) (including the TC portion of a global service) of imaging services that are X-rays taken using film. The reduction is made prior to any other adjustment under this section and without application of this new paragraph.

Section 1848(b)(9)(B) of the Act provides for a 7 percent reduction in payments for imaging services made under the PFS that are X-rays (including the X-ray component of a packaged service) taken using computed radiology furnished during CY 2018, 2019, 2020, 2021, or 2022, and for a 10 percent reduction for such imaging services taken using computed radiology furnished during CY 2023 or a subsequent year. Computed radiology technology is defined for purposes of this paragraph as cassette-based imaging, which utilizes an imaging plate to create the image involved. Section 1848(b)(9) of the Act also requires implementation of the reductions in payment for X-rays through appropriate mechanisms, which can include the use of modifiers. In accordance with section 1848(c)(2)(B)(v)(X), the adjustments under section 1848(b)(9)(A) of the Act are exempt from budget neutrality.

In this section of the rule, we discuss the proposed implementation of the reduction in payment for X-rays taken using film provided for in section 1848(b)(9)(A) of the Act. Because the required reductions in PFS payment for imaging services (including the imaging portion of a service) that are X-rays taken using computed radiography technology does not apply for CY 2017, we will address implementation of section 1848(b)(9)(B) of the Act in future rulemaking.

To implement the provisions of sections 1848(b)(9)(A) of the Act relating to the PFS payment reduction for X-rays taken using film that are furnished during CY 2017 or subsequent years, in this proposed rule, we are proposing to establish a new modifier (modifier ''XX'') to be used on claims, as allowed under the section 1848(b)(9)(D) of the Act. The list of CY 2017 applicable HCPCS codes describing imaging services that are X-ray services are on

the CMS Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/physicianfeesched/downloads/*. We are proposing that, beginning January 1, 2017, this modifier would be required on claims for X-rays that are taken using film. The modifier would be required on claims for the technical component of the X-ray service, including when the service is billed globally, since the PFS payment adjustment is made to the technical component regardless of whether it is billed globally or separately using the –TC modifier. The use of this proposed modifier to indicate an X-ray taken using film would result in a 20-percent reduction for the technical component of the X-ray service, as specified under section 1848(b)(9)(A) of the Act that would be exempt from budget neutrality as specified under section 1848(c)(2)(B)(v)(X) of the Act.

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

Effective January 1, 2012, we implemented an MPPR of 25 percent on the professional component (PC) of advanced imaging services. The reduction applies when multiple imaging procedures are furnished by the same physician (or physician in the same group practice) to the same patient, in the same session, on the same day. Full payment is made for the PC of the highest priced procedure. Payment for the PC of subsequent services is reduced by 25 percent.

Section 502(a)(2)(A) of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113, enacted on December 18, 2015) added a new section 1848(b)(10) of the Act which revises the payment reduction from 25 percent to 5 percent, effective January 1, 2017. Section 502(a)(2)(B) added a new subclause at section 1848(c)(2)(B)(v)(XI) which exempts the reduced expenditures attributable to the revised 5 percent MMPR on the PC of imaging from the PFS budget neutrality provision. We propose to implement these provisions for services furnished on or after January 1, 2017. We refer readers to section VI.C of this proposed rule regarding the necessary adjustment to the proposed PFS conversion factor to account for the mandated exemption from PFS budget neutrality.

We note that the lists of services for the upcoming calendar year that are subject to the MPPR on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services; and the list of procedures that meet the definition of imaging under section 5102(b) of the DRA, and therefore, are subject to the OPPS cap, are displayed in the public use files for the PFS proposed and final rules for each year. The public use files for CY 2017 are available on our Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSFederal-Regulation-Notices.html*.

L. 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 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.B.5. of this proposed 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 with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accepted public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule with comment period. 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 this CY 2017 proposed rule, the new process will be applicable to all codes, except for new codes that describe truly new services. For CY 2017, we are proposing new values in this 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 where 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 are re-proposing values for those codes in this CY 2017 proposed rule.

We will consider public comments received during the 60-day public comment period for this proposed rule before establishing final values in the final rule with comment period, and 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. Recommendations regarding any new or revised codes received after February 10th will be considered in the next year's proposed rule (that is, CY 2018 PFS rulemaking).

2. Methodology for Proposing Work RVUs

We conduct a review of each code identified in this section and review 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 review of recommended work RVUs and time inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC (Health Care Professionals Advisory Committee), and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75

FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period 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. The building block methodology is used to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code.

Components used in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could be 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 or another family of codes. The statute specifically defines the work component as the resources in time and intensity required in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refine the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently there are six preservice time packages for services typically furnished in the facility setting, reflecting the different combinations of straightforward or difficult procedure, straightforward or difficult patient, and without or with sedation/anesthesia. Currently, there are three preservice time packages for services typically furnished in the nonfacility setting, reflecting procedures without and with sedation/anesthesia care.

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

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

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we do not believe the overlap in time has 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 with our ongoing adjustment of work RVUs based on changes in the best information we have regarding the time resources involved in furnishing individual services. We are 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. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes is not always a straightforward process, so we apply various methodologies to identify several potential work values for individual codes. However, we want to reiterate that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services.

We have observed that for many codes reviewed by the RUC, final recommended work RVUs appear to be incongruous with recommended assumptions regarding the resource costs in time. This is 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 begin by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we employ 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 blocks, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these we sometimes use the relationship between the old time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

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

We want to make it clear that we are not implying 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 believe that since the two components of work are time and intensity that absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, that significant decreases in time should be reflected in decreases

to work RVUs. If the RUC recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we generally use one of the aforementioned referenced methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several commenters, 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. We received several specific comments regarding this issue in response to the CY 2016 PFS final rule with comment period, those comments are summarized below.

Comment: Several commenters, including the RUC, stated that our methodology for adjusting work RVUs appears to be contrary to the statute.

Response: We disagree with these comments. Since section 1848(c)(1)(A) of the Act explicitly identifies time as one of the two types of resources that encompass the work component of the PFS payment, we do not believe that our use of the aforementioned methodologies to adjust the work RVU to account for the changes in time, which is one of the resources involved, is inconsistent with the statutory requirements related to the maintenance of work RVUs, and we have regularly used these and other methodologies in developing values for PFS services. In selecting which methodological approach will best determine the appropriate value for a service, we consider the current and recommended work and time values, as well as the intensity of the service, all relative to other services. In our review of RUC recommended values, we have observed that the RUC also uses a variety of methodologies to develop work RVUs for individual codes, and subsequently validates the results of these approaches through magnitude estimation or crosswalk to established values for other codes.

Comment: Several commenters, including the RUC, stated that we could not take one element of the services that has changed such as intra-service time, and apply an overall ratio for reduction to the work RVU based on changes to time, as that renders the value no longer resource-based in comparison to the RUC-recommended values.

Response: We disagree with the commenters. We continue to believe that the use of time ratios is one of several reasonable methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values do not account for information that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values determines that changes in the resource of time have been unaccounted for in a recommended RVU, then we believe we have the obligation to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios we are using derived intensity measures based on current work RVUs for individual procedures. Were we to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case. Furthermore, we reiterate that we use time ratios to identify potential work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. We also disagree with several commenters' implications that a work RVU developed through such estimation methods is only resource-based through the RUC process.

Comment: Several commenters, including the RUC, stated that our inconsistent use of the time ratio methodology has rendered it ineffective for valuation purposes and that by choosing the starting base work value and/or physician time at random, we are essentially reverse engineering the work value we want under the guise of a standard algorithm.

Response: We do not choose a starting base work value and/or physician time at random as suggested by the commenters. We use the RUC recommended values or the existing values as the base values; essentially, we are taking one of those values and applying adjustments to account for the change in time that based on our analysis of the RUC recommendation, we determine has not been properly accounted for to determine an appropriate work RVU. In circumstances where adjustments to time and the corresponding work RVU are relatively congruent or persuasively explained, our tendency has been to use those values as recommended. Where the RUC recommendations do not account for changes in time, we have made changes to RUC-recommended values to account for the changes in time.

Comment: Commenters, including the RUC, also stated that the use of time ratio methodologies distills the valuation of the service into a basic formula with the only variable being either the new total physician time or the new intra-service physician time, and that these methodologies are based on the incorrect assumption that the per minute physician work intensity established is permanent regardless of when the service was last valued. Other commenters have suggested that previous assumed times are inaccurate.

Response: We agree with commenters that per minute intensity for a given service may change over time. If we believed that the per-minute intensity for a given service were immutable, then a reverse-building block approach to revaluation based on new time data could be appropriate. However, we have not applied such an approach specifically because 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 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.

Regarding the validity of comparing new times to the old times, we, too, hope that time estimates have improved over many years especially when many years have elapsed since the last time the service in question was valued. However, we also believe that our operating assumption regarding the validity of the pre-existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. Pre-existing times are a very important element in the allocation of indirect PE RVUs by specialty, and had the previously recommended times been overestimated, the specialties that furnish such services would be benefitting from these times in the allocation of indirect PE RVUs. As long time observers of the RUC process, we also recognize that the material the RUC uses to develop overall work recommendations includes the data

from the surveys about time. We have previously stated concerns regarding the validity of much of the RUC survey data. However, we believe additional kinds of concern would be warranted if the RUC itself were operating under the assumption that its pre-existing data were typically inaccurate.

We understand stakeholders' concerns regarding how best to consider changes in time in improving the accuracy of work RVUs and have considered all of the issues raised by commenters. In conjunction with our review of recommended code values for CY 2017, we conducted a preliminary analysis to identify general tendencies in the relationship between changes in time and changes in work RVUs for CY 2014 and CY 2015. We looked at services for which there were no coding changes to simplify the analysis. The intent of this preliminary analysis was to examine commenters' beliefs that CMS is only considering time when making refinements to RUC recommended work values. For CY 2014, we found that in the aggregate, the average difference between the RUC recommended intraservice time and existing intraservice time was −17 percent, but the average difference between the RUC recommended work RVU and existing work RVU was only −4 percent. However, the average difference between the CMS refined work RVU and existing work RVU was −7 percent. For CY 2015, the average difference between the RUC recommended intraservice time and existing intraservice time was −17 percent, but the average difference between the RUC recommended work RVU and existing work RVU was 1 percent, and the average difference between the CMS refined work RVU and existing work RVU was −6 percent. This preliminary analysis demonstrates that we are not making refinements solely in consideration of time, if that were the case, the changes in the work RVU values that we adopted would be comparable to the changes in the time that we adopted, but that is not the case.

We believe that we should account for efficiencies in time when the recommended work RVU does not account for those efficiencies, otherwise relativity across the PFS can be significantly skewed over periods of time. For example, if when a code is first valued, a physician was previously able to do only 5 procedures per day, but due to new technologies, the same physician can now do 10 procedures per day, resource costs in time have empirically been lessened, and we believe that relative reduction in resources involved in furnishing that service should be accounted for in the assignment of work RVUs for that service, since the statute explicitly identifies time as one of the two components of work. Of course, if more resource intensive technology has allowed for the increased efficiency in furnishing the procedure, then the nonfacility PE RVUs for the service should also be adjusted to account for this change. Additionally, we believe it may be that the intensity per minute of the procedure may have changed with the greater efficiency in time. Again, that is why we do not generally reduce work RVUs in strict proportion to changes in time. We understand that intensity is not entirely linear, and that data related to time as obtained in the RUC survey instrument may improve over time, and that the number of survey respondents may improve over time. However, we also understand time as a tangible resource cost in furnishing PFS services, and a cost that by statute, is one of the two kinds of resources to be considered as part of the work RVU.

Therefore, we are interested in receiving comments on whether, within the statutory confines, there are alternative suggestions as to how changes in time should be accounted for when it is evident that the survey data and/or the RUC recommendation regarding the overall work RVU does not reflect significant changes in the resource costs of time for codes describing PFS services. We are also seeking comment on potential alternatives, including the application of the reverse building block methodology, to making the adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services.

Table 16 contains a list of codes for which we are proposing work RVUs; this includes all RUC recommendations received by February 10, 2016, and codes for which we established interim final values in the CY 2016 PFS final rule with comment period. When the proposed work RVUs vary from those recommended by the RUC or for which we do not have RUC recommendations, we address those codes in the portions of this section that are dedicated to particular codes. The proposed work RVUs and other payment information for all proposed CY 2017 payable codes are available in Addendum B. Addendum B is available on the CMS Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/physicianfeesched/downloads/*. The proposed time values for all CY 2017 codes are listed in a file called ''CY 2017 PFS Proposed Work Time,'' available on the CMS Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/physicianfeesched/downloads/*.

3. Methodology for Proposing 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, 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 recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, 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 16 details our proposed refinements of the RUC's direct PE recommendations at the code-specific level. In this proposed 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 proposed 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 $0.32 or less, the refinement has no impact on the proposed 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 proposed refinements listed in Table 16 result in changes under the $0.32 threshold and are unlikely to result in a change to the proposed RVUs.

We also note that the proposed direct PE inputs for CY 2017 are displayed in the proposed CY 2017 direct PE input database, available on the CMS Web site under the downloads for the CY 2017 proposed rule at *www.cms.gov/PhysicianFeeSched/*. The inputs displayed there have also been used in developing the proposed CY 2017 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.

In general, clinical labor tasks fall into one of the categories on the PE worksheets. In cases where tasks cannot be attributed to an existing category, the tasks are labeled ''other clinical activity.'' We believe that continual addition of new and distinct clinical labor tasks each time a code is reviewed under the misvalued code initiative is likely to degrade relativity between newly reviewed services and those with already existing inputs. This is because codes more recently reviewed would be more likely to have a greater number of clinical labor tasks as a result of the general tendency to increase the number of clinical labor tasks. To mitigate the potential negative impact of these additions, we review these tasks to determine whether they are fully distinct from existing clinical labor tasks, typically included for other clinically similar services under the PFS, and thoroughly explained in the recommendation. For those tasks that do not meet these criteria, we do not accept these newly recommended 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 2017, we received invoices for several new supply and equipment items. Tables 16 and 17 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.A. of this proposed rule with comment

period, 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 proposed 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 16 and 17 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 do not include clinical labor minutes assigned to the service 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 2017 are available on the CMS Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSFederal-Regulation-Notices.html.*

4. Specialty-Mix Assumptions for Proposed Malpractice RVUs

The proposed CY 2017 malpractice crosswalk table is displayed in the public use files for the PFS proposed and final rules. The public use files for CY 2017 are available on the CMS Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSFederal-Regulation-Notices.html.* The table lists the CY 2017 HCPCS codes and their respective source codes used to set the proposed CY 2017 MP RVUs where the source code for this calculation deviates from the source code for the utilization otherwise used for purposes of PFS ratesetting. The proposed MP RVUs for all PFS services and the utilization crosswalk used to identify the source codes for all other PFS codes are reflected in Addendum B on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/.*

5. Valuation of Specific Codes

a. CY 2017 Proposed Codes That Were Also CY 2016 Proposed Codes

(1) Soft Tissue Localization (CPT Codes 10035 and 10036)

In the CY 2016 PFS final rule with comment period, we established the RUC-recommended work value as interim final for CPT codes 10035 and 10036. We also made standard refinements to remove duplicative clinical labor and utilize standard equipment time formulas for the PACS workstation proxy (ED050).

Comment: A commenter stated that the clinical labor task ''Review/read X-ray, lab, and pathology reports'' occurs during the preservice period, and it is a separate activity than ''Review examination with interpreting MD'', which occurs during the service period.

Response: We continue to believe that this clinical labor is duplicative with the clinical labor for Review examination with interpreting MD because we believe that these two descriptors detail the same clinical labor activity taking place, rather than two separate and distinct tasks. We are proposing to maintain our previous refinement to 0 minutes for this clinical labor task for CPT codes 10035 and 10036.

We are also proposing to maintain the interim final work RVUs for CPT codes 10035 and 10036.

(2) Repair Flexor Tendon (CPT Codes 26356, 26357, and 26358)

In the CY 2016 PFS final rule with comment period, we established an interim final work RVU of 9.56 for CPT code 26356 after considering both its similarity in time to CPT code 25607 (Open treatment of distal radial extra-articular fracture) and the recommended reduction in time relative to the current times assumed for this procedure. We established an interim final work RVU of 10.53 for CPT code 26357 based on a direct crosswalk from CPT code 27654 (Repair, secondary, Achilles tendon, with or without graft), as we believed that this work RVU better reflected the changes in time for this procedure. For the last code in the family, we established an interim final work RVU of 12.13 for CPT code 26358, based on the RUC recommended increment of 1.60 work RVUs relative to CPT code 26357.

Comment: We received several comments regarding the interim final work values for this family of codes.

One commenter stated that it was inappropriate to use time ratios to evaluate CPT code 26356 as it was last valued in 1995, noting that there was an anomalous relationship between the current work RVU and the imputed time components in the RUC database. This commenter also pointed out that when the previous time was developed, fabrication of a splint was considered to be part of the intraservice work, while in the current survey instrument, the fabrication of the splint is considered to be part of the postservice work since it is a dressing. This commenter urged CMS to adopt the RUC recommendations. A different commenter agreed that the CMS crosswalk to CPT code 25607 was an appropriate crosswalk for CPT code 26356 and supported the CMS work RVU of 9.56.

Response: We appreciate the support from the commenter. We continue to believe that our crosswalk for this code is an appropriate choice, due to our estimate of overall work between CPT code 26356 and CPT code 25607. We appreciate the commenters' concerns regarding the time ratio methodologies and have responded to these concerns about our methodology in section II.L.2 of this proposed rule. Although we note the commenter's statement about how the service period in which fabrication of a splint takes place may have evolved over time, we do not agree that this task would be responsible for a decrease in intraservice survey time, as the postservice survey time for CPT code 26356 remained unchanged at 30 minutes. If the decrease in intraservice time had been due to the shift of splinting from the intraservice period to the postservice period, then we would have expected to see an increase in the postservice period minutes. However, they remained exactly the same in the physician survey for CPT 26356. As we wrote earlier in this section, we believe in the validity of using pre-existing time values as a point of comparison, and we believe that we should account for efficiencies in time when the recommended work RVU does not account for those efficiencies. After consideration of comments received, we are proposing to maintain CPT code 26356 at its current work RVU of 9.56 for CY 2017.

Comment: Several commenters disagreed with the work RVU for CPT code 26357. One commenter stated that the CMS crosswalk to CPT code 27654 had less total time and resulted in an inappropriately lower intensity. This commenter urged CMS to adopt the RUC-recommended work value. Another commenter stated that a better crosswalk for CPT code 26357 would be CPT code 25608 (Open treatment of distal radial intra-articular fracture or epiphyseal separation), the next code in the same upper extremity family that CMS used for the initial crosswalk. This commenter stated that the CMS crosswalk for CPT code 26357 created a rank order anomaly in terms of intensity within this family, and that the commenter's suggested crosswalk would create two pairs of matched codes, survey CPT codes 26356/26357 with crosswalk CPT codes 25607/25608.

Response: We appreciate the suggested crosswalk from the commenters, and we agree that the choice of the initial CMS crosswalk creates a rank order anomaly within the family in terms of intensity. As a result, after consideration of comments received, we are proposing to instead value CPT code 26357 at the 25th percentile survey work RVU of 11.00 for CY 2017. This valuation corrects the anomalous intensity within the Repair Flexor Tendon family of codes, and preserves the RUC-recommended increment between CPT codes 26356 and 26357.

Comment: The commenters agreed that the RUC-recommended increment of 1.60 was appropriate for the work RVU of CPT code 26358 when added to the work RVU of CPT code 26357. However, commenters stated that this increment of 1.60 should be added to the RUC-recommended work value for CPT code 26357, and not the CMS refined value from the CY 2016 PFS final rule with comment period.

Response: We also continue to believe that the increment of 1.60 is appropriate for the work RVU of CPT code 26358. After consideration of comments received, we are therefore proposing to set the work RVU for this code at 12.60 for CY 2017, based on the increment of 1.60 from CPT code 26357's proposed work RVU of 11.00.

We are proposing to maintain the current direct PE inputs for all three codes.

(3) Esophagogastric Fundoplasty Trans-Oral Approach (CPT Code 43210)

For CY 2016, the CPT Editorial Panel established CPT code 43210 to describe trans-oral esophagogastric fundoplasty. The RUC recommended a work RVU of 9.00 for CPT code 43210. We noted our determination that a work RVU of 7.75, which corresponds to the 25th percentile survey result, more accurately reflects the resources used in furnishing the service associated with CPT code 43210. Therefore, for CY 2016 we established an interim final work RVU of 7.75 for CPT code 43210.

Comment: A few commenters urged CMS to accept the RUC-recommended work RVU of 9.00 for CPT code 43210. The commenters believed that the RUC-recommended value compared well with the key reference service, CPT code 43276 (Endoscopic retrograde cholangiopancreatography (ERCP); with removal and exchange of stent(s), biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent exchanged), which has a work RVU of 8.94 and an intraservice time of 60 minutes. Commenters believed that due to similar intra-service times and intensities, that CPT code 43210 should be valued nearly identically to CPT code 43276. Some commenters also stated that to maintain relativity within the upper GI code families, CPT code 43210 should not have a lower work RVU than CPT code 43276, especially since the majority of survey participants indicated that CPT code 43210 is ''somewhat more'' complex than CPT code 43276. Additionally, one commenter noted that an EGD (Esophagogastroduodenoscopy) is used twice during this service, before and after fundoplication. They stated that because this is a multi-stage procedure, other EGD codes are not comparable. The commenter also pointed out that this technology has a small number of users and urged us to accept the RUC-recommended work RVU of 9.00 until there is increased volume and then reassess in 2 years. Commenters also requested refinement panel consideration for this service.

Response: Per the commenters' request, we referred this code to the CY 2016 multi-specialty refinement panel for further review. The result of the panel was a recommendation that we accept the RUC-recommended value of 9.00 work RVUs. However, since there are four ERCP codes with 60 minutes of intraservice time, three of which have work RVUs of less than 7.00 and only one of the four codes has a work RVU higher than 7.75 RVUs (8.94), based on our estimate of overall work for this service, we continue to believe that the 25th percentile of the survey most accurately reflects the relative resource costs associated with CPT code 43210. Therefore, for CY 2017 we are proposing a work RVU of 7.75 for CPT code 43210.

(4) Percutaneous Biliary Procedures Bundling (CPT Codes 47531, 47532, 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540, 47541, 47542, 47543, and 47544)

These codes were revalued with new recommendations at the October 2015

RUC meeting; we will discuss the CY 2016 interim final comments alongside the new recommendations. Please see section II.L for a discussion of the CY 2017 proposed code values.

(5) Percutaneous Image Guided Sclerotherapy (CPT Code 49185)

For CY 2016, we established an interim final work RVU of 2.35 for CPT code 49185 based on a crosswalk from CPT code 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)); which we believed accurately reflected the time and intensity involved in furnishing CPT code 49185. We also requested stakeholder input on the price of supply item SH062 (sclerosing solution) as the volume of the solution in this procedure (300 mL) is much higher than other CPT codes utilizing SH062 (between 1 and 10 mL).

Comment: Commenters disagreed with our proposed crosswalk of CPT code 49185 from CPT code 62305. Commenters believed that the RUC-recommended crosswalk from CPT code 31622 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed (separate procedure)) was a more appropriate comparison due to similarity in service. Commenters requested that CPT code 49185 be referred to the refinement panel.

Response: The requests did not meet the requirements related to new clinical information for referral to the refinement panel. After review of the comments, we continue to believe that a crosswalk of CPT code 49185 from the value for CPT code 62305 is most appropriate due to similarities in overall work. Therefore, we are proposing a work RVU of 2.35 for CPT code 49185 for CY 2017 and seek additional rationale for why a different work RVU or crosswalk would more accurately reflect the resources involved in furnishing this service.

Comment: A commenter stated that the procedure described by CPT code 49185 involved a separate clinical labor staff type. Due to the inclusion of this additional individual, the L037D clinical labor and additional gloves were appropriate to include in the procedure.

Response: The commenter did not provide any evidence for this claim. We continue to believe that this additional use of clinical staff would not be typical for CPT code 49185. This procedure does not involve moderate sedation, and therefore, we do not believe that there would be a typical need for a third staff member. As a result, we are proposing to maintain our direct PE refinements from the CY 2016 PFS final rule with comment period.

Additionally, we did not receive any information regarding SH062 that supports maintaining an input of 300 mL, and as noted above, this level far exceeds the volume associated with other CPT codes; therefore, we are proposing to refine the direct practice expense inputs for SH062 from 300 mL to 10 mL, which is the highest level associated with other CPT codes utilizing SH062.

(6) Genitourinary Procedures (CPT Codes 50606, 50705, and 50706)

In the CY 2016 PFS final rule with comment period, we established as interim final the RUC-recommended work RVUs for all three codes. We did not receive any comments on the work values for these codes, and we are proposing to maintain all three at their current work RVUs.

The RUC recommended the inclusion of ''room, angiography'' (EL011) for this family of codes. As we discussed in the CY 2016 PFS final rule with comment period, we did not believe that an angiography room would be used in the typical case for these procedures, and we therefore replaced the recommended equipment item ''room, angiography'' with equipment item ''room, radiographic-fluoroscopic'' (EL014) for all three codes on an interim final basis. We also stated our belief that since the predecessor procedure codes generally did not include an angiography room and we did not have a reason to believe that the procedure would have shifted to an angiography room in the course of this coding change, we did not believe that the use of an angiography room would be typical for these procedures.

Comment: Several commenters disagreed with the CMS substitution of the fluoroscopic room in place of the angiography room. The commenters stated that all three of these procedures were previously reported using CPT code 53899 (Unlisted procedure, urinary system) which does not have any PE inputs, and the RUC recommendations included as a reference CPT code 50387 (Removal and replacement of externally accessible transnephric ureteral stent), which includes an angiography room. The commenters suggested that CPT code 50387 was an example of a predecessor code that included the use of an angiography room, along with other codes that are being bundled together to create the new Genitourinary codes.

Response: We do not agree with the commenter's implication that because CPT code 50387 was an appropriate reference code for use in valuation, that it necessarily would have previously been used to describe services that are now reported under CPT codes 50606, 50705, or 50706. Our perspective is consistent with the RUC-recommended utilization crosswalk for the three new codes, which did not suggest that the services were previously reported using 50706. We do not believe that use of one particular code for reference in developing values for another necessarily means that the all of the same equipment would be used for both services.

We do not believe that these codes describe the same clinical work either. CPT code 50387 is for the ''Removal and replacement of externally accessible transnephric ureteral stent'' while CPT code 50606 describes an ''Endoluminal biopsy of ureter and/or renal pelvis'', CPT code 50705 refers to ''Ureteral embolization or occlusion'', and CPT code 50706 details ''Balloon dilation, ureteral stricture.'' Additionally, the codes do not have the same global periods, which makes comparisons between CPT code 50387 and CPT codes 506060, 50705, and 50706 even more difficult. We note that despite the commenter's claim that CPT code 50387 was provided as a reference for these procedures, 50387 is not in fact listed as a reference for any of these three codes, or mentioned at all in the codes' respective summary of recommendations. However, we acknowledge that among the procedures that are provided as references, many of them include the use of an angiography room, such as CPT code 36227 (Selective catheter placement, external carotid artery) and CPT code 37233 (Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel). Therefore, we agree that the use of the angiography room in these procedures, or at least some of its component parts, may be warranted.

Comment: A commenter stated that the substitution of the fluoroscopic room for the angiography room was clinically unjustified. The commenter stated that the angiography room was needed for these procedures to carry out 3-axis rotational imaging (so as to avoid rolling the patient), ensure sterility, and avoid unacceptable radiation exposure to physicians, their staff, and their patients. The commenter indicated that the only piece of equipment listed in the angiography room that would not be typically utilized for these procedures is the Provis Injector. All of the other

items are used for these Genitourinary procedures. The commenter urged CMS to restore the angiography room to these procedures.

Response: We agree that it is important to provide equipment that is medically reasonable and necessary. Our concern with the use of the angiography room for these codes is that we do not believe all of the equipment would be typically necessary to furnish the procedure. For example, the commenter agreed that the Provis Injector would not be required for these Genitourinary codes. Therefore, we are proposing to remove the angiography room from these three procedures and add in its place the component parts that make up the room. Table 16 details these components:

TABLE 16—ANGIOGRAPHY ROOM (EL011) COMPONENTS

100 KW at 100 kV (DIN6822) generator
C-arm single plane system, ceiling mounted, integrated multispace
T motorized rotation, multiple operating modes
real-time digital imaging
40 cm image intensifier at 40/28/20/14cm
30 × 38 image intensifier dynamic flat panel detector
floor-mounted patient table with floating tabletop designed for angiographic exams and interventions (with peistepping for image intensifiers 13in+)
18 in TFT monitor
network interface (DICOM)
Careposition: Radiation free positioning of collimators
Carewatch: Acquisition and monitoring of configurable dose area product
Carefilter: Cu-prefiltration
DICOM HIS/RIS
Control room interface
Injector, Provis
Shields, lower body and mavig
Leonardo software
Fujitsu-Siemens high performance computers
Color monitors
Singo modules for dynamic replay and full format images
Prepared for internal networking and Siemens remote servicing, both hardware and software

We will include all of the above components except the Provis Injector, as commenters have indicated that its use would not be typical for these procedures. We welcome additional comment regarding if these or other components are typically used in these Genitourinary procedures. We currently lack pricing information for these components; we are therefore proposing to include each of these components in the direct PE input database at a price of $0.00 and we are soliciting invoices from the public for their costs so that we may be able to price these items for use in developing final PE RVUs for CY 2017

We also note that we believe that this issue illustrates a potentially broad problem with our use of equipment ''rooms'' in the direct PE input database. For most services, we only include equipment items that are used and unavailable for other uses due to their use during the services described by a particular code. However, for items included in equipment ''rooms,'' we allocate costs regardless of whether the individual items that comprise the room are actually used in the particular service.

To maintain relativity among different kinds of procedures, we are interested in obtaining more information specifying the exact resources used in furnishing services described by different codes. We hope to address this subject in greater detail in future rulemaking.

(7) Laparoscopic Radical Prostatectomy (CPT code 55866)

In the CY 2016 PFS final rule with comment period, we established an interim final work RVU of 21.36 for CPT code 55866 based on a direct crosswalk to CPT code 55840 (Prostatectomy, retropubic radical, with or without nerve sparing). We stated that we believed these codes were medically similar procedures with nearly identical time values, and we did not believe that the difference in intensity between CPT code 55840 and CPT code 55866 was significant enough to warrant the RUC-recommended difference of 5.50 work RVUs. We also compared CPT code 55866 to the work RVU of 25.18 for CPT code 55845, and stated our belief that, in general, a laparoscopic procedure would not require greater resources than an open procedure.

Comment: Several commenters disagreed with the statement that a laparoscopic procedure, such as CPT code 55866, would generally require fewer resources than an open procedure, such as CPT code 55840. Commenters stated that developing the skill necessary to perform a minimally invasive laparoscopic surgery requires a greater degree of experience and specialized training than that required to perform an open prostatectomy. Commenters indicated that this level of practitioner skill should be reflected in the work RVU for the procedure, as intensity is based in part upon skill, mental effort, and psychological stress.

Response: We agree with the commenters that skill and technique as well as mental effort and psychological stress on the part of the practitioner contribute to the overall intensity of the furnishing a given service, and therefore, are one of the two components in determining code-level work RVUs. However, we do not believe that relative increases in requisite skill or technique can be considered alone. Although the development of new technology (such as robotic assistance) may create a greater burden of knowledge on the part of the practitioner, it can also make procedures faster, safer, and easier to perform. This means that there may be reductions in time for such a procedure (which is the other component of the work RVU), but also that the mental effort and psychological stress for a given procedure may be mitigated by the improvements in safety. Therefore, we do not agree that a newer procedure that includes additional technology and requires greater training would inherently be valued at a higher rate than an older and potentially more invasive procedure.

Comment: A commenter stated that CPT code 55866 describes two very different procedures in one code. The descriptor for the code states ''includes robotic assistance when performed'', and the procedure is performed differently depending on whether or not the robotic assistance is included. The commenter indicated that the vast majority of radical prostatectomies are performed with the robot, and although the outcomes are the same in both cases, the procedures are completely different.

Response: We agree with the commenter that the descriptor includes the possibility for confusion, especially on the part of the survey respondents. Valuing this code based on the typical case is difficult when the procedure differs depending on the inclusion or exclusion of robotic assistance. We would recommend that valuation might be improved if the CPT Editorial Panel were to consider further revisions to this code to describe the two cases of laparoscopic radical prostatectomy: With and without robotic assistance.

Comment: One commenter stated that the application of the phase-in transition for facility-only codes like CPT code 55866 would have a particularly egregious impact in the second year of the transition. The commenter urged CMS to ensure that its implementation of the phase-in transition does not undermine the protections created by the statute.

Response: Please see Sections II.G and II.H or a discussion of the phase-in transition and its implementation in its second year.

Comment: Several commenters requested that CMS refer CPT code 55866 to the refinement panel for

review. At the refinement panel, the presenters brought up new evidence in the form of a study published in 2016 describing discharge data for radical laparoscopic prostatectomies. The presenters stated that there were many more people included in this study as opposed to the 30 respondents in the survey data, and that on average the robotic procedure took 90 minutes longer than the open procedure. The additional time needed to perform the procedure, as indicated by this new study's results, was presented as a new rationale as to why CMS should accept the RUC-recommended work RVU.

Response: CPT code 55866 was referred to the CY 2016 Multi-Specialty Refinement Panel per the request of commenters. The outcome of the refinement panel was a median work RVU of 26.80, the same value as the RUC recommended in the previous rulemaking cycle. After consideration of the comments and the results of the refinement panel, we are proposing for CY 2017 to maintain the interim final work RVU of 21.36 for CPT code 55866. We are interested in the results of the study mentioned at the refinement panel, and we will consider incorporating this data into the valuation of this code, including, if appropriate, adjustments to the work times used in PFS ratesetting. We are also seeking that the study be submitted through the public comment process so that we can allow it proper consideration along with other information submitted by the public, rather than using the results of a single study to propose valuations. We are also curious about the time values regarding the duration of CPT code 55866. One of the members of the refinement panel stated that on average the robotic procedure took 90 minutes longer than the open procedure. This is not what was indicated by the survey data from the RUC recommendations, which had the two procedures valued at virtually identical times (same intraservice time, 6 minutes difference total time). We are therefore seeking comment on whether the times included in this study are more accurate than the time reflected in the RUC surveys.

(8) Intracranial Endovascular Intervention (CPT codes 61645, 61650, and 61651)

For CY 2016, we established interim final work RVUs of 15.00 for CPT code 61645, 10.00 for CPT code 61650 and 4.25 for CPT code 61651. The RUC-recommended values for CPT codes 61645, 61650 and 61651 were 17.00, 12.00 and 5.50, respectively. We valued CPT code 61645 by applying the ratio between the RUC-recommended reference code's, CPT 37231 (revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed), work and time to CPT code 61645. We valued CPT code 61650 based on a crosswalk to CPT code 37221 (revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed), due to similar intensity and intraservice time. We valued CPT code 61651 based on a crosswalk to CPT code 37223 (revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (list separately in addition to the code for primary procedure, due to similar intraservice time and intensity.

Both CPT codes 61645 and 61650 included postservice work time associated with CPT code 99233 (Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit). In the CY 2016 PFS final rule with comment period, we stated that we believe that for the typical patient, these services would be considered hospital outpatient services, not inpatient services. As a result the intraservice time of the hospital observation care service was valued in the immediate postservice time. We refined the work time for CPT code 61645 by removing 55 minutes of work time associated with CPT code 99233, and added 30 minutes of time from CPT code 99233 to the immediate postservice. Therefore the total time for CPT code 61645 was reduced to 241 minutes and the immediate postservice time increased to 83 minutes. We also removed the inpatient visit from CPT code 61650, which reduced the total time to 206 minutes and increased the postservice time to 75 minutes.

Comment: Commenters disagreed with our categorization of these codes as outpatient only, and therefore, subject to the 23-hour outpatient policy. Commenters stated that according to Medicare claims data, the predecessor codes were performed primarily on an inpatient basis. Additionally, commenters pointed out that the new codes would typically be performed on acute stroke patients. Commenters also said as the new codes are inpatient-only, the CMS reductions in work and time based on the assumption of outpatient status are flawed; as a result, commenters suggested we accept the RUC-recommended values. Commenters also requested that these codes be referred to the refinement panel.

Response: We valued CPT codes 61645, 61650, and 61651 based on comparisons to reference CPT codes 37231, 37221, and 37223, respectively. We continue to believe that these codes are appropriate comparisons based on intensity and intra-service time because no persuasive information was presented at the refinement panel that indicated that these comparisons are not appropriate. Therefore we are proposing an RVU of 15.00 for CPT code 61645, 10.00 for CPT code 61650, and 4.25 for CPT code 61651. We are also proposing time inputs based on our refinements of the RUC recommendations, including removing the time associated with hospital inpatient visit CPT code 99233 from the intraservice work time, and adding 30 minutes to the immediate postservice time for both CPT codes 61645 and 61650.

We are also seeking comment on the inclusion of post-operative visits in a 0-day global. Both CPT codes 61645 are 0-day global codes, and the refinements described above reflect changes to more appropriate value these codes as 0-day codes. We do not believe that 0-day globals codes should include post-operative visits; rather, if global codes require post-operative visits, they are more appropriately assigned 10- or 90-day global periods based on our current criteria. Our policy has been to remove the visit from the post-operative period and the associated minutes from the total time while adding 30 minutes to the immediate postservice period without necessarily making an adjustment to the work RVU (see the CY 2010 PFS proposed rule, 74 FR 33557; also see the CY 2011 PFS proposed rule, 75 FR 40072).

(9) Paravertebral Block Injection (CPT codes 64461, 64462, and 64463)

In CY 2015, the CPT Editorial Panel created three new codes to describe paravertebral block injections at single or multiple levels, as well as for continuous infusion for the administration of local anesthetic for post-operative pain control and thoracic and abdominal wall analgesia. For the CY 2016 PFS final rule with comment period, we established the RUC-recommended work RVUs, 1.75 and 1.10, as interim final for CPT codes 64461 and 64462, respectively.

For CPT code 64463, we utilized a direct crosswalk from three other injection codes (CPT codes 64416 (Injection, anesthetic agent; brachial plexus, continuous infusion by catheter (including catheter placement), 64446 (Injection, anesthetic agent; sciatic nerve, continuous infusion by catheter (including catheter placement), and 64449 (Injection, anesthetic agent; lumbar plexus, posterior approach, continuous infusion by catheter (including catheter placement)) which all had a work RVU of 1.81 as we believed this crosswalk more accurately reflected the work involved in furnishing this service.

Comment: The RUC stated that CPT code 64463 is more comparable to CPT code 64483 (Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single), which has a work RVU of 1.90 and requires the same physician work and time to perform. The RUC recommended we accept the 25th percentile survey work RVU of 1.90. Another commenter stated that our value for CPT code 64463 was inappropriate since imaging guidance is not part of our comparison codes. The commenter advocated for us to accept the survey respondent's selection of CPT code 64483 as the most appropriate comparison code and assign a work RVU of 1.90.

Response: After reviewing and considering the comments, we continue to believe that CPT codes 64416, 64446, and 64449, all of which have 20 minutes of intraservice time, are better crosswalks to CPT code 64463, which also has 20 minutes of intraservice time and a similar total time. In contrast, the crosswalk code recommended by commenters, CPT 64483, only has 15 minutes of intraservice time. Therefore, we are proposing a work RVU of 1.81 for CPT code 64463 for CY 2017.

(10) Implantation of Neuroelectrodes (CPT codes 64553 and 64555)

The RUC identified CPT codes 64553 and 64555 as a site of service anomaly during the CY 2016 PFS rulemaking cycle. In the Medicare claims data, these services were typically reported in the nonfacility setting, yet the survey data was predicated on a facility-based procedure. We agreed with the RUC that these two codes should be referred to the CPT Editorial Panel to better define the services, in particular to investigate the possibility of establishing one code to describe temporary or testing implantation and another code to describe permanent implantation. We maintained the CY 2015 work RVUs and direct PE inputs for these two codes on an interim basis until receiving updated recommendations from CPT and the RUC.

Comment: A commenter requested that CMS allow practitioners to bill the MACs separately for a percutaneous electrode kit (SA022) for CPT code 64555. The commenter stated that without allowing for a separate payment for the percutaneous electrode kit, the payment for the procedure would be insufficient to cover the physician's costs.

Response: We agree that CPT codes 64553 and 64555 as currently constructed are potentially misvalued codes, which is why we are maintaining the CY 2015 work RVUs and direct PE inputs on an interim basis. We believe that the disposable supplies furnished incident to the procedure are paid through the nonfacility PE RVUs. The percutaneous electrode kit (SA022) was not previously included in the direct PE inputs for either of these two services, and since we are proposing to maintain current direct PE inputs pending additional recommendations, we do not agree that disposable supplies should be separately payable. We are proposing to maintain the interim final work RVUs and direct PE inputs for these two codes, and we look forward to reviewing recommendations regarding these procedures again for future rulemaking.

Additionally, we were alerted to a discrepancy regarding the times for these codes in the CY 2016 work time file. Our proposed CY 2017 work time file addresses this discrepancy by reflecting the RUC recommended times of 155 minutes for CPT code 64553 and 140 minutes for CPT code 64555.

(11) Ocular Reconstruction Transplant (CPT code 65780)

In CY 2015, the RUC identified CPT code 65780 as potentially misvalued through a misvalued code screen for 90-day global services that included more than 6 office visits. The RUC recommended a direct work RVU crosswalk from CPT code 27829 (Open treatment of distal tibiofibular joint (syndesmosis) disruption, includes internal fixation, when performed). After examining comparable codes, we determined the RUC-recommended work RVU of 8.80 for CPT code 65780 would likely overstate the work involved in the procedure given the change in intraservice and total times compared to the previous values. We believed that the ratio of the total times (230/316) applied to the work RVU (10.73) more accurately reflected the work involved in this procedure. Therefore, we established an interim final work RVU of 7.81 for CPT code 65780.

Comment: The RUC and other commenters disagreed with our interim final values based on objections to our use of time ratios in developing work RVUs for PFS services.

Response: We appreciate the commenters' concerns and have responded to these concerns about our methodology in section II.L of this proposed rule. After review of the comments, we continue to consider the work RVU of 7.81 to accurately represent the work involved in CPT code 65780. We believe this service is similar in overall intensity to CPT code 27766 (Open treatment of medial malleolus fracture, includes internal fixation, when performed) that has a work RVU of 7.89 and a total time that more closely approximates that of CPT code 65780. Therefore, we are proposing a work RVU of 7.81 for CPT code 65780 for CY 2017.

(12) Trabeculoplasty by Laser Surgery (CPT code 65855)

In CY 2015, the RUC identified CPT code 65855 as potentially misvalued through the review of 10-day global services with more than 1.5 postoperative visits. The RUC noted that the code was changed from a 90-day to a 10-day global period when it was last valued in 2000. However, the descriptor was not updated to reflect that change. CPT code 65855 describes multiple laser applications to the trabecular meshwork through a contact lens to reduce intraocular pressure. The current practice is to perform only one treatment session during a 10-day period and then wait for the effect on the intraocular pressure. The descriptor for CPT code 65855 has been revised and removes the language ''1 or more sessions'' to clarify this change in practice.

The RUC recommended a work RVU of 3.00 for CPT code 65855. While the RUC-recommended value represents a reduction from the CY 2015 work RVU of 3.99, we stated that significant reductions in the intraservice time, the total time, and the change in the office visits represent a more significant change in the work resources involved in furnishing the typical service. The intraservice and total times were decreased by approximately 33 percent while the elimination of two post-operative visits (CPT code 99212) alone would reduce the overall work RVU by at least 24 percent under the reverse building block method. However, the RUC-recommended work RVU only represents a 25 percent reduction relative to the previous value. To identify potential work RVUs for this service, we calculated an intraservice time ratio between the CY 2015 intraservice time, 15 minutes, and the RUC-recommended intraservice time, 10 minutes, and applied this ratio to the current work RVU of 3.99 to arrive at a work RVU of 2.66 for CPT code 65855, which we established as interim final for CY 2016.

Comment: A few commenters, including the RUC, provided explanations as to how the RUC recommendation had already accounted for the reduction in physician intra-service time and post-operative visits. Some commenters disagreed with CMS' interim final values based on objections to CMS' use of time ratios in developing work RVUs for PFS services.

Response: We appreciate the commenters' concerns regarding the time ratio methodologies and have responded to these concerns about our methodology in section II.H.2 of this proposed rule. After considering the explanations provided by commenters through public comments describing the RUC's methodologies in more detail, we agree that the proposed value did not accurately reflect the physician work involved in furnishing the service. Therefore, for CY 2017 we are proposing the RUC-recommended work RVU value of 3.00 for CPT code 65855.

(13) Glaucoma Surgery (CPT codes 66170 and 66172)

The RUC identified CPT codes 66170 and 66172 as potentially misvalued through a screen for 90-day global codes that included more than 6 office visits). We believed the RUC-recommended work RVU of 13.94 for CPT code 66170 did not accurately account for the reductions in time. Specifically, the survey results indicated reductions of 25 percent in intraservice time and 28 percent in total time. These reductions suggested that the RUC-recommended work RVU for CPT code 66170 overstated the work involved in furnishing the service, since the recommended value only represented a reduction of approximately seven percent. We believed that applying the intraservice time ratio, the ratio between the CY 2015 intraservice time, 60 minutes, and the RUC-recommended intraservice time, 45 minutes, applied to the current work RVU, 15.02, resulted in a more appropriate work RVU. Therefore, for CY 2016, we established an interim final work RVU of 11.27 for CPT code 66170.

For CPT code 66172, the RUC recommended a work RVU of 14.81. After comparing the RUC-recommended work RVU for this code to the work RVU for similar codes (for example, CPT code 44900 (Incision and drainage of appendiceal abscess, open) and CPT code 52647 (Laser coagulation of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included if performed))), we believed the RUC-recommended work RVU of 14.81 overstated the work involved in this procedure. For the same reasons and following the same valuation methodology utilized above, we applied the intraservice time ratio between the CY 2015 intraservice time and the survey intraservice time, 60/90, to the CY 2015 work RVU of 18.86. This resulted in a work RVU of 12.57 for CPT code 66172. Therefore, for CY 2016, we established an interim final work RVU of 12.57 for CPT code 66172.

Comment: Several commenters, including the RUC, disagreed with our interim final values based on objections to our use of time ratios in developing work RVUs for PFS services. Commenters also requested CMS refer CPT codes 66170 and 66172 to the refinement panel.

Response: We appreciate the commenters' concerns regarding the time ratio methodologies and have responded to these concerns in section II.H.2 of this proposed rule. CPT codes 66170 and 66172 were referred to the CY 2016 multi-specialty refinement panel per commenters' request. The outcome of the refinement panel was a median of 13.94 RVUs for CPT code 66170 and 14.84 RVUs for CPT code 66172. Due to the new information presented to the refinement panel regarding the level of intensity required to perform millimeter incisions in the eye, we agree with the assessment of the refinement panel and therefore, for CY 2017 we are proposing a work RVU of 13.94 for CPT code 66170 and 14.84 for CPT code 66172.

(14) Retinal Detachment Repair (CPT codes 67107, 67108, 67110, and 67113)

CPT codes 67107, 67108, 67110 and 67113 were identified as potentially misvalued through a screen for 90-day global post-operative visits. The RUC recommended a work RVU of 16.00 for CPT code 67107, which corresponded to the 25th percentile of the survey. While the RUC recommendation represented a five percent reduction from the current work RVU of 16.71, we believed the RUC recommendation still overvalued the service given the 15 percent reduction in intraservice time and 25 percent reduction in total time. We used the intraservice time ratio between the existing and new time values to identify an interim final work RVU of 14.06. We believed this value accurately reflected the work involved in this service and was comparable to other codes that have the same global period and similar intraservice time and total time. For CY 2016, we established an interim final work RVU of 14.06 for CPT code 67107.

For CPT code 67108, the RUC recommended a work RVU of 17.13 based on the 25th percentile of the survey, which reflected a 25 percent reduction from the current work RVU. The survey results reflected a 53 percent reduction in intraservice time and a 42 percent reduction in total time. We believe the RUC-recommended work RVU overestimated the work, given the significant reductions in intraservice time and total time and does not maintain relativity among the codes in this family. To determine the appropriate value for this code and maintain relativity within the family, we preserved the 1.13 work RVU increment recommended by the RUC between this code and CPT code 67107 and applied that increment to the interim final work RVU of 14.06 for CPT code 67107. Therefore, we established an interim final work RVU of 15.19 for CPT code 67108.

For CPT code 67110, the RUC recommended maintaining the current work RVU of 10.25. To maintain appropriate relativity with the work RVUs established for the other services within this family, we used the RUC-recommended −5.75 RVU differential between CPT code 67107 and CPT code 67110 to establish the CY 2016 interim final work RVU of 8.31 for CPT code 67110. For CPT code 67113, the RUC recommended and we established an interim final work RVU of 19.00 based on the 25th percentile of the survey.

Comment: Several commenters, including the RUC, disagreed with our interim final values based on objections to our use of time ratios in developing work RVUs for PFS services. Some commenters also stated that by using some RUC-recommended increments and rejecting others, we have not only established inconsistencies within the family of codes, but potentially opened up anomalies across a wide range of services. The RUC also expressed disagreement with using the recommended work RVU increments without using the recommended work RVU. Some commenters also stated the new IWPUT values for these three services are inappropriately low and pointed to the derived per minute intensity of 0.064 for CPT code 67110 as particularly problematic.

Response: We appreciate the commenters' concerns regarding the time ratio methodologies and have responded to these concerns in section II.H.2 of this proposed rule. We disagree with the statement about inconsistencies as the codes in this family are valued relative to one another based on the times and level of physician work required for each code. Also, we generally do not agree that a low IWPUT itself indicates overall misvaluation as the validity of the IWPUT as a measure of intensity depends on the accuracy of the assumptions regarding the number, level, and work RVUs attributable to visits for services in the post-operative global period for individual services. For example, a service with an unrealistic number or level of post-operative visits may have a very low derived intensity for the intra-service time.

CPT codes 67107, 67108, and 67110 were referred to the CY 2016 multi-specialty refinement panel per commenters' request. The outcome of the refinement panel was a median of 16.00, 17.13, and 10.25 work RVUs; respectively. After consideration of the comments and the results of the refinement panel, we are proposing a work RVU of 16.00, 17.13, and 10.25 for CPT codes 67107, 67108, and 66110, respectively, for CY 2017.

(15) Fetal MRI (CPT Codes 74712 and 74713)

For CY 2016, we established the RUC-recommended work RVU of 3.00 as interim final for CPT code 74712. We established an interim final work RVU of 1.78 for CPT code 74713 based on a refinement of the RUC-recommended work RVU of 1.85 using the ratio of work to time for both codes. This proposed value also corresponds to the 25th percentile survey result.

Comment: Commenters stated that the work RVU of 1.78 for CPT code 74713 did not reflect the higher intensity inherent in the procedure's typical patient. The commenter explained that the typical patient is pregnant with twins and has a higher likelihood of complications related to congenital anomalies, as well as of ischemic brain injury with twin gestations. The commenter further stated that twin gestations are more difficult to image. Commenters requested that CPT code 74713 be referred to the multispecialty refinement panel.

Response: CPT code 74713 was referred to the CY 2016 multispecialty refinement panel. After considering the comments and the results of the refinement panel, we agree with commenters that an RVU of 1.78 underestimates the work for CPT code 74713. Therefore, we propose a work RVU of 1.85 for the service for CY 2017.

(16) Interstitial Radiation Source Codes (CPT Codes 77778 and 77790)

In CY 2016 PFS final rule with comment period, we established an interim final value for CPT code 77790 without a work RVU, consistent with the RUC's recommendation. We did not use the RUC-recommended work RVU to establish the interim final values for CPT code 77778. We stated that the specialty society survey included a work time that was significantly higher than the RUC-recommended work time without a commensurate change in RVU. For CY 2016, we established the 25th percentile work RVU survey result of 8.00 as interim final for CPT code 77778.

Comment: Commenters agreed that the preservice survey times and the RUC-recommended survey times were inconsistent and explained that this inconsistency resulted from the RUC's use of preservice packages in developing recommendations. In addition, commenters stated that because the work associated with CPT code 77790 (including pre-time supervision, handling, and loading of radiation seeds into needles) was bundled into CPT code 77778, that the additional work should be reflected in the RVU for CPT code 77778. Commenters encouraged us to accept the RUC-recommended work RVU of 8.78 and requested that CPT code 77778 be referred to the refinement panel.

Response: We did not refer CPT code 77778 to the CY 2016 multispecialty refinement panel because commenters did not provide new clinical information. We continue to believe that, based on the reduction in total work time, an RVU of 8.00 accurately reflects the work involved in furnishing CPT code 77778. Therefore for CY 2017, we are proposing a work RVU of 8.00 for CPT code 77778 and 0 work RVUs for CPT code 77790. We are also seeking comment on whether we should use time values based on preservice packages if the recommended work value is based on time values that are significantly different than those ultimately recommended.

(17) Colon Transit Imaging (CPT Codes 78264, 78265, and 78266)

In establishing CY 2016 interim final values, we accepted the RUC-recommended work RVUs for CPT codes 78265 and 78266. We believed that the RUC-recommended RVU of 0.80 overestimated the work involved in furnishing CPT code 78264 and as a result, we established an interim final work RVU of 0.74 based on a crosswalk to CPT code 78226 (hepatobiliary system imaging, including gallbladder when present), due to similar intraservice times and intensities.

Comment: Commenters did not support our interim final work RVU for CPT code 78264. Commenters disagreed with our assessment of CPT code 78264 as having a higher work RVU and shorter intraservice time relative to the other codes in the family. One commenter stated that a difference of two minutes in intraservice time was insignificant and should not be used as a rationale for revaluing. Another commenter stated that we should have maintained the RUC-recommended crosswalk of CPT code 78264 to CPT code 78227 (Hepatobiliary system imaging, including gallbladder when present; with pharmacologic intervention, including quantitative measurement(s) when performed) due to similarities in service, work and intensity. Based on these concerns, commenters requested that CPT code 78264 be referred to the refinement panel.

Response: CPT code 78264 was referred to the CY 2016 multi-specialty refinement panel for further review. We calculate the refinement panel results as the median of each vote. That result for CPT code 78264 was 0.79 RVUs. After consideration of the comments and the refinement panel results, we agree that 0.79 accurately captures the overall work involved in furnishing this service and are proposing a value of 0.79 for CPT code 78264.

(18) Cytopathology Fluids, Washings or Brushings and Cytopathology Smears, Screening, and Interpretation (CPT Codes 88104, 88106, 88108, 88112, 88160, 88161, and 88162)

In the CY 2016 PFS final rule with comment period, we made a series of refinements to the recommended direct PE inputs for this family of codes. We removed the equipment time for the solvent recycling system (EP038) and the associated clinical labor described by the tasks ''Recycle xylene from stainer'' and ''Order, restock, and distribute specimen containers and or slides with requisition forms'' due to our belief that these were forms of indirect PE. This refinement applied to all seven codes in the family. We also noticed what appeared to be an error in the quantity of non-sterile gloves (SB022), impermeable staff gowns (SB027), and eye shields (SM016) assigned to CPT codes 88108 and 88112. The recommended value of these supplies was a quantity of 0.2, which we believed was intended to be a quantity of 2. We therefore refined the value of these supplies to 2 for CPT codes 88108 and 88112.

Comment: Several commenters disagreed with our characterization of the solvent recycling system and its associated clinical labor tasks as indirect PE. Commenters stated that the solvent recycling system costs are direct expenses since they are based on the amount of recycled solvent allocated to each specimen, with solvents allocated to specific specimens based on batch size. They indicated that the related clinical labor tasks are also forms of direct PE as they are also based on the amount of recycled solvent allocated to each specimen. The time for these tasks varies based on the batch size, which varies by procedure.

Response: We maintain our previously stated belief that these are forms of indirect PE, as they are not allocated to any individual service. We have defined direct PE inputs as clinical labor, medical supplies, or medical equipment that are individually allocable to a particular patient for a particular service. We continue to believe that a solvent recycling system would be in general use for a lab practice, and that the associated clinical labor tasks for ordering and restocking specimen containers can be more accurately described as administrative activities. We are proposing to maintain these refinements from the previous rulemaking cycle for CPT codes 88104–88162.

Comment: A commenter indicated that we did not account for the batch size when considering the supply quantities for CPT codes 88108 and 88112. The commenter indicated that the practice expense inputs should be assumed to have a batch size of five for these two codes, and therefore, no edits should be made. The commenter requested that we restore the quantity of 0.2 for the gloves, gowns, and eye shields associated with these procedures. This did not apply to the other codes on the submitted spreadsheet, which had a batch size of one.

Response: We appreciate the assistance of the commenter in clarifying the batch size for these procedures. As a result, we are proposing to refine the supply quantity of the non-sterile gloves (SB022), impermeable staff gowns (SB027), and eye shields (SM016) back to the RUC-recommended value of 0.2 for CPT codes 88108 and 88112.

(19) Immunohistochemistry (CPT Codes 88341, 88342, 88344, and 88350)

In the CY 2014 PFS final rule with comment period (78 FR 74341), we assigned a status indicator of I (Not valid for Medicare purposes) to CPT codes 88342 and 88343 and instead created two G-codes, G0461 and G0462, to report immunohistochemistry services. We did this in part to avoid creating incentives for overutilization. For CY 2015, the CPT coding was revised with the creation of two new CPT codes, 88341 and 88344, the revision of CPT code 88342 and the deletion of CPT code 88343. In the past for similar procedures in this family, the RUC recommended a work RVU for the add-on code (CPT code 88364) that was 60 percent of the base code (CPT code 88365). In the CY 2015 PFS final rule with comment period, we stated that the relative resources involved in furnishing an add-on service in this family would be reflected appropriately using the same 60 percent metric and subsequently established an interim final work RVU of 0.42 for CPT code 88341, which was 60 percent of the work RVU of the base CPT code 88342 (0.70). In the CY 2016 PFS proposed rule, we revised the add-on codes from 60 percent to 76 percent of the base code and subsequently revalued CPT code 88341 at 0.53 work RVUs. However, we inadvertently published work RVUs for CPT code 88341 in Addendum B without explicitly discussing it in the preamble text. In the CY 2016 PFS final rule with comment period, we maintained CPT code 88341's CY 2015 work RVU of 0.53 as interim final for CY 2016 and requested public comment. Also, in the CY 2016 PFS final rule with comment period, we established an interim final value of 0.70 work RVUs for CPT codes 88342 and 88344.

Comment: Several commenters expressed their opposition to a standard discount for the physician work involved in pathology add-on services and urged us to accept the RUC-recommend value of 0.65 RVUs for CPT code 88341.

Response: We appreciate commenters' concerns regarding a standard discount; however, we believe that it is reasonable to estimate work RVUs for a base and an add-on code, and to recognize efficiencies between them, by looking at how similar efficiencies are reflected in work RVUs for other PFS services. Also we note that the intravascular codes for which we initially established our base/add-on code relationship for CPT codes 88346 and 88350 were deleted in CY 2016 and replaced with two new codes; CPT codes 37252 and 37253. The relationship between 37252 and 37253 represents a 20 percent discount for the add-on code as the base CPT code 37252 has a work RVU of 1.80 and 37523 and work RVU of 1.44. As CPT codes 37252 and 37253 replaced the codes on which our discounts for base and add-on codes were based (please see the CY 2016 PFS final rule with comment period (80 FR 70972) for a detailed discussion) we believed it would be appropriate to maintain the same 20 percent relationship for 88346 and 88350. Therefore, for CY 2017, we are proposing a work RVU of 0.56 for CPT code 88341, which represents 80 percent of 0.70, the work RVU of the base code.

For CY 2016, we finalized a work RVU of 0.56 for CPT code 88350 which represented 76 percent of 0.74, the RVU for the base code. To maintain consistency within this code family, we are proposing to revalue CPT code 88350 using the 20 percent discount discussed above. To value CPT code 88350, we multiplied the work RVU of CPT code 88346, 0.74, by 80 percent, and then subtracted the product from 0.74, resulting in a work RVU of 0.59 for CPT code 88350. Therefore, for CY 2017, we are proposing a work RVU of 0.59 for CPT code 88350.

A stakeholder has suggested to us that an error was made in the implementation of direct PE inputs for code 88341 and several other related codes. This stakeholder stated that when CMS reclassified equipment code EP112 (Benchmark ULTRA automated slide preparation system) and EP113 (E-Bar II Barcode Slide Label System) into a single equipment item, with a price of $150,000 using equipment code EP112,

the equipment minutes assigned to the E-Bar II Barcode Slide Label System should have been added into the new EP112 equipment time. The stakeholder requested that these minutes should be added into the EP112 equipment time; for example, 1 additional minute should be added to CPT code 88341 for a total of 16 minutes.

We appreciate the additional information, and are soliciting additional information on this topic through public comment on this proposed rule to assess whether it would be appropriate to add the former EP113 minutes into EP112. We are specifically seeking comment from other stakeholders, including the RUC, since the assigned number of minutes was originally based on a RUC recommendation. This information would be potentially relevant for CPT codes 88341 (Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure), 88342 (Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure), 88344 (Immunohistochemistry or immunocytochemistry, per specimen; each multiplex antibody stain procedure), 88360 (Morphometric analysis, tumor immunohistochemistry, quantitative or semiquantitative, per specimen, each single antibody stain procedure; manual), and 88361 (Morphometric analysis, tumor immunohistochemistry, quantitative or semiquantitative, per specimen, each single antibody stain procedure; using computer-assisted technology).

(20) Morphometric Analysis (CPT Codes 88364, 88365, 88367, 88368, 88369 and 88373)

For CY 2015, the CPT editorial panel revised the code descriptors for the in situ hybridization procedures, CPT codes 88365, 88367 and 88368, to specify ''each separately identifiable probe per block.'' Additionally, three new add-on codes (CPT codes 88364, 88369, 88373,) were created to specify ''each additional separately identifiable probe per slide.'' Some of the add-on codes in this family had RUC-recommended work RVUs that were 60 percent of the work RVU of the base procedure. We believed this accurately reflected the resources used in furnishing these add-on codes and subsequently established interim-final work RVUs of 0.53 for code 88364 (60 percent of the work RVU of CPT code 88365); 0.53 for CPT code 88369 (60 percent of the work RVU of CPT code 88368); and 0.43 for CPT code 88373 (60 percent of the work RVU of CPT code 88367).

For CY 2016, the RUC re-reviewed these services due to the specialty society's initially low survey response rate. In our review of these codes, we noticed that the latest RUC recommendation was identical to the RUC recommendation provided for CY 2015. Therefore, we proposed to retain the CY 2015 work RVUs and work time for CPT codes 88367 and 88368 for CY 2016. For CPT code 88365 we finalized a work RVU of 0.88.

For CPT codes 88364 and 88369, we increased the work RVUs of these add-on codes from 0.53 to 0.67, which reflected 76 percent of the work RVUs of the base procedures for these services. However, we inadvertently omitted the rationale for this revision to the work RVUs in the proposed rule. Consequently, we maintained the CY 2015 interim final values of the work RVU of 0.67 for CPT codes 88464 and 88369 and sought comment on these values for CY 2016. For CPT code 88373 we finalized a work RVU of 0.43.

Comment: A few commenters stated their objection to our use of a standard discount for pathology add-on services and for suggesting that each service is separate and unique. Commenters also stated there should be no comparison of intravascular ultrasound services to morphometric analysis, immunohistochemistry, immunofluorescence, or any pathology service.

Response: In reviewing the RUC-recommended base/add-on relationships between several pathology codes, we continue to believe the base/add-on code time relationships for pathology services are appropriate and have not been presented with any compelling evidence that conflicts with the RUC-recommended relationships. However, as we stated above, the intravascular codes we initially examined in revaluing CPT codes 88364 and 88369 were deleted in CY 2016 and replaced with CPT codes 37252 and 37253. For the reasons stated above we continue to believe this 20 percent discount relationship between the base and add-on code accurately reflects the work involved in furnishing these services.

Therefore, for CY 2017, we are proposing a work RVU of 0.70 for CPT codes 88364 and 88369 which represents a 20 percent discount from the base code. As the relationship between the base code and add-on code now represents a 20 percent difference we are proposing to revalue CPT code 88373 at 0.58 work RVUs. Therefore, for CY 2017 we are proposing a work RVU of 0.58 for CPT code 88373.

(21) Liver Elastography (CPT Code 91200)

For CY 2016, we received a RUC recommendation of 0.27 RVU for CPT code 91200. After careful review of the recommendation, we established the RUC-recommended work RVU and direct PE inputs as interim final for CY 2016.

Comment: A few commenters requested that we reconsider the level of payment assigned to this service when furnished in a non-facility setting, stating that the code met the definition for the potentially misvalued code list as there is a significant difference in payment between sites of service. The commenters also asked us to reconsider the assigned 50 percent utilization rate for the FibroScan equipment in this procedure as the current utilization rate would translate to over 50 procedures per week. Instead, the commenters suggested the typical number of procedures done per week ranges between 15 and 25 and requested we adopt a 25 percent utilization rate which corresponds to that number of procedures.

Response: We refer commenters to the CY 2016 final rule with comment period (80 FR 71057–71058) where we discussed and addressed the comparison of the PFS payment amount to the OPPS payment amount for CPT 91200. For the commenter's statement about the utilization rate, we have previously addressed the accuracy of these default assumptions as they apply to particular equipment resources and particular services. In the CY 2008 PFS proposed rule (72 FR 38132), we discussed the 50 percent utilization assumption and acknowledged that the default 50 percent usage assumption is unlikely to capture the actual usage rates for all equipment. However, we stated that we did not believe that we had strong empirical evidence to support any alternative approaches. We indicated that we would continue to monitor the appropriateness of the equipment utilization assumption, and evaluate whether changes should be proposed in light of the data available. The commenters did not provide any verifiable data suggesting a lower utilization rate. Therefore, for CY 2017 we are proposing a work RVU of 0.27 for CPT code 91200, consistent with the CY 2016 interim final value, and we continue to explore and seek comments regarding publicly available data sources to identify the most accurate equipment utilization rate assumptions possible. We also note that following the

publication of the CY 2016 PFS final rule with comment period (80 FR 70886) there was an inconsistency in the Work Time file published on the CMS Web site. For CPT code 91200 the RUC recommended 16 minutes total service time whereas our file reflected 18 minutes total time for the service. For CY 2017, we are proposing to update the Work Time file to reflect the RUC's recommendation, which is 16 minutes for CPT code 91200.

b. CY 2017 Proposed Codes

(1) Anesthesia Services Furnished in Conjunction with Lower Gastrointestinal (GI) Procedures (CPT Codes 00740 and 00810)

The anesthesia procedure CPT codes 00740 and 00810 are used for anesthesia furnished in conjunction with lower gastrointestinal (GI) procedures. In the CY 2016 PFS proposed rule (80 FR 41686), we discussed that in reviewing Medicare claims data, a separate anesthesia service is now reported more than 50 percent of the time that several types of colonoscopy procedures are reported. We discussed that given the significant change in the relative frequency with which anesthesia codes are reported with colonoscopy services, we believe the relative values of the anesthesia services should be reexamined. We proposed to identify CPT codes 00740 and 00810 as potentially misvalued and sought public comment regarding valuation for these services.

The RUC recommended maintaining the base unit value of 5 as an interim base value for both CPT code 00740 and 00810 on an interim basis, due to their concerns about the specialty society surveys. The RUC suggested that the typical patient vignettes used in the surveys for both CPT codes 00740 and 00810 were not representative of current typical practice and recommended that the codes be resurveyed with updated vignettes. We agree that it is premature to propose any changes to the valuation of CPT codes 00740 and 00810, but continue to believe that these services are potentially misvalued and look forward to receiving input from interested parties and specialty societies for consideration during future notice and comment rulemaking.

(2) Removal of Nail Plate (CPT Code 11730)

We identified CPT code 11730 (Avulsion of nail plate, partial or complete, simple; single) through a screen of high expenditures by specialty. The HCPAC recommended a work RVU of 1.10. We believe the recommendation for this service overestimates the work involved in performing this procedure, specifically given the decrease in physician intraservice and total time concurrently recommended by the HCPAC. We believe that a work RVU of 1.05, which corresponds to the 25th percentile of the survey results, more accurately represents the time and intensity of furnishing the service. To further support the validity of the use of the 25th percentile of the survey, a work RVU of 1.05, we identified two crosswalk CPT codes, 20606 (Arthrocentesis, aspiration and/or injection, intermediate joint or bursa), with a work RVU of 1.00, and 50389 (Removal of nephrostomy tube, requiring fluoroscopic guidance) with a work RVU of 1.10, both of which have identical intraservice times, similar total times and similar intensity. We note that our proposed work RVU of 1.05 for CPT code 11730 falls halfway between the work RVUs for these two crosswalk-codes. CPT Code 11730 may be reported with add-on CPT code 11732 to report performance of the same procedure for each additional nail plate procedure.

Since CPT code 11732 was not reviewed by the HCPAC for CY 2017, we are proposing a new work value to maintain the consistency of this add-on code with the base code, CPT code 11730. We are proposing to remove 2 minutes from the physician intraservice time to maintain consistency with the HCPAC-recommended reduction of 2 minutes from the physician intraservice time period for the base code. We are using a crosswalk from the value for CPT code 77001 (Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal (includes fluoroscopic guidance for vascular access and catheter manipulation, any necessary contrast injections through access site or catheter with related venography radiologic supervision and interpretation, and radiographic documentation of final catheter position) (List separately in addition to code for primary procedure)), which has similar physician intraservice and total time values; therefore, we are proposing a work RVU of 0.38 for CPT code 11732. As further support for this proposal, we note that this proposed RVU reduction is similar to the value obtained by subtracting the incremental difference in the current and recommended work RVUs for the base code from the current value of CPT code 11732.

We are proposing to use the HCPAC-recommended direct PE inputs for CPT code 11730. We are proposing to apply some of HCPAC-recommended refinements for CPT code 11730 to11732, including the removal of the penrose drain (0.25in x 4in), lidocaine 1%–2% inj (Xylocaine), applicator (cotton-tipped, sterile) and silver sulfadiazene cream (Silvadene), as well as the reduction of the swab-pad, alcohol from 2 to 1. In addition, we are proposing not to include the recommended the supply items ''needle, 30g, and syringe, 10–12ml'' since other similar items are present, and we think inclusion of these additional supply items would be duplicative. For clinical labor, we are proposing to assign 8 minutes to ''Assist physician in performing procedure'' for to maintain a reduction that is proportionate to that recommended for 11730. For the supply item ''ethyl chloride spray,'' we believe that the listed input price of $4.40 per ounce overestimates the cost of this supply item, and we are seeking comment on the accuracy of this supply item price. Finally, we are adding two equipment items as was done in the base code, basic instrument pack and mayo stand, and are proposing to adjust the times for all pieces of equipment to 8 minutes to reflect the clinical service period time.

(3) Bone Biopsy Excisional (CPT Code 20245)

In CY 2014, CPT code 20245 was identified by the RUC's 10-Day Global Post-Operative Visits Screen.

For CY 2017, the RUC recommended a value of 6.50 work RVUs for CPT code 20245, including a change in global period from 10- to 0- days. We disagree with this value given the significant reductions in the intraservice time, total time, and the change in the office visits assuming the change in global period. The intraservice and total times were decreased by approximately 33 and 53 percent respectively; while the elimination of three post-operative visits (one CPT code 99214 and two CPT code 99213 visits) alone would reduce the overall work RVU by at least 38 percent under the reverse building block methodology. We also note that the RUC-recommended work RVU of 6.50 only represents a 27 percent reduction relative to the previous work RVU of 8.95. To develop a work RVU for this service, we used a crosswalk from CPT code 19298 (Placement of radiotherapy after loading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance), since we believe the codes share similar intensity and total time and the same intraservice time of 60 minutes. Therefore, for CY

2017, we are proposing a work RVU of 6.00 for CPT code 20245.

(4) Insertion of Spinal Stability Distractive Device (CPT Codes 228X1, 228X2, 228X4, and 228X5)

For CY 2016, the CPT Editorial Panel converted two Category III codes to Category I codes describing the insertion of an interlaminar/interspinous process stability device (CPT codes 228X1 and 228X4) and developed two corresponding add-on codes (CPT codes 228X2 and 228X5). The RUC recommended a work RVU of 15.00 for CPT code 228X1, 4.00 for CPT code 228X2, 7.39 for CPT code 228X4, and 2.34 for CPT code 228X5.

We believe that the RUC recommendations for CPT codes 228X1 and 228X4 overestimate the work involved in furnishing these services. We believe that a crosswalk to CPT code 36832 (Revision, open, arteriovenous fistula; without thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure)) which has a work RVU of 13.50 is an accurate comparison. CPT code 36832 is similar in total time, work intensity, and number of visits to 228X1. This is supported by the ratio between total time and work in the key reference service, CPT code 63047 (Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; lumbar). Therefore, we are proposing a work RVU of 13.50 for CPT code 228X1. For CPT code 228X4, we believe that CPT code 29881 (Arthroscopy, knee, surgical; with meniscectomy (medial OR lateral, including any meniscal shaving) including debridement/shaving of articular cartilage (chondroplasty), same or separate compartment(s), when performed) is an appropriate crosswalk based on clinical similarity as well as intensity and total time. CPT code 29881 has an RVU of 7.03; therefore, we are proposing a work RVU of 7.03 for CPT code 228X4. We are proposing to accept the RUC-recommended work RVU for CPT codes 228X2 and 228X5 without refinement.

(5) Biomechanical Device Insertion (CPT Codes 22X81, 22X82, and 22X83)

For CY 2016, the CPT Editorial Panel established three new category I add-on codes and deleted one code to provide a more detailed description of the placement and attachment of biomechanical spinal devices. For CPT code 22X81, the RUC recommended a work RVU of 4.88. For CPT code 22X82, and CPT code 22X83, the recommended work RVUs are 5.50 and 6.00, respectively.

In reviewing the code descriptors, descriptions of work and vignettes associated with CPT codes 22X82 and 22X83, we determined that the two procedures, in addition to having identical work time, contain many clinical similarities and do not have quantifiable differences in overall intensity. Therefore, we are proposing the RUC-recommended work RVU of 5.50 for both CPT code 22X82 and CPT code 228X3. We believe that the RUC-recommended work RVU for CPT code 22X81 overestimates the work in the procedure relative to the other codes in the family. We are proposing a work RVU of 4.25 for CPT code 228X1 based a crosswalk from CPT code 37237 (Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; each additional artery (List separately in addition to code for primary procedure)), which is similar in time and intensity to the work described by CPT code 22X81.

(6) Closed Treatment of Pelvic Ring Fracture (CPT Codes 271X1 and 271X2)

For CY 2017, the CPT Editorial Panel deleted CPT codes 27193 and 27194 and replaced them with two new codes, 271X1 and 271X2, and the RUC recommended a work RVU of 5.50 for CPT code 27193, and a work RVU of 9.00 for CPT code 271X2 to describe closed treatment of pelvic ring fracture. We are proposing to change the global period for these services from 90 days to 0 days because these codes typically represent emergent procedures with which injuries beyond pelvic ring fractures are likely to occur; we believe it is typical that multiple practitioners would be involved in providing post-operative care and it is likely that a practitioner furnishing a different procedure is more likely to be providing the primary post-operative care. If other practitioners are typically furnishing care in the post-surgery period, we believe that the six postservice visits included in CPT code 271X1, and the seven included in 271X2, would likely not occur. This is similar to our CY 2016 review and valuation of CPT codes 21811 (Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 1–3 ribs), 21812 (Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 4–6 ribs), and 21813 (Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 7 or more ribs). In our valuation of those codes, we determined that a 0-day, rather than a 90-day global period was preferable, in part because those codes describe rib fractures that would typically occur along with other injuries, and the patient would likely already be receiving post-operative care because of the other injuries. We believe that the same rationale applies here. To establish a work RVU for 271X1, we are crosswalking this code to CPT code 65800 (Paracentesis of anterior chamber of eye (separate procedure); with removal of aqueous), due to its identical intraservice time and similar total time, after removing the work associated with postoperative visits, and its similar level of intensity. Therefore, we are proposing a work RVU of 1.53 for CPT code 271X1. For 271X2, we are crosswalking to CPT code 93452 (Left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed) which has an identical intraservice time and similar total time after removing the work associated with postoperative visits from 271X2. We are proposing a work RVU of 4.75 for code 271X2.

(7) Bunionectomy (CPT Codes 28289, 282X1, 28292, 28296, 282X2, 28297, 28298, and 28299)

The RUC identified CPT Code 28293 as a 90-day global service with more than 6 office visits and CPT codes 28290–28299 as part of the family of services. In October 2015, the CPT Editorial Panel created two new CPT codes (282X1, 282X2), deleted CPT codes 28290, 28293, 28294 and revised CPT codes 28289, 28292, 28296, 28297, 28298 and 28299 based on the rationale that more accurate descriptions of the services needed to be developed.

For CPT codes 28289, 28292, 28296, 28297, 28298, and 28299 the RUC recommended and we are proposing work RVUs of 6.90, 7.44, 8.25, 9.29, 7.75, and 9.29 respectively. For CPT code 282X1, the RUC recommended a work RVU of 8.01 based on the 25th percentile of the survey. We believe the recommendation for this service overestimates the overall work involved in performing this procedure given the decrease in intraservice time, total time, and post-operative visits when compared to deleted predecessor CPT code 28293. Due to similarity in

intraservice and total times, we believe a direct crosswalk of the work RVUs for CPT code 65780 (Ocular surface reconstruction; amniotic membrane transplantation, multiple layers), to CPT code 282X1 more accurately reflects the time and intensity of furnishing the service. Therefore, for CY 2017, we are proposing a work RVU of 7.81 for CPT code 282X1.

For CPT code 282X2, the RUC recommended a work RVU of 8.57 based on the 25th percentile of the survey. We believe the recommendation for this service overestimates the work involved in performing this procedure given the similarity in the intensity of the services and identical intraservice and total times as CPT code 28296. Therefore, we propose a direct RVU crosswalk from CPT code 28296 to CPT code 282X2. For CY 2017, we are proposing a work RVU of 8.25 for CPT code 282X2.

(8) Endotracheal Intubation (CPT Code 31500)

In the CY 2016 PFS final rule with comment period (80 FR 70914), we identified CPT code 31500 as potentially misvalued. The specialty societies surveyed this code, and after reviewing the survey responses, including increases in time, the RUC recommended an increase in work RVUs to 3.00 for CPT code 31500. After reviewing the RUC's recommendation, we are proposing a work RVU of 2.66, based on a direct crosswalk to CPT code 65855, which has similar intensity and service times as reflected in the survey data reported by the specialty groups.

(9) Closure of Left Atrial Appendage With Endocardial Implant (CPT Code 333X3)

The CPT Editorial Panel deleted category III code 0281T (Percutaneous transcatheter closure of the left atrial appendage with implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, radiological supervision and interpretation) and created new CPT code 333X3 to describe percutaneous transcatheter closure of the left atrial appendage with implant. The RUC recommended a work RVU of 14.00, which is the 25th percentile survey result. After reviewing that recommendation, we are proposing a work RVU of 13.00 for CPT code 333X3, which is the minimum survey result. Based on our clinical judgment and that the key reference codes discussed in the RUC recommendations have higher intraservice and total service times than the median survey results for CPT code 333X3, we believe a work RVU of 13.00 more accurately represents the work value for this service.

(10) Valvuloplasty (CPT Codes 334X1 and 334X2)

The CPT Editorial Committee created new codes to describe valvuloplasty procedures and deleted existing CPT code 33400 (Valvuloplasty, aortic valve; open, with cardiopulmonary bypass). New CPT code 334X1 represents a simple valvuloplasty procedure and new CPT code 334X2 describes a more complex valvuloplasty procedure. We are proposing to use the RUC-recommended values for CPT code 334X1. For CPT code 334X2, the RUC recommended a work RVU of 44.00, the 25th percentile survey result. The RUC estimated that approximately 70 percent of the services previously reported using CPT code 33400 would have been reported using CPT code 334X2 with 30 percent reported using new CPT code 334X1. Therefore, the typical service previously reported with 33400 ought to now be reported with 334X2. Compared to deleted CPT code 33400, the survey results for CPT 334X2 showed the median intraservice time to be similar but total service time to be decreased. Therefore, we do not believe the increase recommended by the RUC is warranted, and we are proposing a work RVU of 41.50 for CPT code 334X2. This is the current value of CPT code 33400, and given that the typical service should remain consistent between the two codes, we believe the work RVU should remain consistent as well.

(11) Dialysis Circuit (CPT Codes 369X1, 369X2, 369X3, 369X4, 369X5, 369X6, 369X7, 369X8, 369X9)

In January 2015, a CPT/RUC workgroup identified the following CPT codes as being frequently reported together in various combinations: 35475 (Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel), 35476 (Transluminal balloon angioplasty, percutaneous; venous), 36147 (Introduction of needle and/or catheter, arteriovenous shunt created for dialysis (graft/fistula); initial access with complete radiological evaluation of dialysis access, including fluoroscopy, image documentation and report), 36148 (Introduction of needle and/or catheter, arteriovenous shunt created for dialysis (graft/fistula); additional access for therapeutic intervention), 37236 (Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery), 37238 (Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein), 75791 (Angiography, arteriovenous shunt (*e.g.*, dialysis patient fistula/graft), complete evaluation of dialysis access, including fluoroscopy, image documentation and report (includes injections of contrast and all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava), radiological supervision and interpretation), 75962 (Transluminal balloon angioplasty, peripheral artery other than renal, or other visceral artery, iliac or lower extremity, radiological supervision and interpretation), and 75968 (Transluminal balloon angioplasty, each additional visceral artery, radiological supervision and interpretation). These codes are frequently reported together for both dialysis circuit services and transluminal angioplasty services. At the October 2015 CPT Editorial Panel meeting, the panel approved the creation of nine new codes and deletion of four existing codes used to describe bundled dialysis circuit intervention services, and the creation of four new codes and deletion of 13 existing codes used to describe bundled percutaneous transluminal angioplasty services (see discussion of the latter code family in the next section). The Dialysis Circuit family of codes overlaps with the Open and Percutaneous Transluminal Angioplasty family of codes (CPT codes 372X1–372X4), as they are both being constructed from the same set of frequently reported together codes. We reviewed these two families of codes concurrently to maintain relativity between these clinically similar procedures based upon the same collection of deleted codes.

For CPT code 369X1, we are proposing a work RVU of 2.82 instead of the RUC-recommended work RVU of 3.36. When we compared CPT code 369X1 against other codes in the RUC database, we found that the RUC-recommended work RVU of 3.36 would be the highest value in the database among the 32 0-day global codes with 25 minutes of intraservice time. Generally speaking, we are particularly skeptical of RUC-recommended values for newly ''bundled'' codes that appear not to recognize the full resource

overlap between predecessor codes. Since the recommended values would establish a new highest value when compared to other services with similar time, we believe it likely that the recommended value for the new code does not reflect the efficiencies in time. Of course, were the compelling evidence for this valuation accompanying the recommendation, we would consider such information. We also note that the reference code selected by the survey participants, CPT code 36200 (Introduction of catheter, aorta), has a higher intraservice time and total time, but a lower work RVU of 3.02. We believe that there are more accurate CPT codes that can serve as a reference for CPT code 369X1. As a result, we are proposing to crosswalk CPT code 369X1 to CPT code 44388 (Colonoscopy through stoma; diagnostic). CPT code 44388 has a work RVU of 2.82, and we believe it is a more accurate crosswalk for valuation due to its similar overall intensity and shared intraservice time of 25 minutes with 369X1 and similar total time of 65 minutes.

We are proposing a work RVU of 4.24 for CPT code 369X2 instead of the RUC-recommended work RVU of 4.83. The RUC-recommended work RVU is based upon a direct crosswalk to CPT code 43253 (Esophagogastroduodenoscopy, flexible, transoral) which shares the same 40 minutes of intraservice time with CPT code 369X2. However, CPT code 43253 has significantly longer total time than CPT code 369X2, 104 minutes against 86 minutes, which we believe reduces its utility for comparison. We are instead proposing to crosswalk the work RVU for CPT code 369X2 from CPT code 44408 (Colonoscopy through stoma), which has a work RVU of 4.24. In addition to our assessment that the two codes share similar intensities, CPT code 44408 also shares 40 minutes of intraservice time with CPT code 369X2 but has only 95 minutes of total time and matches the duration of the procedure under review more closely than the RUC-recommended crosswalk to CPT code 43253. We also note that the RUC-recommended work increment between CPT codes 369X1 and 369X2 was 1.47, and by proposing a work RVU of 4.24 for CPT code 369X2, we maintain a very similar increment of 1.42. As a result, we are proposing a work RVU of 4.24 for CPT code 369X2, based on this direct crosswalk to CPT code 44408.

For CPT code 369X3, we are proposing a work RVU of 5.85 instead of the RUC-recommended work RVU of 6.39. The RUC-recommended value is based on a direct crosswalk to CPT code 52282 (Cystourethroscopy, with insertion of permanent urethral stent). Like the previous pair of RUC-recommended crosswalk codes, CPT code 52282 shares the same intraservice time of 50 minutes with CPT code 369X3, but has substantially longer total time (120 minutes against 96 minutes) which we believe limits its utility as a crosswalk. We are proposing a work RVU of 5.85 based on maintaining the RUC-recommended work RVU increment of 3.03 as compared to CPT code 369X1 (proposed at a work RVU of 2.82), the base code for this family of related procedures. We also point to CPT code 44403 (Colonoscopy through stoma; with endoscopic mucosal resection) as a reference point for this value. CPT code 44403 has a work RVU of 5.60, but also lower intraservice time (45 minutes as compared to 50 minutes) and total time (92 minutes as compared to 96 minutes) in relation to CPT code 369X3, suggesting that a work RVU a bit higher than 5.60 would be an accurate valuation. Therefore, we are proposing a work RVU of 5.85 for CPT code 369X3, based on an increment of 3.03 from the work RVU of CPT code 369X1.

We are proposing a work RVU of 6.73 instead of the RUC-recommended work RVU of 7.50 for CPT code 369X4. Our proposed value comes from a direct crosswalk from CPT code 43264 (Endoscopic retrograde cholangiopancreatography), which shares the same intraservice time of 60 minutes with CPT code 369X4 and has a higher total time. We also looked to the intraservice time ratio between CPT codes 369X1 and 369X4; this works out to 60 minutes divided by 25 minutes, for a ratio of 2.4, and a suggested work RVU of 6.77 (derived from 2.4 times CPT code 369X1's work RVU of 2.82). This indicates that our proposed work RVU of 6.73 maintains relativity within the Dialysis Circuit family. As a result, we are proposing a work RVU of 6.73 for CPT code 369X4, based on a direct crosswalk to CPT code 43264.

We are proposing a work RVU of 8.46 instead of the RUC-recommended work RVU of 9.00 for CPT code 369X5. We looked at the intraservice time ratio between CPT codes 369X1 and 369X5 as one potential method for valuation, which is a 1:3 ratio (25 minutes against 75 minutes) for this case. This means that one potential value for CPT code 369X5 would be triple the work RVU of CPT code 369X1, or 2.82 times 3, which results in a work RVU of 8.46. We also investigated preserving the RUC-recommended work RVU increment between CPT code 369X1 and 369X5, which was an increase of 5.64. When this increment is added to the work RVU of 2.82 for CPT code 369X1, it also resulted in a work RVU of 8.46 for CPT code 369X5. Therefore, we are proposing a work RVU of 8.46 for CPT code 369X5, based on both the intraservice time ratio with CPT code 369X1 and the RUC-recommended work increment with the same code.

For CPT code 369X6, we are proposing a work RVU of 9.88 instead of the RUC-recommended work RVU of 10.42. We based the proposed value upon the RUC-recommended work RVU increment between CPT codes 369X1 and 369X6, which is 7.06. When added to the work RVU of 2.82 for CPT code 369X1, the work RVU for CPT code 369X6 would be 9.88. We are supporting this value through the use of two crosswalks that both share the same 90 minutes of intraservice time with 369X6. These are CPT code 31546 (Laryngoscopy, direct, with submucosal removal of non-neoplastic lesion(s) of vocal cord) at a work RVU of 9.73 and CPT code 61623 (Endovascular temporary balloon arterial occlusion, head or neck) at a work RVU of 9.95.

The final three codes in the Dialysis Circuit family are all add-on codes, which make comparisons difficult to the global 0-day codes that make up the rest of the family. We are proposing a work RVU of 2.48 instead of the RUC-recommended work RVU of 3.00 for CPT code 369X7. Due to the difficulty of comparing CPT code 369X7 with the non-add-on codes in the rest of the Dialysis Circuit family, we looked instead to compare the value to the add-on codes in the Open and Percutaneous Transluminal Angioplasty family of codes (CPT codes 372X1–372X4). As we stated previously, both of these groups of new codes are being constructed from the same set of frequently reported together codes. We reviewed these two families of codes together to maintain relativity across the two families, and so that we could compare codes that shared the same global period.

We are proposing the RUC-recommended work RVUs for all four codes in the Open and Percutaneous Transluminal Angioplasty family of codes. As a result, we compared CPT code 369X7 with the RUC-recommended work RVU of 2.97 for CPT code 372X4, which is also an add-on code. These procedures should be clinically very similar, since both of them are performing percutaneous transluminal angioplasty on a central vein, and both of them are add-on procedures. We looked at the intraservice time ratio between these two codes, which was a comparison between 25 minutes for CPT code 369X7 against 30 minutes for CPT code 372X4.

This produces a ratio of 0.83, and a proposed work RVU of 2.48 for CPT code 369X7 when multiplied with the RUC-recommended work RVU of 2.97 for CPT code 372X4. We note as well that the intensity was markedly higher for CPT code 369X7 as compared to CPT code 372X4 when using the RUC-recommended work values, which did not make sense since CPT code 369X7 would typically be a clinically less intense procedure. Using the intraservice time ratio results in the two codes having exactly the same intensity. As a result, we are therefore proposing a work RVU of 2.48 for CPT code 369X7, based on this intraservice time ratio with the RUC-recommended work RVU of CPT code 372X4.

For CPT code 369X8, we disagree with the RUC-recommended work RVU of 4.25, and we are instead proposing a work RVU of 3.73. We do not consider the RUC work value of 4.25 to be accurate for CPT code 369X8, as this was higher than our proposed work value for CPT code 369X2 (4.24), and we do not believe that an add-on code should typically have a higher work value than a similar non-add-on code with the same intraservice time. We identified two appropriate crosswalks for valuing CPT code 369X8: CPT code 93462 (Left heart catheterization by transseptal puncture through intact septum or by transapical puncture) and CPT code 37222 (Revascularization, endovascular, open or percutaneous, iliac artery). Both of these codes share the same intraservice time as CPT code 369X8, and both of them also have the same work RVU of 3.73, which results in these codes also sharing the same intensity since they are all add-on codes. We are therefore proposing a work value of 3.73 for CPT code 369X8, based on a direct crosswalk to CPT codes 93462 and 37222.

Finally, we are proposing a work RVU of 3.48 for CPT code 369X9 instead of the RUC-recommended work RVU of 4.12. The RUC recommended value comes from a direct crosswalk from CPT code 38746 (Thoracic lymphadenectomy by thoracotomy). We compared the RUC-recommended work RVU for this procedure to other add-on codes with 30 minutes of intraservice time and found that the recommended work RVU of 4.12 would overestimate the overall intensity of this service relative to those with similar times. In reviewing the range of these codes, we believe that a more appropriate crosswalk is to CPT code 61797 (Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator)) at a work RVU of 3.48. We believe that this value is more accurate when compared to other add-on procedures with 30 minutes of intraservice time across the PFS. As a result, we are proposing a work RVU of 3.48 for CPT code 369X9 based on a direct crosswalk from CPT code 61797.

We are proposing to use the RUC-recommended direct PE inputs for these nine codes with several refinements. We are not proposing to include the recommended additional preservice clinical labor for CPT codes 369X4, 369X5, and 369X6. The preservice work description is identical for all six of the global 0-day codes in this family; there is no justification given in the RUC recommendations as to why the second three codes need additional clinical labor time beyond the minimal preservice clinical labor assigned to the first three codes. We do not believe that the additional staff time would be typical. Patient care already would have been coordinated ahead of time in the typical case, and the need for unscheduled dialysis or other unusual circumstances would be discussed prior to the day of the procedure. We are therefore proposing to refine the preservice clinical labor for CPT codes 369X4, 369X5, and 369X6 to match the preservice clinical labor of CPT codes 369X1, 369X2, and 369X3.

We are proposing to refine the L037D clinical labor for ''Prepare and position patient/monitor patient/set up IV'' from 5 minutes to 3 minutes for CPT codes 369X1–369X6. The RUC recommendation included a written justification for additional clinical labor time beyond the standard 2 minutes for this activity, stating that the extra time is needed to prepare the patient's arm for the procedure. We agree that extra time may be needed for this activity as compared to the default standard of 2 minutes; however, we are assigning 1 extra minute for preparing the patient's arm, resulting in a total of 3 minutes for this task. We do not believe that 3 extra minutes would be typically needed for arm positioning.

We are proposing to remove the ''kit, for percutaneous thrombolytic device (Trerotola)'' supply (SA015) from CPT codes 369X4, 369X5, and 369X6. We believe that this thrombolytic device kit and the ''catheter, thrombectomy-Fogarty'' (SD032) provide essentially the same supply, and the use of only one of them would be typical in these procedures. We believe that each of these supplies can be used individually for thrombectomy procedures. We are proposing to remove the SA015 supply and retain the SD032 supply, and we seek additional comment and information regarding the use of these two supplies.

We are also proposing to remove the recommended supply item ''covered stent (VIABAHN, Gore)'' (SD254) and replace it with the ''stent, vascular, deployment system, Cordis SMART'' (SA103) for CPT codes 369X3 and 369X6. The Cordis SMART vascular stent was previously used in the past for CPT code 37238, which is the deleted code for transcatheter placement of an intravascular stent that CPT codes 369X3 and 369X6 are replacing. We do not have a stated rationale as to the need for this supply substitution, and therefore, we do not believe it would be appropriate to replace the current items with a significantly higher-priced item without additional information.

We are also proposing to refine the quantity of the ''Hemostatic patch'' (SG095) from 2 to 1 for CPT codes 369X4, 369X5, and 369X6. This supply was not included in any of the deleted base codes out of which the new codes are being constructed, and while we agree that the use of a single hemostatic patch has become common clinical practice, we do not agree that CPT codes 369X4–369X6 would typically require a second patch. As a result, we are proposing to refine the SG095 supply quantity from 2 to 1 for CPT codes 369X4–369X6, which also matches the supply quantity for CPT codes 369X1–369X3.

Included in the RUC recommendation for the Dialysis Circuit family of codes were a series of invoices for a ''ChloraPrep applicator (26 ml)'' supply. We are soliciting comments regarding whether the Betadine solution has been replaced by a Chloraprep solution in the typical case for these procedures. We are also soliciting comments regarding whether the ''ChloraPrep applicator (26 ml)'' detailed on the submitted invoices is the same supply as the SH098 ''chlorhexidine 4.0% (Hibiclens)'' applicator currently in the direct PE database.

Finally, we are also interested in soliciting comments about the use of guidewires for these procedures. We are requesting feedback about which guidewires would be typically used for these procedures, and which guidewires are no longer clinically necessary.

(12) Open and Percutaneous Transluminal Angioplasty (CPT Codes 372X1, 372X2, 372X3, and 372X4)

In January 2015, a CPT/RUC workgroup identified the following CPT codes as being frequently reported together in various combinations: 35475 (Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel), 35476 (Transluminal balloon angioplasty,

percutaneous; venous), 36147 (Introduction of needle and/or catheter, arteriovenous shunt created for dialysis (graft/fistula); initial access with complete radiological evaluation of dialysis access, including fluoroscopy, image documentation and report), 36148 (Introduction of needle and/or catheter, arteriovenous shunt created for dialysis (graft/fistula); additional access for therapeutic intervention), 37236 (Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery), 37238 (Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein), 75791 (Angiography, arteriovenous shunt (*e.g.*, dialysis patient fistula/graft), complete evaluation of dialysis access, including fluoroscopy, image documentation and report (includes injections of contrast and all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava), radiological supervision and interpretation), 75962 (Transluminal balloon angioplasty, peripheral artery other than renal, or other visceral artery, iliac or lower extremity, radiological supervision and interpretation), and 75968 (Transluminal balloon angioplasty, each additional visceral artery, radiological supervision and interpretation). At the October 2015 CPT Editorial Panel meeting, the panel approved the creation of four new codes and deletion of 13 existing codes used to describe bundled percutaneous transluminal angioplasty services. The Open and Percutaneous Transluminal Angioplasty family of codes overlaps with the Dialysis Circuit family of codes (CPT codes 369X1–369X9), as they are both being constructed from the same set of frequently reported together codes. We reviewed these two families of codes concurrently to maintain relativity between these clinically similar procedures based upon the same collection of deleted codes. After consideration of these materials, we are proposing to accept the RUC-recommended work RVU for CPT codes 372X1, 372X2, 372X3, and 372X4.

For the clinical labor direct PE inputs, we are proposing to use the RUC-recommend inputs with several refinements. Our proposed inputs refine the recommended clinical labor time for ''Prepare and position patient/monitor patient/set up IV'' from 5 minutes to 3 minutes for CPT codes 372X1 and 372X3. The RUC recommendation included a written justification for additional clinical labor time beyond the standard 2 minutes for this activity, stating that the extra time was needed to move leads out of X-ray field, check that X-ray is not obstructed and that there is no risk of collision of X-ray equipment with patient. As we wrote for the same clinical labor activity in the Dialysis Circuit family, we agree that extra time may be needed for this activity as compared to the default standard of 2 minutes; however, we are assigning 1 extra minute for the additional positioning tasks, resulting in a total of 3 minutes for this task. We do not believe that 3 extra minutes would be typically needed for preparation of the X-ray. The equipment times for the angiography room (EL011) and the PACS workstation (ED050) have been refined to reflect this change in clinical labor.

We are proposing to remove the ''drape, sterile, femoral'' supply (SB009) and replace it with a ''drape, sterile, fenestrated 16in x 29in'' supply (SB011) for CPT codes 372X1 and 372X3. The two base codes out of which these new codes are being constructed, CPT codes 35471 and 35476, both made use of the SB011 fenestrated sterile drape supply, and there was no rationale provided for the switch to the SB009 femoral sterile drape in the two new codes. We are seeking comment on the use of sterile drapes for these procedures, and what rationale there is to support the use of the SB009 femoral sterile drape as typical for these new procedures.

(13) Percutaneous Biliary Procedures Bundling (CPT Codes 47531, 47532, 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540, 47541, 47542, 47543, and 47544)

This group of fourteen codes was reviewed by the RUC at the April 2015 meeting. We established interim final values for this group of codes during the CY 2016 PFS rulemaking cycle, and subsequently received updated RUC recommendations from the October 2015 meeting for the CY 2017 PFS rulemaking cycle. Our proposals for these codes incorporate both the updated RUC recommendations, as well as public comments received as part of the interim final status of these procedures.

We received several comments regarding the CMS refinements to the work values for this family of codes in the CY 2016 final rule with comment period. The relevance of many of these comments has been diminished by the new series of RUC recommendations for work values that we received as a result of the October 2015 meeting. Given that we are proposing the updated RUC-recommended work RVUs for CPT codes 47531, 47532, 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540, 47542, 47543, and 47544, we seek additional comments relative to these proposed values. We agree that the second round of physician surveys conducted for the October 2015 RUC meeting more accurately captured the work and time required to perform these procedures. The one exception is CPT code 47541; the survey times for this procedure were identical as conducted for the April and October 2015 RUC meetings, yet the RUC recommendation increased from a work RVU of 5.61 in April to a work RVU of 7.00 in October. Given that the time values for the procedure remained unchanged between the two surveys, we do not understand why the work RVU would have increased by nearly 1.50 in the intervening months. Since this code also has an identical intraservice time (60 minutes) and total time (121 minutes) as CPT code 47533, we do not agree that it should be valued at a substantially higher rate compared to a medically similar procedure within the same code family. We are therefore proposing to crosswalk the work value of CPT code 47541 to the work value of CPT code 47533, and we are proposing a work RVU of 5.63 for both procedures.

We also note that many of the codes in the Percutaneous Biliary Procedures family were previously included in Appendix G, and were valued under the assumption that moderate sedation was typically performed on the patient. As part of the initiative to pay separately for moderate sedation when it is performed, we are removing a portion of the work RVU and preservice work time from CPT codes 47532, 47533, 47534, 47535, 47536, 47538, 47539, 47540, and 47541. For example, we are proposing that CPT code 47541 undergoes a 0.25 reduction in its work RVU from 5.63 to 5.38, and a 10 minute reduction in its preservice work time from 33 minutes to 23 minutes, to reflect the work that will now be reported separately using the new moderate sedation codes. CPT codes 47542, 47533, and 47544 are also included in the moderate sedation initiative; however, as add-on codes, they are not subject to alterations in

their work RVUs or work times since the moderate sedation code with work RVUs and work time (991X2) will only be billed once for each base-code and not additionally with the add-on codes. These changes are reflected in Appendix B and the work time file posted to the Web; see section II.D for more details.

For the direct PE inputs, we are proposing to remove the L051A clinical labor for ''Sedate/apply anesthesia'' and the L037D for ''Assist Physician in Performing Procedure'' for CPT codes 47531 and 47537. As we wrote in last year's final rule with comment period (80 FR 71053), we believe that this clinical labor describes activities associated with moderate sedation, and moderate sedation is not typical for these procedures. We are also proposing to refine the L037D clinical labor for ''Clean room/equipment by physician staff'' from 6 minutes to 3 minutes for all of the codes in this family. Three minutes is the standard for this clinical labor activity, and we continue to maintain that the need for additional clinical labor time for this cleaning activity would not be typical for these procedures.

Comment: One commenter disagreed with our refinement to replace supply item ''catheter, balloon, PTA'' (SD152) with supply item ''catheter, balloon ureteral (Dowd)'' (SD150). The commenter stated that a Dowd catheter is designed and FDA approved for use in the prostatic urethra by retrograde placement through the penile urethra, and it is not designed for use in an antegrade ureteral dilation procedure. The commenter stated that this replacement is inappropriate. The updated RUC recommendations for this family of codes also restored the balloon PTA catheter.

Response: We are proposing again to replace the recommended supply item ''catheter, balloon, PTA'' (SD152) with supply item ''catheter, balloon ureteral (Dowd)'' (SD150). We believe that the use of this ureteral balloon catheter, which is specifically designed for catheter and image guidance procedures, would be more typical than the use of a PTA balloon catheter. While we recognize that the Dowd catheter is not FDA approved, it is our understanding that the PTA balloon catheter has also not been FDA approved for use in these procedures. We are uncertain if the commenter was requesting that we should no longer include catheters that lack FDA approval in the direct PE database; this would preclude the use of most of the catheters in our direct PE database. We welcome additional comment on the use of FDA approved catheters; in the meantime, we will continue our long-standing practice of using the catheters in the direct PE database without explicit regard to FDA approval in particular procedures.

We are also proposing to remove the recommended supply item ''stone basket'' (SD315) from CPT code 47543 and add it to CPT code 47544. Based on the code descriptors, we believe that the stone basket was intended to be included in CPT code 47544 and was erroneously listed under CPT code 47543. We are soliciting comments from the public to help clarify this issue.

We note again that many of the codes in the Percutaneous Biliary Procedures family were previously included in Appendix G, and as part of the initiative to pay separately for moderate sedation when performed, we are removing some of the recommended direct PE inputs related to moderate sedation from CPT codes 47532, 47533, 47534, 47535, 47536, 47538, 47539, 47540, and 47541. We are removing the L051A clinical labor time for ''Sedate/apply anesthesia'', ''Assist Physician in Performing Procedure (CS)'', and ''Monitor pt. following moderate sedation''. We are also removing the conscious sedation pack (SA044) supply, and some or all of the equipment time for the stretcher (EF018), the mobile instrument table (EF027), the 3-channel ECG (EQ011), and the IV infusion pump (EQ032). These changes are reflected in the public use files posted to the web; see section II.D for more details.

(14) Flexible Laryngoscopy (CPT Codes 31575, 31576, 31577, 31578, 317X1, 317X2, 317X3, and 31579)

After we identified CPT codes 31575 and 31579 as potentially misvalued in (80 FR 70912–70914) the RUC referred the entire flexible laryngoscopy family of codes back to CPT for revision and the addition of several codes representing new technology within this family of services. At the May 2015 CPT meeting, the Editorial Panel added three new codes to describe laryngoscopy with ablation or destruction of lesion and therapeutic injection. Based on the survey results, the time resources involved in furnishing the procedures described by this code family experienced a significant reduction in the intraservice period, yet the recommended work RVUs were not similarly reduced. Therefore, in reviewing the recommended values for this family of codes we looked for a rationale for increased intensity and absent such rationale, propose to adjust the recommend work RVUs to account for significant changes in time.

For CPT code 31575, we disagree with the RUC-recommended work RVU of 1.00, and we are instead proposing a work RVU of 0.94. We looked at the total time ratio for CPT code 31575, which is decreasing from 28 minutes to 24 minutes, and applied this ratio of 0.86 times the current work RVU of 1.10 to derive our proposed work RVU of 0.94. We are supporting this value for CPT code 31575 through a crosswalk to CPT code 64405 (Injection, anesthetic agent; greater occipital nerve), which shares 5 minutes of intraservice time and also has a work RVU of 0.94.

We agree with the RUC that CPT code 31575 serves as the base code for the rest of the Flexible Laryngoscopy family. As a result, we are proposing to maintain the same RUC-recommended increments for the rest of the codes in this family, measuring the increments from CPT code 31575's refined work RVU of 0.94 instead of the RUC-recommended work RVU of 1.00. This means that each of the work RVUs for the codes in the rest of the family has decreased by 0.06 when compared to the RUC-recommended value. We are therefore proposing a work RVU of 1.89 for CPT code 31576, a work RVU of 2.19 for CPT code 31577, a work RVU of 2.43 for CPT code 31578, a work RVU of 3.01 for CPT code 317X1, a work RVU of 2.43 for CPT code 317X2, a work RVU of 2.43 for CPT code 317X3, and a work RVU of 1.88 for CPT code 31579.

Amongst the direct PE inputs, we are proposing to refine the clinical labor time for ''Obtain vital signs'' for CPT codes 31577 and 31579 from 3 minutes to 2 minutes. We believe that this extra clinical labor time is duplicative, as these codes are typically performed with a same day E/M service. Each procedure is only allotted a maximum of 5 minutes for obtaining vital signs, and since 3 minutes are already included in the E/M code, we are proposing to reduce the time to 2 minutes for these services. Similarly, we are proposing to remove the 3 minutes of clinical labor time for ''Clean room/equipment by physician staff'' from CPT codes 31575, 31577, and 31579. These procedures are typically reported with a same day E/M service, making the clinical labor minutes for cleaning the room in these procedure codes duplicative of the time already included in the E/M codes.

For CPT code 317X1, we are proposing to remove the ''laser tip, diffuser fiber'' supply (SF030) and replace it with the ''laser tip, bare (single use)'' supply (SF029) already present in our direct PE database. We

believe that the invoice for SF030 submitted with the RUC recommendation is not current enough to establish a new price for this supply; as a result, we are substituting the SF029 supply for this input. We welcome the submission of new invoices to accurately price the diffuser fiber with laser tip.

We are also proposing to make significant changes to the prices of several of the supplies and equipment related to Flexible Laryngoscopy, as well as to the prices of scopes more broadly. We are proposing to set the price of the disposable biopsy forceps supply (SD318) at $26.84, based on the submission of an invoice with a price of $536.81 for a unit size of 20. In our search for additional information regarding scope inputs, we obtained a quote from a vendor listing the current price for several equipment items related to the use of scopes. Since we believe that the prices in vendor quotes would typically be equal to or higher than prices actually paid by practitioners, we are updating the prices in our direct PE database to reflect this new information. As part of this process, we are proposing to increase the price of the ''light source, xenon'' (EQ167) from $6,723.33 to $7,000 to reflect current pricing information. We are also proposing to adjust the price of the ''fiberscope, flexible, rhinolaryngoscopy'' (ES020) from $6,301.93 to $4,250.00.

In accordance with the wider proposal that we are making involving the use of scope equipment, we are proposing to separate the scopes used in these procedures from the scope video systems. In the course of researching different kinds of scopes, we obtained vendor pricing for two different types of scopes used in these procedures. We are proposing to price the ''rhinolaryngoscope, flexible, video, non-channeled'' (ES063) at $8,000 and the ''rhinolaryngoscope, flexible, video, channeled'' (ES064) at $9,000 in accordance with our vendor quotes. We are proposing to use the non-channeled scope for CPT codes 31575, 31579, and 317X3 and the channeled scope for CPT codes 31576, 31577, 31578, 317X1, and 317X2 in accordance with the RUC-recommended video systems that stipulated channeled versus non-channeled scope procedures.

We believe that the ''Video-flexible laryngoscope system'' listed in the recommendations is not a new form of equipment, but rather constitutes a version of the existing ''video system, endoscopy'' equipment (ES031). We are not adding a new equipment item to our direct PE database; instead, we are proposing to use the submitted invoices to update the price of the ES031 endoscopy video system. As the equipment code for ES031 indicates, we are proposing to define the endoscopy video system as containing a processor, digital capture, monitor, printer, and cart. We are proposing to price ES031 at $15,045.00; this reflects a price of $2,000.00 for the monitor, $9,000.00 for the processor, $1,750.00 for the cart, and $2,295.00 for the printer. These prices were obtained from our vendor invoice, with the exception of the printer, which is a crosswalk to the ''video printer, color (Sony medical grade)'' equipment (ED036).

We do not agree that there is a need for multiple different video systems for this collection of Flexible Laryngoscopy codes based on our understanding of the clinical differences among the codes. In keeping with this understanding, we are proposing to use the same existing ''video system, endoscopy'' equipment (ES031) for the remaining codes in the family that included RUC recommendations for new equipment items named ''Video-flexible channeled laryngoscope system'' and ''Video-flexible laryngoscope stroboscopy system.'' For CPT codes 31576, 31577, 31578, 317X1, and 317X2, we are proposing to replace the Video-flexible channeled laryngoscope system with the existing endoscopy video system (ES031) along with a channeled flexible video rhinolaryngoscope (ES064). For CPT code 31579, we are proposing to rename the RUC-recommended ''Video-flexible laryngoscope stroboscopy system'' to the shortened ''stroboscopy system'' (ES065) and assign it a price of $19,100.00. This reflects the price of the StrobeLED Stroboscopy system included on the submitted invoice. We are proposing to treat the stroboscopy system as a scope accessory, which will be included along with the ''video system, endoscopy'' equipment (ES031) and the ''rhinolaryngoscope, flexible, video, non-channeled'' (ES063) for CPT code 31579. When the price of the scope, the scope video system, and the stroboscopy system are summed together, the total proposed equipment price is $42,145.00.

We are proposing to refine the recommended equipment times for several equipment items to conform to changes in clinical labor time. These are: The fiberoptic headlight (EQ170), the suction and pressure cabinet (EQ234), the reclining exam chair with headrest (EF008), and the basic instrument pack (EQ137). We are proposing to use the standard equipment time formula for scope accessories for the endoscopy video system (ES031) and the stroboscopy scope accessory system (ES065). We are also proposing to refine the equipment time for the channeled and non-channeled flexible video rhinolaryngoscopes to use the standard equipment time formula for scopes. For this latter pair of two new equipment items, this proposal results in small increases to their respective equipment times.

(15) Laryngoplasty (CPT Codes 31580, 31584, 31587, and 315X1–315X6)

CPT code 31588 (Laryngoplasty, not otherwise specified (*e.g.*, for burns, reconstruction after partial laryngectomy) was identified as potentially misvalued based on the RUC's 90-Day Global Post-Operative Visits screen. When this code family was reviewed by the RUC, it was determined that some codes in the family required revision to reflect the typical patient before a survey could be conducted and the code family was referred to the CPT Editorial Panel for revision. At the October 2015 CPT Editorial Panel meeting, the CPT Editorial Panel approved the creation of six new codes, revision of three codes, and deletion of three codes. For CPT codes 31580, 31587, 315X1, 315X2, 315X3, 315X4, and 315X6, CMS is proposing the RUC-recommended work RVUs.

For CPT code 31584, the RUC recommended a work RVU of 20.00. We believe that the 25th percentile of the survey, which is a work RVU of 17.58, better represents the time and intensity involved with furnishing this service based on a comparison with and assessment of the overall intensity of other codes with similar instraservice and total time. This value is also supported by a crosswalk code of CPT code 42844 (Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; closure with local flap (*e.g.*, tongue, buccal)), which has identical intraservice time and identical total time. Therefore, we are proposing a work value of 17.58 RVUs for CPT code 31584.

For CPT code 315X5, the RUC recommended a work value of 15.60 RVUs. We believe that the 25th percentile of the survey, which is a work RVU of 13.56, better represents the time and intensity involved with furnishing this service based on a comparison of the overall intensity of other codes with similar instraservice and total time. The 25th percentile of the survey is additionally bracketed by two crosswalk codes that we estimate have slightly lower and slighter higher overall intensities, CPT code 36819

(Arteriovenous anastomosis, open; by upper arm basilic vein transposition), which has a work RVU of 13.29, and CPT code 49654 (Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); reducible), which has a work RVU of 13.76; both of these codes have identical intraservice time and similar total time. Therefore, we are proposing a work RVU of 13.56 for CPT code 315X5.

Additionally, the RUC forwarded invoices provided by a medical specialty society for the video-flexible laryngoscope system used in these services. As discussed in section II.A of this proposed rule, we have proposed changes to the items included in equipment item ES031 (video system, endoscopy). Consistent with those proposed changes, we are proposing to add a Nasolaryngoscope, non-channeled, to the list of equipment items used for CPT codes 31580, 31584, 31587, and 315X1–315X6, along with the modified equipment item ES031.

(16) Mechanochemical Vein Ablation (MOCA) (CPT Codes 364X1 and 364X2)

At the October 2015 CPT meeting, the CPT Editorial Panel established two Category I codes for reporting venous mechanochemical ablation, CPT codes 364X1 and 364X2. We are proposing the RUC-recommended work RVU of 3.50 for CPT code 364X1. For CPT code 364X2 we believe that the RUC-recommended work RVU of 2.25 does not accurately reflect the typical work involved in furnishing this procedure. The specialty society survey recommended that this add-on code has half the work of the base code, CPT code 364X1. This value is supported by the ratio between work and time in the key reference service, CPT code 36476 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)). Therefore, we are proposing a work RVU of 1.75 for CPT code 364X2.

The RUC-recommended direct practice expense inputs for CPT codes 364X1 and 364X2 included inputs for an ultrasound room (EL015). Based on the clinical nature of these procedures, we do not believe that an ultrasound room would typically be used to furnish these procedures. We are proposing to remove inputs for the ultrasound room and put in a portable ultrasound (EQ250), power table (EF031), and light (EF014). The RUC also recommended that the ultrasound machine be allocated clinical staff time based on the PACS workstation formula. We do not believe that an ultrasound machine would be used like a PACS workstation, as images are generated and reviewed in real time. Therefore, we are proposing to remove all inputs associated with the PACS workstation.

(17) Esophageal Sphincter Augmentation (CPT Codes 432X1 and 432X2)

In October 2015, the CPT Editorial Panel created two new codes to describe laparoscopic implantation and removal of a magnetic bead sphincter augmentation device used for treatment of gastroesophageal reflux disease (GERD). The RUC noted that the specialty societies conducted a targeted survey of the 145 physicians who have been trained to furnish these services and who are the only physicians who have performed these procedures. They noted that only 18 non-conflicted survey responses were received despite efforts to follow up and that nine physicians had no experience in the past 12 months with the procedure. The RUC agreed with the specialty society that the expertise of those responding was sufficient to consider the survey, however, neither entity used the survey results as the as the primary basis for their recommended value.

For CPT code 432X1, the RUC recommended a work RVU of 10.13. We compared this code to CPT code 43180 (Esophagoscopy, rigid, transoral with diverticulectomy of hypopharynx or cervical esophagus (*e.g.,* Zenker's diverticulum), with cricopharyngeal myotomy, includes use of telescope or operating microscope and repair, when performed), which has a work RVU of 9.03 and has identical intraservice time and similar total time. We believe the overall intensity of these procedures is similar, therefore, we are proposing a work RVU of 9.03 for CPT code 432X1.

For CPT code 432X2, the RUC recommended a work RVU of 10.47. To value this code, we used the increment between the RUC-recommended work RVU for this code and CPT code 432X1 (0.34 RVUs) to develop our proposed work RVU of 9.37 for CPT code 432X2.

(18) Electromyography Studies (CPT Code 51784)

We identified CPT code 51784 as potentially misvalued through a screen of high expenditure by specialty. This family also includes CPT code 51785 (Needle electromyography studies (EMG) of anal or urethral sphincter, any technique) but was not included in this survey. Both services have 0-day global periods. The RUC recommended a work RVU of 0.75 for CPT code 51784. We believe that this service is more accurately valued without a global period, since that is more consistent with other diagnostic services, and specifically, with all the other diagnostic electromyography services. We are proposing a change to the global period from 0-day to no global period, and we are proposing the RUC-recommended work RVU of 0.75 for CY 2017. We are also proposing to change the global period for CPT code 51785 from 0-day to no global period, to be consistent with 51784. Additionally, we are proposing to add CPT code 51785 to the list of potentially misvalued codes to update the value of the service considering the change in global period, and to maintain consistency with 51784.

(19) Cystourethroscopy (CPT Code 52000)

In the CY 2016 PFS final rule with comment period, CMS identified CPT code 52000 through the screen for high expenditure services by specialty screen. The RUC-recommended work RVUs of 1.75 for CPT code 52000 is larger than the work RVUs for all 0-day global codes with 10 minutes of intraservice time and we do not believe that the overall intensity of this service is greater than all of the other codes. Instead, we believe the overall work compares for this code compares favorably to CPT code 58100 (Endometrial sampling (biopsy) with or without endocervical sampling (biopsy), without cervical dilation, any method (separate procedure)), which has a work RVU of 1.53, and has identical intraservice time and similar total time. Therefore, we are using a direct crosswalk to CPT code 58100 and are proposing a work RVU of 1.53 for CPT code 52000.

(20) Biopsy of Prostate (CPT Code 55700)

In the CY 2016 PFS final rule with comment period, CMS identified CPT code 55700 as potentially misvalued based on the high expenditure by specialty screen.

The RUC subsequently reviewed this code for physician work and practice expense and recommended a work RVU of 2.50 based on the 25th percentile of the survey. We believe the RUC-recommended work RVU overestimates the work involved in furnishing this service given the reduction in total service time; specifically, the reduction in preservice and postservice times. The RUC recommendation also appears overvalued when compared to similar 0-day global services with 15 minutes of intraservice time and comparable total

times. To develop a proposed work RVU, we crosswalked the work RVUs for this code from CPT code 69801 (Labyrinthotomy, with perfusion of vestibuloactive drug(s), transcanal), noting similar levels of intensity, similar total times, and identical intraservice times. Therefore, we are proposing a work RVU of 2.06 for CPT code 55700.

As part of the recommended direct PE inputs for CPT code 55700, the RUC recommended inclusion of a new equipment item, Biopsy Guide, but we have not received any invoices to price this item. Given our longstanding difficulties in acquiring accurate pricing information for equipment items, we are seeking invoices and public comment for pricing this equipment prior to adding this new equipment item code.

(21) Hysteroscopy (CPT Codes 58555–58563)

In the CY 2016 PFS proposed rule, we proposed CPT code 58558 as a potentially misvalued code based on the screen for high expenditure by specialty screen. This code was reviewed at the January 2016 RUC meeting and CPT codes 58559–58563 were included in the review as part of the family.

For CPT code 58555, the RUC recommended a work RVU of 3.07. We believe that the 25th percentile of the survey, a work RVU of 2.65, more accurately reflects the resources involved in furnishing this service. This value is bracketed by two crosswalk codes, CPT code 43191 (Esophagoscopy, rigid, transoral; diagnostic, including collection of specimen(s) by brushing or washing when performed (separate procedure)), which has a work RVU of 2.49, and CPT code 31295 (Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (*e.g.*, balloon dilation), transnasal or via canine fossa), which has a work RVU of 2.70. Compared with CPT code 58555, CPT codes 43191 and 31295 have identical intraservice times and similar total times. Therefore, we are proposing a work RVU of 2.65 for CPT code 58555.

For CPT code 58558, the RUC recommended a work RVU of 4.37. However, we believe that a direct crosswalk from CPT code 36221 (Non-selective catheter placement, thoracic aorta, with angiography of the extracranial carotid, vertebral, and/or intracranial vessels, unilateral or bilateral, and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed), which has a work RVU of 4.17, and which has identical intraservice time and very similar total time, more accurately reflects the time and intensity of furnishing this service. This value is additionally supported by using an increment between this code and the base code for this family, CPT code 58555. The increment between the RUC-recommended values for these two codes is 1.3. That increment added to the proposed work RVU of 2.65 for the base code, CPT code 58555, results in a work RVU of 3.95. Therefore, we are proposing a work value of 4.17 RVUs for CPT code 58558.

For CPT code 58559, the RUC recommended a work RVU of 5.54. However, we believe that a direct crosswalk of the work RVUs for CPT code 52315 (Cystourethroscopy, with removal of foreign body, calculus, or ureteral stent from urethra or bladder (separate procedure); complicated), which has a work RVU of 5.20 and which has a similar (slightly higher) intraservice time and similar total time as compared with CPT code 58589 more accurately reflects the time and intensity of furnishing this service. This value is additionally supported by using an increment between CPT code 58559 and the base code for this family, CPT code 58555. The increment between the RUC recommended values for the two codes is 2.47. That increment added to the proposed value for the base code, CPT code 58555 (2.65), results in a work RVU of 5.12. Therefore, we are proposing a work RVU of 5.20 for CPT code 58559.

For CPT code 58560, the RUC recommended a work RVU of 6.15. However, we believe that a direct crosswalk of the work RVUs for CPT code 52351 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy; diagnostic), which has a work RVU of 5.75 and which has more intraservice time and very similar total time, more accurately reflects the time and intensity of furnishing this service. This value is additionally supported by using an increment between CPT code 58560 and the base code for this family, CPT code 58555. The increment between the RUC recommended values for the two codes is 3.08. That increment added to the proposed value for the base code, CPT code 58555 (2.65), results in a work RVU of 5.73. Therefore, we are proposing a work RVU of 5.75 for CPT code 58560.

For CPT code 58561, the RUC recommended a work RVU of 7.00. However, we believe that a direct crosswalk of the work RVUs for CPT code 35475 (Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel), which has a work RVU of 6.60 and which has similar intraservice and total times, more accurately reflects the time and intensity of furnishing this service. This value is additionally supported by using an increment between CPT code 58561 and the base code for this family, CPT code 58555. The increment between the RUC recommended values for the two codes is 3.93. That increment added to the proposed value for the base code, CPT code 58555 (2.65), results in a work RVU of 6.58. Therefore, we are proposing a work RVU of 6.60 for CPT code 58561.

For CPT code 58562, the RUC recommended a work RVU of 4.17. However, we believe that a direct crosswalk of the work RVUs for CPT code 15277 (Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children), which has a work RVU of 4.00 and which has identical intraservice time and similar total time, more accurately reflects the time and intensity of furnishing this service. The RUC also used this code as one of its supporting codes for its recommendation. This value is additionally supported by using an increment between CPT code 58562 and the base code for this family, CPT code 58555. The increment between the RUC recommended values for the two codes is 1.10. That increment added to the proposed value for the base code, CPT code 58555 (2.65), results in a work RVU of 3.75. Therefore, we are proposing a work RVU of 4.00 for CPT code 58562.

For CPT code 58563, the RUC recommended a work RVU of 4.62. However, we believe that a direct crosswalk of the work RVUs for CPT code 33962 (Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), open, 6 years and older (includes fluoroscopic guidance, when performed)), which has a work RVU of 4.47 and which has identical intraservice time and similar total time, more accurately reflects the resources involved in furnishing this service. This value is additionally supported by using an increment between CPT code 58563 and the base code for this family, CPT code 58555. The increment between the RUC recommended values for the two codes is 1.55. That increment added to the proposed value for the base code, CPT code 58555 (2.65), results in a work RVU of 4.20. We note that CPT code 58563 has the same instraservice time and the same total time as CPT code 58558; however, we agree that the

intensity would be slightly higher for this service. Therefore, we are proposing a work RVU of 4.47 for CPT code 58562.

The RUC submitted invoices for two new equipment items used in furnishing CPT code 58558, the Hysteroscopic Fluid Management System and the Hysteroscopic Resection System. We are proposing to use these invoice prices for the Hysteroscopic Fluid Management System, which totaled $14,698.38. The Hysteroscopic Resection System included the price of the hysteroscope as well as other items necessary for tissue removal. However, we generally price endoscopes separately and not as a part of a system. In order to maintain consistency, we are proposing not to include the hysteroscope from the Resection System. Instead, we are proposing to update the equipment item ''endoscope, rigid, hysteroscopy'' (ES009) with the invoice price, $6,207.50. We are not proposing to include the sterilization tray from the Hysteroscopic Resection System because we believe this tray has generally been characterized as an indirect expense. For the Hysteroscopic Resection System, we are proposing to include the Hysteroscopic tissue remover ($18,375), the sheath ($1,097.25), and the calibration device ($300), and creating a new equipment item code, priced at $19,857.50 in the proposed direct PE input database. We did not propose to include the calibration device since the submitted price was not documented with a paid invoice.

(22) Epidural Injections (CPT Codes 623X5, 623X6, 623X7, 623X8, 623X9, 62X10, 62X11, and 62X12)

We are proposing the RUC-recommended work RVU for all eight of the codes in this family.

We are proposing to remove the 10–12ml syringes (SC051) and the RK epidural needle (SC038) from all eight of the codes in this family. These supplies are duplicative, as they are included in the epidural tray (SA064). As an alternative, we could remove the epidural tray and replace it with the individual supply components used in each procedure; we are seeking public comment on either the inclusion of the epidural tray or its individual components for this family of codes.

(23) Endoscopic Decompression of Spinal Cord (CPT code 630X1)

For CY 2016, the CPT Editorial Panel created CPT code 630X1 to describe the endoscopic decompression of neural elements. The RUC recommended a work RVU of 10.47 based on a crosswalk to CPT code 47562 (Laparoscopy, surgical; cholecystectomy) with a higher intraservice time than reflected in the survey data. Since we believe CPT codes 630X1 and 47562 are similar in intensity, we believe using the same work RVU as the crosswalk code overestimates the work involved in furnishing CPT code 630X1. Reference CPT code 49507 (Repair initial inguinal hernia, age 5 years or older; incarcerated or strangulated) has a work RVU of 9.09 and has similar intensity and an identical intraservice time compared to CPT code 630X1. Therefore, we are proposing a work RVU of 9.09 for CPT code 630X1.

(24) Retinal Detachment Repair (CPT Codes 67101 and 67105)

For CY 2015, the CPT Editorial Panel made several changes to CPT codes 67101 and 67105. These changes include revising the code descriptors to exclude ''diathermy'' and ''with or without drainage of subretinal fluid'' and removing the reference to ''1 or more sessions''. The recommended global period has also changed from 90 days to 10 days.

For CPT code 67101 we propose the RUC recommendation of 3.50 work RVUs, which was based on the 25th percentile of the survey. For CPT code 67105, the RUC recommended a work RVU of 3.84 based on the 25th percentile of the survey. The RUC also stated that CPT code 67105 was a more intense procedure, and therefore, should have a higher work RVU than CPT code 67101. Currently, CPT code 67101 has a higher work RVU than CPT code 67105 and according to the surveys the intraservice and total times remain higher for CPT code 67101. It was not clearly explained and we do not understand why the RUC believes that CPT code 67105 is more work than CPT code 67101. Therefore we are not proposing the RUC-recommended work value of 3.50 for CPT code 67105. We do not find evidence that CPT code 67105 is more intense than CPT code 67101 and accordingly propose a new value for CPT code 67105. To value CPT code 67105 we used the RVU ratio between 67101 and 67105. We divided the current work RVU of CPT code 67105 (8.53), by the current work RVU of CPT code 67101 (8.80) and multiplied the quotient by the RUC-recommended work RVU for CPT code 67101 (3.50) to arrive at a product of 3.39 work RVUs.

Therefore, for CY 2017 we are proposing a work RVU of 3.39 for CPT code 67105.

(25) Abdominal Aortic Ultrasound Screening (CPT Code 767X1)

For CY 2017, the CPT Editorial Panel created a new code, CPT 767X1, to describe abdominal aortic ultrasound screening, currently described by HCPCS G-code G0389. The specialties that surveyed CPT code 767X1 for the RUC were vascular surgery and radiology, and the direct practice expense inputs recommended by the RUC included an ultrasound room. Based on an analysis of Medicare claims data, the dominant specialties furnishing the service are family practice and internal medicine. We believe that these specialties may more typically use a portable ultrasound device rather than an ultrasound room. Therefore, we are proposing to accept the RUC-recommended work value of 0.55, and the RUC-recommended PE inputs for this service, but we are seeking comment regarding whether or not it would be more accurate to substitute a portable ultrasound device or possibly a hand-held device for an ultrasound room for CPT code 767X1. We note that while the phase-in of significant reductions in RVUs ordinarily would not apply to new codes, we believe that it would be appropriate to consider this change from a G-code to a CPT code to be fundamentally similar to an editorial coding change since the service is not described differently, and therefore, we propose to apply the phase-in to this service by comparing the previous value of the G-code to the value for the new CPT code.

(26) Fluoroscopic Guidance (CPT Codes 77001, 77002, and 77003)

In the CY 2015 PFS final rule with comment period, CMS indicated that while CPT codes 77002 and 77003 had been previously classified as stand-alone codes without global periods, we believe their vignettes and CPT Manual parentheticals are consistent with an add-on code as has been established for CPT code 77001. Therefore, the global periods for CPT codes 77002 and 77003 now reflect an add-on code global period with modifications to the vignettes and parentheticals.

For CPT code 77001, we are proposing the RUC-recommended work RVU of 0.38. The RUC-recommended work RVUs for CPT codes 77002 and 77003 do not appear to account for the significant decrease in total times for these codes relative to the current total times. We note that these three codes describe remarkably similar services and have identical intraservice and total times. Based on the identical times and

notable similarity for all three of these codes, we are proposing a work RVU of 0.38 for all three codes.

(27) Radiation Treatment Devices (CPT Codes 77332, 77333, and 77334)

We identified CPT codes 77332, 77333, and 77334 through the high expenditures by specialty screen. These services represent an incremental increase of complexity from the simple to the intermediate to the complex in design of radiation treatment devices. The RUC recommended no change from the current work RVUs for these codes, which are currently 0.54 for CPT code 77332, 0.84 for CPT code 77333 and 1.24 for CPT code 77334. We believe the recommended work RVUs overstate the work involved in furnishing these services, as they do not sufficiently reflect the degree to which the RUC concurrently recommended a decrease in intraservice or total time. For CPT code 77332, we believe the RUC recommendation to maintain its current value despite a 34 percent decrease in total time appears to ignore the change in time. Therefore, we are proposing a value for this code based on a crosswalk from the value from CPT code 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)), due to its identical intraservice time, similar total time, and similar level of intensity. We are therefore proposing a work RVU of 0.45 for CPT code 77332. We are further supporting this valuation with HCPAC 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), which has similar physician time and intensity measurements and a work RVU of 0.45. As these codes are designed to reflect an incremental increase in work value from simple, to intermediate, and complex device designs, we used an incremental difference methodology to value CPT codes 77333 and 77334. We are proposing a work RVU of 0.75 for CPT code 77333, maintaining its recommended increment from CPT code 77332, For CPT code 77334, we are proposing a work RVU of 1.15 which maintains its increment from CPT code 77332.

(28) Special Radiation Treatment (CPT Code 77470)

We identified CPT code 77470 through the high expenditure charges by specialty. We are proposing the RUC-recommended work RVU of 2.03. However, we believe the description of service and vignette describe different and unrelated treatments being performed by the physician and clinical staff for a typical patient, and this presents a disparity between the work RVUs and PE RVUs. We seek public comment on information that would clarify this apparent disparity to help determine appropriate PE inputs. In addition, we seek comment to determine if creating two G-codes, one which describes the work portion of this service, and one which describes the PE portion, may be a potentially more accurate method of valuing and paying for the service or services described by this code.

(29) Flow Cytometry Interpretation (CPT Codes 88184, 88185, 88187, 88188, and 88189)

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), which do not have a work component, and a trio of codes (CPT codes 88187, 88188, and 88189) which do not have direct practice expense 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. The full family of codes was reviewed again at the January 2016 RUC meeting, and new recommendations were submitted to CMS as part of the CY 2017 PFS rulemaking cycle.

We are proposing the RUC-recommended work RVU of 0.74 for CPT code 88187, and the RUC-recommended work RVU of 1.70 for CPT code 88189. For CPT code 88188, we are proposing a work RVU of 1.20 instead of the RUC-recommended work RVU of 1.40. We arrived at this value by noticing that there were no comparable codes with no global period in the RUC database with intraservice time and total time of 30 minutes that had a work RVU higher than 1.20. The RUC-recommended work RVU of 1.40 would go beyond the current maximum value and establish a new high, which is not consistent with our estimation of the overall intensity of this service relative to the others. As a result, we believe it is more accurate to crosswalk CPT code 88188 to the work value of the code with the current highest value, which is CPT code 88120 (Cytopathology, in situ hybridization (for example, FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes) at a work RVU of 1.20. We believe that CPT code 88120 is crosswalk comparable code since it shares the identical intraservice time and total time of 30 minutes with CPT code 88188.

We also noted that the survey increment between CPT codes 88187 and 88188 at the RUC-recommended 25th percentile was 0.40 (between work RVUs of 1.00 and 1.40), and this increment of 0.40 when added to CPT code 88187's work RVU of 0.74 would arrive at a value of 1.14. In addition, the total time for CPT code 88188 decreases from 43 minutes to 30 minutes, which is a ratio of 0.70, and when this time ratio is multiplied by CPT code 88188's previous work value of 1.69, the result would be a new work RVU of 1.18. With this information in mind, we are proposing a work RVU of 1.20 for CPT code 88188 as a result of a direct crosswalk to CPT code 88120.

For CPT codes 88184 and 88185, which describe the technical component of flow cytometry, we are proposing to use the RUC-recommended inputs with a series of refinements. However, we believe that the coding for these two procedures may inhibit accurate valuation. CPT code 88184 describes the first marker for flow cytometry, while CPT code 88185 is an add-on code that describes each additional marker. We believe that it may be more accurate to have a single CPT code that describes the technical component of flow cytometry on a per patient case basis, as these two procedures are always performed together and it is difficult to determine the clinical labor, supplies, and equipment used in the typical case under the current coding structure. We are soliciting comments regarding the public interest in consolidating these two procedures into a single code used to describe the technical component of flow cytometry.

Absent such a change in coding, we are proposing to refine the clinical labor time for ''Instrument start-up, quality control functions, calibration, centrifugation, maintaining specimen tracking, logs and labeling'' from 15 minutes to 13 minutes for CPT code 88184. We maintain that 13 minutes for this activity, which is the current time value, would be typical for the procedure, as CPT code 88182 also uses 13 minutes for the identical clinical labor task. We are also proposing to refine the L054A clinical labor for

''Load specimen into flow cytometer, run specimen, monitor data acquisition, and data modeling, and unload flow cytometer'' from 10 minutes to 7 minutes using the same rationale, a comparison to CPT code 88182.

We are proposing to maintain the clinical labor for ''Print out histograms, assemble materials with paperwork to pathologists Review histograms and gating with pathologist'' for CPT code 88184 at 2 minutes, as opposed to the RUC-recommended 5 minutes. A clinical labor time of 2 minutes is standard for this activity; we disagree with the RUC rationale that reviewing histograms and gating with the pathologist in this procedure is not similar to other codes. We also note that the review of histograms with a pathologist is not even described by CPT code 88184, which again refers to the technical component of flow cytometry, not the professional component. We are also proposing to refine the L033A clinical labor time for ''Clean room/equipment following procedure'' from 2 minutes to 1 minute for CPT code 88184. We have established 1 minute in previous rulemaking (80 FR 70902) as the standard time for this clinical labor activity in the laboratory setting.

We are proposing to maintain our removal of the clinical labor time for ''Enter data into laboratory information system, multiparameter analyses and field data entry, complete quality assurance documentation'' for both CPT code 88182 and CPT code 88184. As we stated in last year's final rule with comment period (80 FR 70979), we have not recognized the laboratory information system as an equipment item that can be allocated to an individual service. We continue to believe that this is a form of indirect PE, and therefore, we do not recognize the laboratory information system as a direct PE input, and we not consider this task as typically performed by clinical labor on a per-service basis.

We are proposing to maintain the quantity of the ''lysing reagent'' supply (SL089) at 2 ml for CPT code 88185, as opposed to the RUC-recommended quantity of 3 ml. In our discussions with pathology specialists who perform flow cytometry, we were informed that the use of 50–55 ml of the lysing reagent would be typical for an entire patient case. The RUC recommendation similarly suggested a quantity of 46 ml or 48 ml per patient case. We were also told that the most typical number of markers used for flow cytometry is 24, consisting of 1 service of CPT code 88184 and 23 services of CPT code 88185. An investigation of our claims data confirmed this information, indicating that 24 markers is the most frequent per patient case for flow cytometry, and the use of more than 20 markers is typical. We believe that this data supports our refinement of the lysing reagent from a quantity of 3 ml to a quantity of 2 ml for CPT code 88185, which is also the current value for the procedure and the RUC-recommended value from the previous set of recommendations. For the typical case of 24 markers, our value would produce a total lysing reagent quantity of 51 ml (5 ml from the single service of CPT code 88184 and 46 ml from the 23 services of CPT code 88185), which matches with the amount required for a total per patient case. If we were to adopt the RUC recommendation, the total lysing reagent quantity would be 74 ml, which is well in excess of what we believe to be typical for these procedures.

We are also proposing to refine the quantity of the ''antibody, flow cytometry'' supply (SL186) from quantity 1.6 to quantity 1, which is also the current value for the supply and the RUC-recommended value from the previous set of recommendations. We do not agree that more than one antibody would be typically used for each marker. We are reaffirming the previous RUC recommendation, and maintaining the current quantity of 1 antibody for each marker.

We are not proposing the recommended additional time for the ''printer, dye sublimation (photo, color)'' equipment (ED031). We are proposing to maintain the equipment time at 2 minutes for CPT code 88184, and at 1 minute for CPT code 88185. As we stated in the CY 2016 PFS final rule with comment period (80 FR 70979), we are proposing to assign equipment time for the dye sublimation printer to match the clinical labor time for ''Print out histograms, assemble materials with paperwork to pathologists.'' We do not believe that it would be typical for the printer to be in use longer than it takes to accomplish this clinical labor task.

(30) Mammography—Computer Aided Detection Bundling (CPT Codes 770X1, 770X2 and 770X3)

Section 104 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) required us to create separate codes with higher payment amounts for digital mammography compared to film mammography, which was the technology considered to be typical at the time. In addition, the statute required additional payment to be made when computer-aided detection (CAD) was used.

In CY 2002, we began valuing digital mammography services using three G-codes, G0202, G0204, and G0206 to describe screening mammography, unilateral diagnostic mammography, and bilateral diagnostic mammography, respectively. CMS implemented the requirements of BIPA section 104(d)(1), which applied to tests furnished in 2001, by using the work RVUs of the parallel CPT codes, but establishing a fixed PE RVU rather than using PE RVUs developed under the standard PE methodology. The fixed amount of PE RVUs for these codes has generally remained unchanged since implementation of the G-codes that specifically described digital imaging.

Most mammography services under Medicare have since been billed with these G-codes when digital mammography was used, and with CPT codes 77055, 77056, and 77057 when film mammography was used. The use of CAD has been reported with CPT codes 77051 and 77052. For CY 2017, the CPT Editorial Panel deleted CPT codes 77051, 77052, 77055, 77056, 77057 and created three new CPT codes, 770X1, 770X2, and 770X3, to describe mammography services bundled with CAD. For CY 2017, the RUC recommended a work RVU of 0.81 for CPT code 770X1, a work RVU of 1.00 for CPT code 770X2, and a work RVU of 0.76 for CPT code 770X3, as well as new PE inputs for use in developing resource-based PE RVUs based on our standard methodologies. The RUC has recommended these inputs and only one medical specialty society has provided us with a set of single invoices to price the equipment used in furnishing these services.

We have reviewed these coding changes and recommended changes to valuation for CY 2017. The revised CPT coding mitigates the need for both separate G-codes and the CAD add-on codes. Based upon these coding changes and the recommended input values, overall Medicare payment for mammography services would be drastically reduced. This is especially the case for the technical component of these services, which could possibly be reduced up to 50 percent relative to the PE RVUs currently used for payment for these services.

Based on our initial review of the recommended inputs for the new codes, we believe that these changes would likely result in values more closely related to the relative resources involved in furnishing these services. However, we recognize that these services, particularly the preventive

screenings, are of particular importance to the Medicare program and the health of the Medicare beneficiaries. We are concerned that making drastic changes in coding and payment for these services could be disruptive in ways that could affect beneficiary access to necessary services. We also recognize that unlike almost any other high-volume PFS service, the RVUs used for payment for many years have not been developed through the generally applicable PFS methodologies, and instead reflect the statutory directive under section 104 of the BIPA. Similarly, we recognize that the changes in both coding and valuation are significant changes for those who provide these services. Therefore, instead of proposing to simultaneously adopt the revised CPT coding and drastic reductions in overall payment rates, we believe it is advisable to adopt the new coding, including the elimination of separate billing for CAD, for CY 2017 without proposing immediate implementation of the recommended resource inputs. We anticipate that we will consider the recommended inputs, including the pricing of the required equipment, as carefully as possible prior to proposing revised PE values through subsequent rulemaking.

Therefore, for CPT codes 770X1, 770X2, and 770X3, we are proposing to accept the RUC-recommended work RVUs, but to crosswalk the PE RVUs for the technical component of the current corresponding G-codes, as we seek further pricing information for these equipment items.

In addition to seeking comment on this proposal, we are also seeking comment on rates for these services in the commercial market to help us understand the potential impacts of any future proposed revisions to PFS payment rates.

Finally, we note that by adopting the new coding for CY 2017, any subsequent significant reduction in RVUs (greater than 20 percent) for the codes would be subject to the statutory phase-in under section 1848(c)(7).

To help us examine the resource inputs for these services, we are seeking public comment on the list of items recommended as equipment inputs for mammography services. We also invite commenters to provide any invoices that would help with future pricing of these items.

TABLE 17—RECOMMENDED EQUIPMENT ITEMS FOR MAMMOGRAPHY SERVICES

#	Item description	Quantity	Purpose
1	2D Selenia Dimensions Mammography System.	1	Mammography unit and in-room console itself.
2	Mammo Accreditation Phantom	1	Required for MQSA. The phantom is currently valued into the existing mammography room.
3	Phantom Case	1	Protects expensive required phantom from damage.
4	Paddle Storage Rack	3	It requires 3 racks to hold and prevent damage to all of the paddles that are part of the typical standard mammography system.
5	Needle Localization Kit	1	Needed for a full functioning mammography room. Allows for the performance of needle localizations. Input is not separately in the PE for the mammography guided procedure codes, 19281–19282, as a fully functioning mammography room is needed for those procedures.
6	Advanced Workflow Manager System.	1	Workflow system connecting mammography room and workstations.
7	Cenova 2D Tower System	1	CAD server, and also used for post-processing.
8	Image Checker CAD (9.4) License for One FFDM.	1	License required for using CAD. This is a one-time fee.
9	Film Digitizing System	1	Digitizes analog films to digital for comparison purposes.
10	Mammography Chair	1	A special chair needed for patients who cannot stand to safely have their mammogram performed.
11	Laser Imager Printer	1	Prints high resolution copies of the mammograms to send to surgeons and oncologists, and to use in the OR.
12	Barcode Scanner	1	Allows selection of individual patient file for interpretation.
13	MRS V7 SQL Reporting System	1	MQSA requires that the facility develop and maintain a database that tracks recall rates from screening, true and false positive and true and false negative rates, sensitivity, specificity, and cancer detection rate. A reporting system is required to build the required database and produce the federally required quality audit. Components below needed for the reporting system. The reporting system is currently valued into the existing mammography room.
14	Worksheet Printing Module	1	Database reports are required for federal tracking purposes. This is used to generate reports for MQSA.
15	Site License	1	License for site to use the reporting system. This is a one-time fee.
16	Additional Concurrent User License	3	Licenses for radiologists to use the reporting system. A minimum of three additional licenses is typical.
17	Densitometer	1	Required for MQSA.

We also received specialty society recommendations for a new Equipment Item, a physician PACS mammography workstation. We note that we discuss physician PACS workstation in section II.A of this rule. The items that comprise the physician PACS mammography workstation are listed in Table 18. We are requesting public comment as to the appropriateness of this list and if some items are indirect expenses or belong in other codes. We also invite commenters to provide any invoices that would help with future pricing of these items.

TABLE 18—PHYSICIAN PACS MAMMOGRAPHY WORKSTATION

PC Tower.
Monitors 5 MP (mammo) (x2).
3rd & 4th monitor (for speech recognition, etc.).
Admin Monitor (the extra working monitor).
Keyboard & Mouse.

TABLE 18—PHYSICIAN PACS MAMMOGRAPHY WORKSTATION—Continued

Powerscribe Microphone.
Software—SV APP SYNC 1.3.0.
Software—R2 Cenova.

We also note that for CY 2015, the CPT Editorial Panel created CPT codes 77061, 77062, and 77063 to describe unilateral, bilateral, and screening digital breast tomosynthesis, respectively. CPT code 77063 is an add-on code to 77057, the CPT code for screening mammography. To be consistent with our use of G codes for digital mammography, we did not implement two of these three CPT codes for Medicare purposes. We only adopted CPT code 77063 an add-on code to G0202. Instead of adopting stand-alone codes 77061 and 77062, we created a new code, G0279 Diagnostic digital breast tomosynthesis, as an add-on code to the diagnostic digital mammography codes G0204 and G0206 and assigned it values based on CPT code 77063. Pending revaluation of the mammography codes using direct PE inputs, we propose to maintain the current coding structure for digital breast tomosynthesis with the technical change that G0279 be reported with 770X1 or 770X2 as the replacement codes for G0204 and G0206.

(31) Microslide Consultation (CPT Codes 88321, 88323, and 88325)

CPT codes 88321, 88323, and 88325 were reviewed by the RUC in April 2014 for their direct PE inputs only, and the CMS refined values were included in the CY 2016 PFS final rule with comment period. The family of codes was reviewed again at the January 2016 RUC meeting for both work values and direct PE inputs, and new recommendations were submitted to CMS as part of the CY 2017 PFS rulemaking cycle.

In the CY 2016 PFS final rule with comment period, we finalized our proposal to remove many of the inputs for clinical labor, supplies, and equipment for CPT code 88325. The descriptor for this code did not state that slide preparation was taking place, and therefore, we refined the labor, supplies, and equipment inputs to align with the inputs recommended for CPT code 88321, which also does not include the preparation of slides. After further discussion with pathologists and consideration of comments received, we have been persuaded that slide preparation does take place in conjunction with the service described by CPT code 88325. In the RUC-recommended direct PE inputs from the January 2016 meeting, the labor, supplies, and equipment inputs related to slide preparation were added once again to CPT code 88325. We are proposing to accept these restorations related to slide preparation without refinement.

Regarding the clinical labor direct PE inputs, we are proposing to assign 1 minute of L037B clinical labor for ''Complete workload recording logs. Collate slides and paperwork. Deliver to pathologist'' for CPT codes 88323 and 88325. We are maintaining this at the current value for CPT code 88323, and adding this 1 minute to CPT code 88325 based on our new understanding that slide preparation is undertaken as part of the service described by this code. We are proposing to remove the clinical labor for ''Assemble and deliver slides with paperwork to pathologists'' from all three codes, as we believe this clinical labor is redundant with the labor assigned for ''Complete workload recording logs.'' We are similarly proposing to remove the clinical labor for ''Clean equipment while performing service'' from CPT codes 88323 and 88325, as we believe it to be redundant with the clinical labor assigned for ''Clean room/equipment following procedure.''

We are proposing to maintain the quantity of the ''stain, hematoxylin'' supply (SL135) at 16 ml for CPT codes 88323 and 88325, as opposed to the RUC-recommended quantity of 32 ml. The RUC recommendation stated that the hematoxylin supply does not include eosin and should not be redundant; the stains are not mixed together, but are instead sequential. The recommendation also made a comparison to the use of the hematoxylin supply quantity in CPT code 88305. However, we note that CPT code 88305 does not include 8 ml of eosin stain (SL201), but instead 8 gm of eosin solution (SL063), and these are not the same supply. Therefore we do not agree that a direct comparison of the supply quantities is the most accurate way to value these procedures. For CPT codes 88323 and 88325, we continue to note that the prior supply inputs for these procedures had quantity 2.4 of the eosin solution (SL063) and quantity 4.8 of the hematoxylin stain (SL135); in other words, a 1:2 ratio between the eosin and hematoxylin. We are proposing to maintain that 1:2 ratio with 8 ml of the eosin stain (SL201) and 16 ml of the hematoxylin stain (SL135).

We are also proposing to update the use of the eosin solution (sometimes listed as ''eosin y'') in our supply database. We believe that the eosin solution supply (SL063), which is measured in grams, reflects an older process of creating eosin stains by hand. This is in contrast to the eosin stain supply (SL201), which is measured in milliliters, and can be ordered in a state that is ready for staining immediately. We do not believe that the use of eosin solution would reflect typical lab practice today, with the readily availability for purchase of inexpensive eosin staining materials. We also note that in the CY 2016 PFS final rule with comment period, we removed 8 gm of the eosin solution and replaced it with 8 ml of the eosin stain, and this substitution was accepted without further change in the most recent set of RUC recommendations. As a result, we are proposing to update the price of the eosin stain supply from $0.044 per ml to $0.068 per ml to reflect the current cost of the supply. We are also proposing to use CPT codes 88323 and 88325 as a model, and replace the use of eosin solution with an equal quantity of eosin stain for the rest of the codes that make use of this supply. This applies to 15 other CPT codes: 88302 (Level II—Surgical pathology, gross and microscopic examination), 88304 (Level III—Surgical pathology, gross and microscopic examination), 88305 (Level IV—Surgical pathology, gross and microscopic examination), 88307 (Level V—Surgical pathology, gross and microscopic examination), 88309 (Level VI—Surgical pathology, gross and microscopic examination), 88364 (In situ hybridization (*e.g.*, FISH), per specimen; each additional single probe stain procedure), 88365 (In situ hybridization (*e.g.*, FISH), per specimen; initial single probe stain procedure), 88366 (In situ hybridization (*e.g.*, FISH), per specimen; each multiplex probe stain procedure), 88367 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; initial single probe stain procedure), 88368 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; initial single probe stain procedure), 88369 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each additional single probe stain procedure), 88373 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each additional single probe stain procedure), 88374 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative),

using computer-assisted technology, per specimen; each multiplex probe stain procedure), 88377 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each multiplex probe stain procedure), and G0416 (Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method).

(32) Closure of Paravalvular Leak (CPT Codes 935X1, 935X2, and 935X3)

The CPT Editorial Committee developed three new codes (two base codes and one add-on code) to describe paravalvular leak closure procedures that were previously reported using an unlisted code. The RUC recommended a work RVU of 17.97 for CPT code 935X2. We are proposing a work RVU of 14.50 for CPT code 935X2, a direct crosswalk from CPT code 37227. We believe that a direct crosswalk to CPT code 37227 accurately reflects the time and intensity described in CPT code 935X2 since CPT code 37227 also describes a transcatheter procedure with similar service times.

To maintain relativity among the codes in this family, we are proposing refinements to the recommended work RVUs for CPT code 935X1. The RUC noted the additional work associated with CPT code 935X1 compared to CPT code 935X2 was due to the addition of a transseptal puncture to access the mitral valve. The RUC identified a work RVU of 3.73 for a transseptal puncture. Therefore, for CPT code 935X1, we are proposing a work RVU of 18.23 arrived at by using our proposed work RVU for CPT code 935X2 (14.50) and adding the value of a transseptal puncture (3.73).

CPT code 935X3 is an add-on code used to report placement of additional occlusion devices for percutaneous transcatheter paravalvular leak closure, performed in conjunction with either an initial mitral or aortic paravalvular leak closure. The RUC recommended a work RVU of 8.00 for this code. We considered applying the relative increment between CPT codes 935X1 and 935X2, however, we believe that a direct crosswalk to CPT code 35572, with a work RVU of 6.81, more accurately reflects the time and intensity of furnishing the service. Therefore, for CPT code 935X3, we are proposing a work RVU of 6.81.

(33) Electroencephalogram (EEG) (CPT Codes 95812, 95813, and 95957)

In February 2016, the RUC submitted recommendations for work and direct PE inputs for CPT codes 95812, 95813, and 95957. We are proposing to use the RUC-recommended physician work and direct PE inputs for CPT code 95957 and to use the RUC-recommended work RVUs for CPT codes 95812 and 95813.

In the CY 2016 PFS final rule with comment period (80 FR 70886), we finalized direct PE input refinements for several clinical labor times for CPT codes 95812 and 95813. The RUC's February 2016 PE summary of recommendations indicated that the specialty society expert panel disagreed with CMS' refinements to clinical labor time for these two codes. The RUC recommended 62 minutes for clinical labor task ''perform procedure'' for CPT code 95812 and 96 minutes for the same clinical labor task for CPT code 95813, similar to the values recommended by the RUC in April 2014.

We are proposing to maintain the CMS-refined CY 2016 PE inputs for clinical labor task ''perform procedure'' for CPT codes 95812 (50 minutes) and 95813 (80 minutes). The PE summary of recommendations state that CPT code 95812 requires 50 minutes of clinical labor time for EEG recording, and CPT code 95813 requires 80 minutes of clinical labor time for the same clinical labor task.

(34) Parent, Caregiver-Focused Health Risk Assessment (CPT Code 961X0)

In October 2015, the CPT Editorial Panel created two new PE-only codes, 961X0 (Administration of patient-focused health risk assessment instrument (*e.g.*, health hazard appraisal) with scoring and documentation, per standardized instrument) and 961X1 (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). For CPT code 961X0, we are proposing the RUC-recommended direct PE inputs. For CPT code 961X1, the service is furnished to a patient who may not be a Medicare beneficiary and thus we do not believe would be eligible for Medicare payment. We are proposing to assign a procedure status of I (Not valid for Medicare purposes) for CPT code 961X1.

We note that we believe that this code describes a service that is frequently reasonable and necessary in the treatment of illness or injury, such as when there has been a change in health status. However, when the service described by CPT code 961X0 is explicitly included in another service being furnished, such as the Annual Wellness Visit (AWV), this code should not be billed separately, much like other codes that describe services included in codes with broader descriptions. We also note that this service should not be billed separately if furnished as a preventive service as it would describe a non-covered service. However, we are also seeking comment on whether this service may be better categorized as an add-on code and welcome stakeholder input regarding whether or not there are circumstances when this service might be furnished as a stand-alone service.

(35) Reflectance Confocal Microscopy (CPT Codes 96931, 96932, 96933, 96934, 96935, and 96936)

For CY 2015, the CPT Editorial panel established six new Category I codes to describe reflectance confocal microscopy (RCM) for imaging of skin. For CPT codes 96931 and 96933, the specialty society and the RUC agreed that the physician work required for both codes were identical, and therefore, should be valued the same. The RUC recommended a work RVU of 0.80 for CPT codes 96931 and 96933 based on the 25th percentile of the survey. Based on the similarity of the services being performed in CPT codes 96931 and 96933 and the identical intra-service times of 96931, 96933 and 88305, the key reference code from the survey, we believe a direct crosswalk from CPT code 88305 to 96931 and 96933 would more accurately reflect the work involved in furnishing the procedure. Therefore, for CY 2017 we are proposing a value of 0.75 RVUs for CPT codes 96931 and 96933. In addition, we are removing 3 minutes of preservice time in CPT codes 96931 and 96933 since it is not included in CPT code 88305 and as a result, we do not believe it is appropriate in CPT codes 96931 and 96933 either.

For CPT codes 96934 and 96936 the specialty society and the RUC agreed that the physician work required for both codes were identical, and therefore, should be valued the same. In its recommendation, the RUC stated that it believed the survey respondents somewhat overestimated the work for CPT code 96934 with the 25th percentile yielding a work RVU of 0.79. Consequently, the RUC reviewed the survey results from CPT code 96936 and agreed that the 25th percentile work RVU of 0.76 accurately accounted for the work involved for the service. Therefore, the RUC recommended a work RVU of 0.76 for CPT codes 96934 and 96936.

We believe that the incremental difference between the RUC-recommended values for the base and add-on codes accurately captures the difference in work between the code pairs. However, because we valued the base codes differently than the RUC, we are proposing values for the add-on

codes that maintain the RUC's 0.04 increment instead of the RUC-recommended values. Therefore we are proposing a work RVU of 0.71 for CPT codes 96934 and 96936.

We are also proposing to reduce the preservice clinical labor for Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by physician CPT codes 96934 and 93936 as this work is performed in the two CPT base codes 93931 and 93933. The service period clinical labor for ''Prepare and position patient/monitor patient/set up IV'' was reduced from 2 to 1 minute for CPT codes 93934 and 93936 since we believe that less positioning time is needed with subsequent lesions. The service period clinical labor for ''Other Clinical Activity—Review imaging with interpreting physician'' was refined to zero minutes for CPT codes 96933 and 96936 as these are interpretation and report only codes and not image acquisition.

(36) Evaluative Procedures for Physical Therapy and Occupational Therapy (CPT Codes 97X61, 97X62, 97X63, 97X64, 97X65, 97X66, 97X67, 97X68)

For CY 2017, the CPT Editorial Panel deleted four CPT codes (97001, 97002, 97003, and 97004) and created eight new CPT codes (97X61–97X68) to describe the evaluative procedures furnished by physical therapists and occupational therapists. There are three new codes, stratified by complexity, to replace a single code, 97001, for physical therapy (PT) evaluation, three new codes, also stratified by complexity, to replace a single code, 97003, for occupational therapy (OT) evaluation, and one new code each to replace the reevaluation codes for physical and occupational therapy—97002 and 97004. Table 19 includes the long descriptors and the required components of each of the eight new CPT codes for the PT and OT services.

The CPT Editorial Panel's creation of the new codes for PT and OT evaluative procedures grew out of a CPT workgroup that was originally convened in January 2012 when contemplating major revision of the Physical Medicine and Rehabilitation CPT section of codes in response to our nomination of therapy codes as potentially misvalued codes, including CPT code 97001 (and, as a result, all four codes in the family) in the CY 2012 PFS proposed rule.

In reviewing the eight new CPT codes for evaluative procedures, the HCPAC forwarded recommendations for work RVUs and direct PE inputs for each code. Currently, CPT codes 97001 and 97003 both have a work RVU of 1.20, and CPT codes 97002 and 97004 both have a work RVU of 0.60. These CPT codes have reflected the same work RVUs since CY 1998 when we accepted the HCPAC values during CY 1998 rulemaking.

i. Valuation of Evaluation Codes

The HCPAC submitted work RVU recommendations for each of the six new PT and OT evaluation codes. These recommendations are intended to be work neutral relative to the valuation for the previous single evaluation code for PT and OT, respectively. However, that assessment for each family of codes is dependent on the accuracy of the utilization forecast for the different complexity levels within the PT or OT family. As used in this section, work neutrality is distinct from the budget neutrality that is applied broadly in the PFS. Specifically, work neutrality is intended to reflect that despite changes in coding, the overall amount of work RVUs for a set of services is held constant from one year to the next. For example, if a service is reported using a single code with a work RVU of 2.0 for one year but that same service would be reported using two codes, one for ''simple'' and another for ''complex'' in the subsequent year valued at 1.0 and 3.0 respectively, work neutrality could only be attained if exactly half the services were reported using each of the two new codes. If more than half of the services were reported using the ''simple'' code, then there would be fewer overall work RVUs. If more than half of the services were reported using the ''complex'' code, then there would be more overall work RVUs. Therefore, work neutrality can only be assessed with an understanding of the relative frequency of how often particular codes will be reported.

The HCPAC recommended a work RVU of 0.75 for CPT code 97X61, a work RVU of 1.18 for CPT code 97X62, and a work RVU of 1.5 for CPT code 97X63. The PT specialty society projected that the moderate complexity evaluation code would be reported 50 percent of the time because it is the typical evaluation, and the CPT codes for the low and high complexity evaluations are each expected to be billed 25 percent of the time. The HCPAC-recommended work RVU of 1.18 for CPT code 97X62 represents the survey median with 30 minutes of intraservice time, 10 minutes of preservice time, and 15 minutes postservice time. The HCPAC notes this work value is appropriately ranked between levels 2 and 3 of the E/M office visit codes for new patients.

The HCPAC recommended a work RVU of 0.88 for CPT code 97X65, a work RVU of 1.20 for CPT code 97X66, and a work RVU of 1.70 for CPT code 97X67. For the OT codes, work neutrality would be achieved only with a projected utilization in which the low-complexity evaluation is billed 50 percent of the time; the moderate-complexity evaluation is billed 40 percent of the time, and the high-complexity evaluation only billed 10 percent of the time. For purposes of calculating work neutrality, the HCPAC recommended assuming that the low-complexity code will be most frequently reported even though the HCPAC-recommended work RVU of 1.20 and 45 minutes of intraservice time for moderate complexity code is identical to that of the current OT evaluation code. The HCPAC believes that the work RVU of 1.20 is appropriately ranked between 99202 and 99203, levels 2 and 3 for E/M office visits for new outpatients.

ii. Valuation of Evaluation Codes and Discussion of PAMA

In our review of the HCPAC recommendations, we noted the work neutrality and the inherent reliance on the utilization assumptions. We considered the three complexity levels for the PT evaluations and the three complexity levels for the OT evaluations; and we also considered the evaluation services described by the codes as a whole. The varying work RVUs and the dependence on utilization for each complexity level to ensure work neutrality in the PT and OT code families make it difficult for us evaluate the HCPAC's recommended values or to predict with a high degree of certainty whether physical and occupational therapists will actually bill for these services at the same rate forecast by their respective specialty societies.

We are concerned that the coding stratification in the PT and OT evaluation codes may result in upcoding incentives, especially while physical and occupational therapists gain familiarity and expertise in the differential coding of the new PT and OT evaluation codes that now include the typical face-to-face times and new required components that are not enumerated in the current codes. We are also concerned that stratified payment rates may provide, in some cases, a payment incentive to therapists to upcode to a higher complexity level than was actually furnished to receive a higher payment.

We understand that there may be multiple reasons for the CPT Editorial Panel to stratify coding for OT and PT

evaluation codes based on complexity. We also note that the codes will be used by payers in addition to Medicare, and other payers may have direct interest in making such differential payment based on complexity of OT and PT evaluation. Given our concerns regarding appropriate valuation, work neutrality, and potential upcoding, however, we do not believe that making different payment based on the reported complexity for these services is, at current, advantageous for Medicare or Medicare beneficiaries.

Given the advantages inherent and public interest in using CPT codes once they become part of the code set, we are proposing to adopt the new CPT codes for use in Medicare for CY 2017. However, given our concerns about appropriate pricing and payment for the stratified services, we are proposing to price the services described by these stratified codes as a group instead of individually. To do that, we are proposing to utilize the authority in section 220(f) of the Protecting Access to Medicare Act (PAMA), which revised section 1848(c)(2)(C) of the Act to authorize the Secretary to determine RVUs for groups of services, rather than determining RVUs at the individual service level. We believe that using this authority instead of proposing to make payment based on Medicare G-codes will preserve consistency in the code set across payers, thus lessening burden on providers, while retaining flexibilities that are beneficial to Medicare.

We propose a work RVU of 1.20 for both the PT and the OT evaluation groups of services. We are proposing this work RVU because we believe it best represents the typical PT and OT evaluation. This is the value recommended by the HCPAC for the OT moderate-complexity evaluation and nearly the same work RVU for corresponding PT evaluation (1.18). Additionally, 1.20 work RVUs is the long-standing value for the current evaluation codes, 97001 and 97003, and, thus, assures work neutrality without reliance on particular assumptions about utilization, which we believe was the intent of the HCPAC recommendation.

Because we are proposing to use the same work RVU for the six evaluation codes, we are not addressing any additional concerns about the utilization assumptions recommended to us. By proposing the same work values for each code in the family, there will be no ratesetting impact to work neutrality. As such, we are not revising the utilization crosswalks as projected by the respective therapy specialties to achieve work neutrality. However, were we to value each code in the PT or OT evaluation families individually, we would seek objective data from stakeholders to support the utilization crosswalks, particularly those for the OT family in which the low-level complexity evaluation is depicted as typical and the high-complexity is projected to be billed infrequently at 10 percent of the overall number of OT evaluations.

We are proposing to use the direct PE inputs forwarded by the HCPAC (with the refinements described below) for the typical PT evaluation and also for the typical OT evaluation in the development of PE RVUs for the PT and OT codes as a group of services. For the PT codes, we are proposing to use the recommended inputs for the moderate-complexity code for the direct PE inputs of all three codes based on its assumption as the typical service. Our proposed direct PE inputs reflect the recommended values minus 2 minutes of physical therapist assistant (PTA) time in the service period because we believe that PTA tasks to administer certain assessment tools are appropriately included as part of the physical therapist's work and the time of the PTA to explain and/or score self-reported outcome measures is not separately included in the clinical labor of other codes. We are proposing to include the recommended four sheets of laser paper without an association to a specific equipment item, but we are seeking comment regarding the paper's use.

For the OT evaluation codes, we considered proposing to use the direct PE inputs for the low-complexity evaluation because the OT specialty organization believes it represents the typical OT evaluation service with a projected 50 percent utilization rate. However, we propose to use the moderate-level direct inputs instead, because the direct PE for this level is based on a vignette that is valued with the same intraservice time, 45 minutes, as the current code, CPT code 97003. Consequently, we propose to use the recommended direct PE inputs for the moderate-complexity code for use in developing PE RVUs for this group of services.

Our proposed direct PE inputs reflect the recommended values minus 2 minutes of occupational therapist assistant (OTA) time in the service period because we believe that OTA tasks to administer certain assessment tools are appropriately included as part of the occupational therapist's work and the time of the OTA to explain and/or score self-reported outcome measures is not separately included in the clinical labor of other codes. We also rounded up the recommended 6.8 minutes to 7 minutes to represent the time the OTA assists the occupational therapist during the intraservice time period. For the Vision Kit equipment item, our proposed price reflects the submitted invoice that clearly defined a kit.

iii. Valuation of Reevaluation Codes

The recommendations the HCPAC sent to us for the PT and OT reevaluation codes are not work neutral. For the new PT reevaluation code, CPT code 97X64, the HCPAC recommended a work RVU of 0.75 compared to the work RVU of 0.60 for CPT code 97002. This recommended work RVU falls between the 25th percentile of the survey and the survey's median value and was based on a direct crosswalk to CPT code 95992 for canalith repositioning with 20 minutes intraservice time and 10 minutes immediate postservice time. The HCPAC supported this 0.15 work RVU increase based on an anomalous relationship between PT services and E/M office visit codes for established patients, noting that physician E/M codes have historically been used as a relative comparison. The HCPAC stated its 0.75 work RVU recommendation for code 97X64 appropriately ranks it between the key reference codes for this service 99212 and 99213, levels 2 and 3 E/M office-visit codes for established patients.

The HCPAC provided a work RVU of 0.80 for the OT reevaluation code, CPT code 97X68, based on the 25th percentile of the survey, which represents an increase over the current work RVU of 0.60 for CPT code 97004. This work value includes 30 minutes of intraservice time, 5 minutes preservice time, and 10 minutes immediate postservice time. The HCPAC noted that the increase in work compared to the PT reevaluation code (0.75) is because the occupational therapist spends more time observing and assessing the patient and, in general, the OT patient typically has more functional and cognitive disabilities. The HCPAC recommendation notes that the 0.80 work RVU recommendation appropriately ranks it between the level 1 and 2 E/M office-visit codes for new patients.

The HCPAC's recommended increases to work RVUs for the PT and OT reevaluation codes are not work neutral. We are unclear why the HCPAC did not maintain work neutrality for the OT and PT reevaluation codes since maintaining work neutrality was important to the establishment of the six new evaluation codes. We are proposing to maintain the

overall work RVUs for these services by proposing 0.60 work RVUs for CPT codes 97X64 and 97X68, consistent with the work RVUs for the deleted reevaluation codes. We are seeking comments from stakeholders on whether there are reasons that the reevaluation codes should be revalued without regard to work neutrality particularly given the HCPAC's interest in preserving work neutrality for the new evaluation codes.

We are proposing the HCPAC-recommended direct PE inputs for CPT code 97X64 with a reduction in time for the PTA by 1 minute (from 5 to 4) in the service period– the line for ''Other Clinical Activity''—because the time to explain and score the self-reported outcome measure (for example, Oswestry) is not separately included in the clinical labor of other codes.

We are proposing the HCPAC-recommended direct PE inputs for CPT code 97X68 with a reduction in time for the OTA by 1 minute (from 3 to 2) in the service period—the line for ''Other Clinical Activity''—for the same reason we reduced the corresponding line for PTAs—because the time to explain and score any patient-self-administered functional and/or other standardized outcome measure is not separately included in the clinical labor of other codes.

Because the new CPT code descriptors contain new coding requirements for each complexity level, we seek comment from the PT and OT specialty organizations as well as other stakeholders to clarify how therapists will be educated to distinguish the required complexity level components and the selection of the number of elements that impact the plan of care. For example, for the OT codes, we invite comment on how to define performance deficits, what process the occupational therapist uses to identify the number of these performance deficits that result in activity limitations, and performance factors needed for each complexity level. For the PT codes, we would like more information about how the physical therapist differentiates the number of personal factors that actually affect the plan of care. We would also be interested in understanding more about how the physical therapist selects the number of elements from any of the body structures and functions, activity limitations, and/or participation restrictions to make sure there is no duplication during the physical therapist's examination of body systems.

iv. Always Therapy Codes

It is also important to note that CMS defines the codes for these evaluative services as ''always therapy.'' This means that they always represent therapy services regardless of who performs them and always require a therapy modifier, GP or GO, to signify that the services are furnished under a PT or OT plan of care, respectively. These codes will also be subject to the therapy MPPR and to statutory therapy caps.

TABLE 19—CPT LONG DESCRIPTORS FOR PHYSICAL MEDICINE AND REHABILITATION

New CPT code	CPT long descriptors for physical medicine and rehabilitation
97X61	Physical therapy evaluation: Low complexity, requiring these components: • A history with no personal factors and/or comorbidities that impact the plan of care; • An examination of body system(s) using standardized tests and measures addressing 1–2 elements from any of the following: Body structures and functions, activity limitations, and/or participation restrictions; • A clinical presentation with stable and/or uncomplicated characteristics; and • Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.
97X62	Physical therapy evaluation: Moderate complexity, requiring these components: • A history of present problem with 1–2 personal factors and/or comorbidities that impact the plan of care; • An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: Body structures and functions, activity limitations, and/or participation restrictions; • An evolving clinical presentation with changing characteristics; and • Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.
97X63	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. Typically, 45 minutes are spent face-to-face with the patient and/or family.
97X64	Reevaluation of physical therapy established plan of care, requiring these components: • An examination including a review of history and use of standardized tests and measures is required; and • Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome Typically, 20 minutes are spent face-to-face with the patient and/or family.
97X65	Occupational therapy evaluation, low complexity, requiring these components: • An occupational profile and medical and therapy history, which includes a brief history including review of medical and/or therapy records relating to the presenting problem; • An assessment(s) that identifies 1–3 performance deficits (*i.e.*, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and • Clinical decision making of low complexity, which includes an analysis of the occupational profile, analysis of data from problem-focused assessment(s), and consideration of a limited number of treatment options. Patient presents with no comorbidities that affect occupational performance. Modification of tasks or assistance (*e.g.*, physical or verbal) with assessment(s) is not necessary to enable completion of evaluation component. Typically, 30 minutes are spent face-to-face with the patient and/or family.

TABLE 19—CPT LONG DESCRIPTORS FOR PHYSICAL MEDICINE AND REHABILITATION—Continued

New CPT code	CPT long descriptors for physical medicine and rehabilitation
97X66	Occupational therapy evaluation, moderate complexity, requiring these components: • An occupational profile and medical and therapy history, which includes an expanded review of medical and/or therapy records and additional review of physical, cognitive, or psychosocial history related to current functional performance; • An assessment(s) that identifies 3–5 performance deficits (*i.e.*, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and • Clinical decision making of moderate analytic complexity, which includes an analysis of the occupational profile, analysis of data from detailed assessment(s), and consideration of several treatment options. Patient may present with comorbidities that affect occupational performance. Minimal to moderate modification of tasks or assistance (*e.g.*, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 45 minutes are spent face-to-face with the patient and/or family.
97X67	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 identify 5 or more performance deficits (*i.e.*, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and • A clinical decision-making is of high analytic complexity, which includes an analysis of the patient profile, analysis of data from comprehensive assessment(s), and consideration of multiple treatment options. Patient presents with comorbidities that affect occupational performance. Significant modification of tasks or assistance (*e.g.*, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 60 minutes are spent face-to-face with the patient and/or family.
97X68	Reevaluation of occupational therapy established plan of care, requiring these components: • An assessment of changes in patient functional or medical status with revised plan of care; • An update to the initial occupational profile to reflect changes in condition or environment that affect future interventions and/or goals; and • A revised plan of care. A formal reevaluation is performed when there is a documented change in functional status or a significant change to the plan of care is required. Typically, 30 minutes are spent face-to-face with the patient and/or family.

v. Potentially Misvalued Therapy Codes

Since 2010, in addition to the codes for evaluative services, CMS has periodically added codes that represent therapy services to the list of potentially misvalued codes. The current list of 10 therapy codes was based on the statutory category ''codes that account for the majority of spending under the physician fee schedule,'' as specified in section 1848(c)(2)(K)(ii)(VII) of the Act. We understand that the therapy specialty organizations have pursued the development of coding changes through the CPT process for these modality and procedures services. While we understand that, in some cases, it may take several years to develop appropriate coding revisions, we are, in the meantime, seeking information regarding appropriate valuation for the existing codes. See Table 20.

TABLE 20—POTENTIALLY MISVALUED CODES IDENTIFIED THROUGH HIGH EXPENDITURE BY SPECIALTY SCREEN

HCPCS code	Short descriptor
97032	Electrical stimulation.
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.
97535	Self care mngment training.
G0283	Elec stim other than wound.

(37) Proposed Valuation of Services Where Moderate Sedation Is an Inherent Part of the Procedure and Proposed Valuation of Moderate Sedation Services (CPT Codes 991X1, 991X2, 991X3, 991X4, 991X5, and 991X6; and HCPCS Code GMMM1)

In the CY 2015 PFS proposed rule (79 FR 40349), we noted that it appeared that practice patterns for endoscopic procedures were changing. Anesthesia services are increasingly being separately reported for endoscopic procedures, meaning that resource costs associated with sedation were no longer incurred by the practitioner reporting the procedure. Subsequently, in the CY 2016 PFS proposed rule (80 FR 41707), we sought public comment and recommendations on approaches to address the appropriate valuation of moderate sedation related to the approximately 400 diagnostic and therapeutic procedures for which the CPT Editorial Committee has determined that moderate sedation is an inherent part of furnishing the service. The CPT Editorial Committee created separate codes for reporting of moderate sedation services.

TABLE 21—MODERATE SEDATION CODES AND DESCRIPTORS

CPT/HCPCS code	Descriptor
991X1	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time, patient younger than 5 years of age.

TABLE 21—MODERATE SEDATION CODES AND DESCRIPTORS—Continued

CPT/HCPCS code	Descriptor
991X2	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time, patient age 5 years or older.
991X3	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 minutes of intra-service time, patient younger than 5 years of age.
991X4	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 minutes of intra-service time, patient age 5 years or older.
991X5	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; each additional 15 minutes of intra-service time (List separately in addition to code for primary service).
991X6	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; each additional 15 minutes intra-service time (List separately in addition to code for primary service).

For the newly created moderate sedation CPT codes, we are proposing to use the RUC-recommended work RVUs for CPT codes 991X1, 991X2, 991X3, and 991X6. CPT codes 991X1 and 991X2 make a distinction between moderate sedation services furnished to patients younger than 5 years of age and patients 5 years or older, with CPT codes 991X3 and 991X4 making a similar distinction. The RUC recommendations include a work RVU increment of 0.25 between CPT code 991X1 and 991X2. For CPT code 991X4, we are proposing a work RVU of 1.65 to maintain the 0.25 increment relative to CPT code 991X3 (a RUC-recommended work RVU of 1.90) and maintain relativity among the CPT codes in this family. We are proposing to use the RUC-recommended direct PE inputs for all six codes.

When moderate sedation is reported for Medicare beneficiaries, we expect that it would most frequently reported using the code that describes moderate sedation furnished by the same person who also performs the primary procedure for patients 5 years of age or older. Under the new coding structure, these services would be reported using CPT code 991X2. Stakeholders have presented information that illustrates that the specialty group survey data regarding the work involved in furnishing the moderate sedation described by CPT code 991X2 showed a significant bimodal distribution between procedural services furnished by gastroenterologists (GI) and those services furnished by other specialties. The GI societies' survey data reported a median valuation of 0.10 work RVUs for moderate sedation furnished by the same person furnishing the base procedure; all other specialty groups (combined) reported a median valuation of 0.25 work RVUs. Given the significant volume of moderate sedation furnished by GI practitioners and the significant difference in RVUs reported in the survey data, we are proposing to make payment using a gastrointestinal (GI) endoscopy-specific moderate sedation code GMMM1 that would be used in lieu of the new CPT moderate sedation coding used more broadly: GMMM1: Moderate sedation services provided by the same physician or other qualified health care professional performing a gastrointestinal endoscopic service (excluding biliary procedures) that sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time; patient age 5 years or older.

We are proposing to value GMMM1 at 0.10 work RVUs based on the median survey result for GI respondents in the survey data. We are proposing that when moderate sedation services are furnished by the same practitioner reporting the GI endoscopy procedure, practitioners would report the sedation services using GMMM1 instead of 991X2. In all other cases, we propose that practitioners would report moderate sedation using one of the new moderate sedation CPT codes consistent with CPT guidance. This would include the full range of codes for those furnishing moderate sedation with the remaining (non-GI endoscopy) base procedures as well as for the other circumstances during which moderate sedation is furnished along with a GI endoscopy (for example, to a patient under 5 years of age or for a biliary procedure, the endoscopist furnishing moderate sedation should not use GMMM1, but instead use the appropriate CPT code; see Table 22 for more information about when GMMM1 should be used in lieu of the newly created moderate sedation CPT codes).

In addition to providing recommended values for the new codes used to separately report moderate sedation, the RUC has provided recommendations that value the procedural services without moderate sedation. However, the RUC recommends removing fewer RVUs from the procedures than it recommends for valuing the sedation services. In other words, the RUC is recommending that overall payments for these procedures should be increased now that practitioners will be required to report the sedation services that were previously included as inherent parts of the procedures. We believe that if we were to use the RUC recommendations for re-valuation of the procedural services without refinement, the RVUs currently attributable to the redundant payment for sedation services when anesthesia is separately reported would be used exclusively to increase overall payment for these services. We refer readers to Section II.D.5. of this proposed rule, which includes a more extensive discussion of our general principle that overall resource costs for the procedures including moderate sedation do not inherently change based solely on changes in coding.

To account for the separate billing of moderate sedation services, we are proposing to maintain current values for the procedure codes less the work RVUs associated with the most frequently reported corresponding moderate sedation code so that practitioners furnishing the moderate sedation

services previously considered to be inherent in the procedure will have no change in overall work RVUs. Since we are proposing 0.10 work RVUs for moderate sedation for the GI endoscopy procedures, this means we are proposing a corresponding .10 reduction in work RVUs for these procedures. For all other Appendix G procedures that currently include moderate sedation as an inherent part of the procedure, we are proposing to remove 0.25 work RVUs from the current values.

Table 22 lists the existing work RVUs for each applicable service and our proposed refined work RVU using the proposed revaluation methodology described above. Additionally, the table identifies the GI endoscopic services for which we are proposing that GMMM1 would be used to report moderate sedation services. This information will be made available and maintained in the ''downloads'' section of the PFS Web site at *http://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

TABLE 22—PROPOSED VALUATIONS FOR ENDOSCOPY SERVICES MINUS MODERATE SEDATION

HCPCS	CY 2016 work RVU	CY 2017 proposed work RVU	Use GMMM1 to report moderate sedation (Y/N)
10030	3.00	2.75	N
19298	6.00	5.75	N
20982	7.27	7.02	N
20983	7.13	6.88	N
22510	8.15	7.90	N
22511	7.58	7.33	N
22512	4.00	4.00	N
22513	8.90	8.65	N
22514	8.24	7.99	N
22515	4.00	4.00	N
22526	6.10	5.85	N
22527	3.03	3.03	N
31615	2.09	1.84	N
31622	2.78	2.53	N
31623	2.88	2.63	N
31624	2.88	2.63	N
31625	3.36	3.11	N
31626	4.16	3.91	N
31627	2.00	2.00	N
31628	3.80	3.55	N
31629	4.00	3.75	N
31632	1.03	1.03	N
31633	1.32	1.32	N
31634	4.00	3.75	N
31635	3.67	3.42	N
31645	3.16	2.91	N
31646	2.72	2.47	N
31647	4.40	4.15	N
31648	4.20	3.95	N
31649	1.44	1.44	N
31651	1.58	1.58	N
31652	4.71	4.46	N
31653	5.21	4.96	N
31654	1.40	1.40	N
31660	4.25	4.00	N
31661	4.50	4.25	N
31725	1.96	1.71	N
32405	1.93	1.68	N
32550	4.17	3.92	N
32551	3.29	3.04	N
32553	3.80	3.55	N
33010	2.24	1.99	N
33011	2.24	1.99	N
33206	7.39	7.14	N
33207	8.05	7.80	N
33208	8.77	8.52	N
33210	3.30	3.05	N
33211	3.39	3.14	N
33212	5.26	5.01	N
33213	5.53	5.28	N
33214	7.84	7.59	N
33216	5.87	5.62	N
33217	5.84	5.59	N
33218	6.07	5.82	N
33220	6.15	5.90	N
33221	5.80	5.55	N
33222	5.10	4.85	N
33223	6.55	6.30	N
33227	5.50	5.25	N
33228	5.77	5.52	N
33229	6.04	5.79	N
33230	6.32	6.07	N
33231	6.59	6.34	N
33233	3.39	3.14	N
33234	7.91	7.66	N
33235	10.15	9.90	N
33240	6.05	5.80	N
33241	3.29	3.04	N
33244	13.99	13.74	N
33249	15.17	14.92	N
33262	6.06	5.81	N
33263	6.33	6.08	N
33264	6.60	6.35	N
33282	3.50	3.25	N
33284	3.00	2.75	N
33990	8.15	7.90	N
33991	11.88	11.63	N
33992	4.00	3.75	N
33993	3.51	3.26	N
35471	10.05	9.80	N
35472	6.90	6.65	N
35475	6.60	6.35	N
35476	5.10	4.85	N
36010	2.43	2.18	N
36140	2.01	1.76	N
36147	3.72	3.47	N
36148	1.00	1.00	N
36200	3.02	2.77	N
36221	4.17	3.92	N
36222	5.53	5.28	N
36223	6.00	5.75	N
36224	6.50	6.25	N
36225	6.00	5.75	N
36226	6.50	6.25	N
36227	2.09	2.09	N
36228	4.25	4.25	N
36245	4.90	4.65	N
36246	5.27	5.02	N
36247	6.29	6.04	N
36248	1.01	1.01	N
36251	5.35	5.10	N
36252	6.99	6.74	N
36253	7.55	7.30	N
36254	8.15	7.90	N
36481	6.98	6.73	N
36555	2.68	2.43	N
36557	5.14	4.89	N
36558	4.84	4.59	N
36560	6.29	6.04	N
36561	6.04	5.79	N
36563	6.24	5.99	N
36565	6.04	5.79	N
36566	6.54	6.29	N
36568	1.92	1.67	N
36570	5.36	5.11	N
36571	5.34	5.09	N
36576	3.24	2.99	N
36578	3.54	3.29	N
36581	3.48	3.23	N
36582	5.24	4.99	N
36583	5.29	5.04	N
36585	4.84	4.59	N
36590	3.35	3.10	N
36870	5.20	4.95	N
37183	7.99	7.74	N
37184	8.66	8.41	N
37185	3.28	3.28	N
37186	4.92	4.92	N
37187	8.03	7.78	N
37188	5.71	5.46	N
37191	4.71	4.46	N
37192	7.35	7.10	N
37193	7.35	7.10	N
37197	6.29	6.04	N
37211	8.00	7.75	N
37212	7.06	6.81	N
37213	5.00	4.75	N
37214	2.74	2.49	N
37215	18.00	17.75	N
37216	0.00	0.00	N
37218	15.00	14.75	N
37220	8.15	7.90	N
37221	10.00	9.75	N
37222	3.73	3.73	N
37223	4.25	4.25	N
37224	9.00	8.75	N
37225	12.00	11.75	N
37226	10.49	10.24	N
37227	14.50	14.25	N
37228	11.00	10.75	N
37229	14.05	13.80	N
37230	13.80	13.55	N
37231	15.00	14.75	N
37232	4.00	4.00	N
37233	6.50	6.50	N
37234	5.50	5.50	N
37235	7.80	7.80	N
37236	9.00	8.75	N
37237	4.25	4.25	N
37238	6.29	6.04	N
37239	2.97	2.97	N
37241	9.00	8.75	N
37242	10.05	9.80	N

TABLE 22—PROPOSED VALUATIONS FOR ENDOSCOPY SERVICES MINUS MODERATE SEDATION—Continued

HCPCS	CY 2016 work RVU	CY 2017 proposed work RVU	Use GMMM1 to report moderate sedation (Y/N)
37243	11.99	11.74	N
37244	14.00	13.75	N
37252	1.80	1.80	N
37253	1.44	1.44	N
43200	1.52	1.42	Y
43201	1.82	1.72	Y
43202	1.82	1.72	Y
43204	2.43	2.33	Y
43205	2.54	2.44	Y
43206	2.39	2.29	Y
43211	4.30	4.20	Y
43212	3.50	3.40	Y
43213	4.73	4.63	Y
43214	3.50	3.40	Y
43215	2.54	2.44	Y
43216	2.40	2.30	Y
43217	2.90	2.80	Y
43220	2.10	2.00	Y
43226	2.34	2.24	Y
43227	2.99	2.89	Y
43229	3.59	3.49	Y
43231	2.90	2.80	Y
43232	3.69	3.59	Y
43233	4.17	4.07	Y
43235	2.19	2.09	Y
43236	2.49	2.39	Y
43237	3.57	3.47	Y
43238	4.26	4.16	Y
43239	2.49	2.39	Y
43240	7.25	7.15	Y
43241	2.59	2.49	Y
43242	4.83	4.73	Y
43243	4.37	4.27	Y
43244	4.50	4.40	Y
43245	3.18	3.08	Y
43246	3.66	3.56	Y
43247	3.21	3.11	Y
43248	3.01	2.91	Y
43249	2.77	2.67	Y
43250	3.07	2.97	Y
43251	3.57	3.47	Y
43252	3.06	2.96	Y
43253	4.83	4.73	Y
43254	4.97	4.87	Y
43255	3.66	3.56	Y
43257	4.25	4.15	Y
43259	4.14	4.04	Y
43260	5.95	5.70	N
43261	6.25	6.00	N
43262	6.60	6.35	N
43263	6.60	6.35	N
43264	6.73	6.48	N
43265	8.03	7.78	N
43266	4.17	3.92	N
43270	4.26	4.01	N
43273	2.24	2.24	N
43274	8.58	8.33	N
43275	6.96	6.71	N
43276	8.94	8.69	N
43277	7.00	6.75	N
43278	8.02	7.77	N
43450	1.38	1.13	N
43453	1.51	1.26	N
44360	2.59	2.49	Y
44361	2.87	2.77	Y

TABLE 22—PROPOSED VALUATIONS FOR ENDOSCOPY SERVICES MINUS MODERATE SEDATION—Continued

HCPCS	CY 2016 work RVU	CY 2017 proposed work RVU	Use GMMM1 to report moderate sedation (Y/N)
44363	3.49	3.39	Y
44364	3.73	3.63	Y
44365	3.31	3.21	Y
44366	4.40	4.30	Y
44369	4.51	4.41	Y
44370	4.79	4.69	Y
44372	4.40	4.30	Y
44373	3.49	3.39	Y
44376	5.25	5.15	Y
44377	5.52	5.42	Y
44378	7.12	7.02	Y
44379	7.46	7.36	Y
44380	0.97	0.87	Y
44381	1.48	1.38	Y
44382	1.27	1.17	Y
44384	2.95	2.85	Y
44385	1.30	1.20	Y
44386	1.60	1.50	Y
44388	2.82	2.72	Y
44388–53	1.41	1.36	Y
44389	3.12	3.02	Y
44390	3.84	3.74	Y
44391	4.22	4.12	Y
44392	3.63	3.53	Y
44394	4.13	4.03	Y
44401	4.44	4.34	Y
44402	4.80	4.70	Y
44403	5.60	5.50	Y
44404	3.12	3.02	Y
44405	3.33	3.23	Y
44406	4.20	4.10	Y
44407	5.06	4.96	Y
44408	4.24	4.14	Y
44500	0.49	0.39	Y
45303	1.50	1.40	Y
45305	1.25	1.15	Y
45307	1.70	1.60	Y
45308	1.40	1.30	Y
45309	1.50	1.40	Y
45315	1.80	1.70	Y
45317	2.00	1.90	Y
45320	1.78	1.68	Y
45321	1.75	1.65	Y
45327	2.00	1.90	Y
45332	1.86	1.76	Y
45333	1.65	1.55	Y
45334	2.10	2.00	Y
45335	1.14	1.04	Y
45337	2.20	2.10	Y
45338	2.15	2.05	Y
45340	1.35	1.25	Y
45341	2.22	2.12	Y
45342	3.08	2.98	Y
45346	2.91	2.81	Y
45347	2.82	2.72	Y
45349	3.62	3.52	Y
45350	1.78	1.68	Y
45378	3.36	3.26	Y
45378–53	1.68	1.63	Y
45379	4.38	4.28	Y
45380	3.66	3.56	Y
45381	3.66	3.56	Y
45382	4.76	4.66	Y
45384	4.17	4.07	Y
45385	4.67	4.57	Y

TABLE 22—PROPOSED VALUATIONS FOR ENDOSCOPY SERVICES MINUS MODERATE SEDATION—Continued

HCPCS	CY 2016 work RVU	CY 2017 proposed work RVU	Use GMMM1 to report moderate sedation (Y/N)
45386	3.87	3.77	Y
45388	4.98	4.88	Y
45389	5.34	5.24	Y
45390	6.14	6.04	Y
45391	4.74	4.64	Y
45392	5.60	5.50	Y
45393	4.78	4.68	Y
45398	4.30	4.20	Y
47000	1.90	1.65	N
47382	15.22	14.97	N
47383	9.13	8.88	N
47532	4.25	4.25	N
47533	6.00	5.38	N
47534	8.03	7.60	N
47535	4.50	3.95	N
47536	2.88	2.61	N
47538	6.60	4.75	N
47539	9.00	8.75	N
47540	10.75	9.03	N
47541	5.61	5.38	N
47542	2.50	2.85	N
47543	3.07	3.00	N
47544	4.29	3.28	N
49405	4.25	4.00	N
49406	4.25	4.00	N
49407	4.50	4.25	N
49411	3.82	3.57	N
49418	4.21	3.96	N
49440	4.18	3.93	N
49441	4.77	4.52	N
49442	4.00	3.75	N
49446	3.31	3.06	N
50200	2.63	2.38	N
50382	5.50	5.25	N
50384	5.00	4.75	N
50385	4.44	4.19	N
50386	3.30	3.05	N
50387	2.00	1.75	N
50430	3.15	2.90	N
50432	4.25	4.00	N
50433	5.30	5.05	N
50434	4.00	3.75	N
50592	6.80	6.55	N
50593	9.13	8.88	N
50606	3.16	3.16	N
50693	4.21	3.96	N
50694	5.50	5.25	N
50695	7.05	6.80	N
50705	4.03	4.03	N
50706	3.80	3.80	N
57155	5.40	5.15	N
66720	5.00	4.75	N
69300	6.69	6.44	N
77371	0.00	0.00	N
77600	1.56	1.31	N
77605	2.09	1.84	N
77610	1.56	1.31	N
77615	2.09	1.84	N
92920	10.10	9.85	N
92921	0.00	0.00	N
92924	11.99	11.74	N
92925	0.00	0.00	N
92928	11.21	10.96	N
92929	0.00	0.00	N
92933	12.54	12.29	N

TABLE 22—PROPOSED VALUATIONS FOR ENDOSCOPY SERVICES MINUS MODERATE SEDATION—Continued

HCPCS	CY 2016 work RVU	CY 2017 proposed work RVU	Use GMMM1 to report moderate sedation (Y/N)
92934	0.00	0.00	N
92937	11.20	10.95	N
92938	0.00	0.00	N
92941	12.56	12.31	N
92943	12.56	12.31	N
92944	0.00	0.00	N
92953	0.23	0.01	N
92960	2.25	2.00	N
92961	4.59	4.34	N
92973	3.28	3.28	N
92974	3.00	3.00	N
92975	7.24	6.99	N
92978	0.00	0.00	N
92979	0.00	0.00	N
92986	22.85	22.60	N
92987	23.63	23.38	N
93312	2.55	2.30	N
93313	0.51	0.26	N
93314	2.10	1.85	N
93315	2.94	2.69	N
93316	0.85	0.60	N
93317	2.09	1.84	N
93318	2.40	2.15	N
93451	2.72	2.47	N
93452	4.75	4.50	N
93453	6.24	5.99	N
93454	4.79	4.54	N
93455	5.54	5.29	N
93456	6.15	5.90	N
93457	6.89	6.64	N
93458	5.85	5.60	N
93459	6.60	6.35	N
93460	7.35	7.10	N
93461	8.10	7.85	N
93462	3.73	3.73	N
93463	2.00	2.00	N
93464	1.80	1.80	N
93505	4.37	4.12	N
93530	4.22	3.97	N
93561	0.50	0.25	N
93562	0.16	0.01	N
93563	1.11	1.11	N
93564	1.13	1.13	N
93565	0.86	0.86	N
93566	0.86	0.86	N
93567	0.97	0.97	N
93568	0.88	0.88	N
93571	0.00	0.00	N
93572	0.00	0.00	N
93582	12.56	12.31	N
93583	14.00	13.75	N
93609	0.00	0.00	N
93613	6.99	6.99	N
93615	0.99	0.74	N
93616	1.49	1.24	N
93618	4.25	4.00	N
93619	7.31	7.06	N
93620	11.57	11.32	N
93621	0.00	0.00	N
93622	0.00	0.00	N
93624	4.80	4.55	N
93640	3.51	3.26	N
93641	5.92	5.67	N
93642	4.88	4.63	N
93644	3.29	3.04	N

TABLE 22—PROPOSED VALUATIONS FOR ENDOSCOPY SERVICES MINUS MODERATE SEDATION—Continued

HCPCS	CY 2016 work RVU	CY 2017 proposed work RVU	Use GMMM1 to report moderate sedation (Y/N)
93650	10.49	10.24	N
93653	15.00	14.75	N
93654	20.00	19.75	N
93655	7.50	7.50	N
93656	20.02	19.77	N
93657	7.50	7.50	N
94011	2.00	1.75	N
94012	3.10	2.85	N
94013	0.66	0.41	N
96440	2.37	2.12	N
G0105	3.36	3.26	Y
G0105–53	1.68	1.63	Y
G0121	3.36	3.26	Y
G0121–53	1.68	1.63	Y
G0341	6.98	6.98	N

(38) Prolonged Evaluation and Management Services (CPT Codes 99354, 99358, and 99359)

We previously received RUC recommendations for face-to-face and non-face-to-face prolonged E/M services. In response to the CY 2016 PFS proposed rule, in which we sought comment about improving payment accuracy for cognitive services, commenters suggested that we consider making separate payment for CPT codes 99358 and 99359. As reflected in section II.E, we are proposing to make separate payment for these services.

We are also proposing values for services in this family of codes based on the RUC-recommended values, including for CPT code 99354, which would increase the current work RVU to 2.33. Likewise, we are proposing to adopt the RUC-recommended work values of 2.10 for CPT code 99358 and of 1.00 for CPT code 99359.

(39) Complex Chronic Care Management Services (CPT Codes 99487 and 99489)

We received RUC recommendations for CPT codes 99487 and 99489 following the October 2012 RUC meeting. For CY 2017, we are proposing to change the procedure status for CPT codes 99487 and 99489 from B (bundled) to A (active), see II.E, and are proposing to adopt the RUC-recommended values for work, 1.00 work RVUs for CPT code 99487 and 0.50 work RVUs for CPT code 99489, as well as direct PE inputs consistent with the RUC recommendations.

(40) Prostate Biopsy, Any Method (HCPCS Code G0416)

The College of American Pathologists and the American Society of Cytopathology formed an expert panel to make recommendations at the October 2015 RUC meeting to determine an appropriate work RVU for HCPCS code G0416, as they felt that the survey results were invalid. The panel made several arguments to the RUC in recommending for a higher work RVU under the RUC's ''compelling evidence'' standard. These arguments were: (1) That incorrect assumptions were made in previous valuations; (2) the value of HCPCS code G0416 remained constant while the code descriptors changed over the years; and (3) the ''anomalous relationship'' between HCPCS code G0416 and CPT code 88305 (Level IV—Surgical pathology, gross and microscopic examination). The expert panel recommended a work RVU of 4.00 based on a crosswalk from CPT code 38240 (Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor). The RUC agreed.

We believe HCPCS code G0416 should not be valued as a direct crosswalk from CPT code 38240. Instead we believe CPT code 88305 is the basis for HCPCS code G0416, and therefore, HCPCS code G0416 should be valued as such. To value HCPCS code G0416, we used the intra-service time ratio between HCPCS code G0416 and CPT code 88305 to arrive at a work RVU of 3.60. To further support this method, we note that the IWPUT for HCPCS code G0416 with a work RVU of 3.60 is the same as CPT code 88305. Using the RUC recommended RVU of 4.00 results in a higher IWPUT, and we do not believe there is a difference in work intensity between these codes. Therefore for CY 2017, we are proposing a work RVU of 3.60 for HCPCS code G0416.

(41) Behavioral Health Integration: Psychiatric Collaborative Care Model (HCPCS Codes GPPP1, GPPP2, and GPPP3) and General Behavioral Health Integration (HCPCS Code GPPPX)

For CY 2017, we are proposing to establish and make separate Medicare payment using four new HCPCS G-codes, GPPP1 (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), GPPP2 (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), GPPP3 (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), and GPPPX (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 time, per calendar month) for collaborative care and care management for beneficiaries with behavioral health conditions, as detailed in section II.E of this proposed rule. To value HCPCS codes GPPP1, GPPP2, and GPPP3, we are proposing to base the portion of the work RVU that accounts for the work of the treating physician or other qualified health care professional on a direct crosswalk to the proposed work values for the complex CCM codes, CPT codes 99487 and 99489. To value the portion of the work RVU that accounts for the psychiatric consultant, we are estimating ten minutes of psychiatric consultant time per patient per month and a value of 0.42 work RVUs, based on the per minute work RVUs for the highest volume codes typically billed by psychiatrists. Since the behavioral health care manager in the services described by HCPCS codes GPPP1, GPPP2, and GPPP3 should have academic with specialized training in behavioral health, we are proposing a new clinical labor type for the behavioral health care manager, L057B, at $0.57 per minute, based on the rates for genetic counselors in the direct PE input database. We are seeking comment on all aspects of these proposed valuations.

To value HCPCS code GPPPX, we are proposing a work value based on a direct crosswalk from CPT code 99490 (Chronic care management services), a work value of 0.61 RVUs. We recognize that the services described by CPT code 99490 are distinct from those furnished under the CoCM and we believe that these alsovary based on different kinds of BHI care. We note that there are relatively few existing codes that describe these kinds of services over a calendar month. We also believe that the resources associated with 99490 may vary based on the ways different practitioners implement the service. Until we have more information about how these services are typically furnished, we believe valuation based on the minimum resources would be most appropriate. To account for the care manager minutes in the direct PE inputs for HCPCS code GPPPX, we are proposing to use clinical labor type L045C, which is the labor type for social workers/psychologists and has a rate of $0.45 per minute.

(42) Resource-Intensive Services (HCPCS Code GDDD1)

As discussed in section II.E, we are proposing to establish payment for services furnished to patients with mobility-related disabilities, through a new add-on G-code, to be billable with office/outpatient E/M and TCM codes. Based on our analysis of the resources typically involved in furnishing office visits to patients with these needs (especially including the typical additional practitioner and staff time), we believe that the physician work and time for HCPCS code GDDD1 is most accurately valued through a direct crosswalk from CPT code 99212 (Level 2 office or other outpatient visit for the evaluation and management of an established patient). Therefore, we are proposing a work RVU of 0.48 and a physician time of 16 minutes for HCPCS code GDDD1. We are seeking comment on whether these work and time values accurately capture the additional physician work typically involved in furnishing services to patients with mobility impairments.

We believe that a direct crosswalk to the clinical staff-time associated with CPT code 99212, which is 27 minutes of LN/LPN/MTA (L037D) accurately represents the additional clinical staff time required to furnish an outpatient office visit or TCM to a patient with a mobility-related disability. We are also proposing to include as direct practice expense inputs 27 minutes for a stretcher (EF018) and a high/low table (EF028), and 27 minutes for new equipment inputs associated with the following: A patient lift system, wheelchair accessible scale, and padded leg support positioning system. These items are included in the CY 2017 proposed direct PE input database. We are seeking comments on whether these inputs are appropriate, and whether any additional inputs are typically used in treating patients with mobility-impairments.

(43) Comprehensive Assessment and Care Planning for Patients With Cognitive Impairment (HCPCS Code GPPP6)

For CY 2017, we are proposing to create and pay separately for new HCPCS code GPPP6 (Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history face-to-face obtained from patient and/or caregiver, in office or other outpatient setting or home or domiciliary or rest home), see II.E for further discussion. Based on similarities between work intensity and time, we believe that the physician work and time for this code would be accurately valued by combining the work RVUs from CPT code 99204 (Level 4 office or other outpatient visit for the evaluation and management of a new patient) and half the work RVUs for HCPCS code G0181 (Physician supervision of a patient receiving Medicare-covered services furnished by a participating home health agency (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of laboratory and other studies, communication (including telephone calls) with other health care professionals involved in the patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month, 30 minutes or more). Therefore, we are proposing a work RVU of 3.30. For direct practice expense inputs we are proposing 70 total minutes of time for RN/LPN/MTA (L037D). We believe this is typical based on information from several specialty societies representing practitioners who typically furnish this service and report, it, when appropriate, using E/M codes. We are seeking comment on these valuation assumptions and would welcome additional information on the work and direct practice expense associated with furnishing this service.

(44) Comprehensive Assessment and Care Planning for Patients Requiring Chronic Care Management (HCPCS Code GPPP7)

For CY 2017 we are proposing to make payment for the resource costs of comprehensive assessment and care planning for patients requiring CCM services through HCPCS code GPPP7 as an add-on code to be billed with the initiating visit for CCM for patients that require extensive assessment and care planning (see section II.E). In valuing this code, we believe that a crosswalk to half the work and time values of HCPCS code G0181 (Physician supervision of a patient receiving Medicare-covered services provided by a participating home health agency (patient not present) requiring complex and

multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of laboratory and other studies, communication (including telephone calls) with other health care professionals involved in the patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month, 30 minutes or more) accurately accounts for the time and intensity of the work associated with furnishing this service over and above the work accounted for as part of the separately billed initiating visit. Therefore, we are proposing a work RVU of 0.87 and 29 minutes of physician time. We are also proposing 36 minutes for a RN/LPN/MTA (L037D) as the only direct PE input for this service.

(45) Telehealth Consultation for a Patient Requiring Critical Care Services (HCPCS Codes GTTT1 and GTTT2)

As discussed in section II.C, we are proposing use of HCPCS G-codes, GTTT1 (Telehealth consultation, critical care, physicians typically spend 60 minutes communicating with the patient via telehealth (initial) and GTTT2 (Telehealth consultation, critical care, physicians typically spend 50 minutes communicating with the patient via telehealth (subsequent)), to report telehealth consultations for a patient requiring critical care services. We note that due to limited coding granularity for high-intensity cognitive services, in the PFS, we do not believe there is an intuitive crosswalk code for ideal estimation of the work and time values for GTTT1. In general, we believe that the overall work for GTTT1 is not as much as 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) but that the service involves more work than G0427 (Telehealth consultation, emergency department or initial inpatient, typically 70 minutes or more communicating with the patient via telehealth). We believe that GTTT1 is most accurately valued by a crosswalk to the work RVU and physician intra-service time of 38240 (Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor) can therefore serve as an appropriate crosswalk. Therefore we are proposing a work RVU of 4.0 and are seeking comment on the accuracy of these assumptions. We do not believe that direct PE inputs would typically be involved with furnishing this service from the distant site. For GTTT2 we are proposing a work RVU of 3.86 based on a crosswalk from G0427. We believe that G0427 has similar overall work intensity to GTTT2 and has a similar intraservice time. We also believe that no direct PE inputs would typically be associated with furnishing this service from the distant site.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
00740	Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum.	0.00	0.00	0.00	No.
00810	Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum.	0.00	0.00	0.00	No.
10035	Placement of soft tissue localization device(s) (*e.g.,* clip, metallic pellet, wire/needle, radioactive seeds), percutaneous, including imaging guidance; first lesion.	1.70		1.70	No.
10036	Placement of soft tissue localization device(s) (*e.g.,* clip, metallic pellet, wire/needle, radioactive seeds), percutaneous, including imaging guidance; each additional lesion.	0.85		0.85	No.
11730	Avulsion of nail plate, partial or complete, simple; single	1.10	1.10	1.05	No.
11732	Avulsion of nail plate, partial or complete, simple; each additional nail plate.	0.44	0.44	0.38	Yes.
20245	Biopsy, bone, open; deep (*e.g.,* humerus, ischium, femur)	8.95	6.50	6.00	No.
20550	Injection(s); single tendon sheath, or ligament, aponeurosis (*e.g.,* plantar ''fascia'').	0.75	0.75	0.75	No.
20552	Injection(s); single or multiple trigger point(s), 1 or 2 muscle(s).	0.66	0.66	0.66	No.
20553	Injection(s); single or multiple trigger point(s), 3 or more muscles.	0.75	0.75	0.75	No.
228X1	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level.	NEW	15.00	13.50	No.
228X2	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level.	NEW	4.00	4.00	No.
228X4	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level.	NEW	7.39	7.03	No.
228X5	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level.	NEW	2.34	2.34	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
22X81	Insertion of interbody biomechanical device(s) (*e.g.,* synthetic cage, mesh) with integral anterior instrumentation for device anchoring (*e.g.,* screws, flanges) when performed to intervertebral disc space in conjunction with interbody arthrodesis, each interspace.	NEW	4.88	4.25	No.
22X82	Insertion of intervertebral biomechanical device(s) (*e.g.,* synthetic cage, mesh) with integral anterior instrumentation for device anchoring (*e.g.,* screws, flanges) when performed to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect.	NEW	5.50	5.50	No.
22X83	Insertion of intervertebral biomechanical device(s) (*e.g.,* synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect.	NEW	6.00	5.50	No.
26356	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (*e.g.,* no man's land); primary, without free graft, each tendon.	9.56		9.56	No.
26357	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (*e.g.,* no man's land); secondary, without free graft, each tendon.	10.53		11.00	No.
26358	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (*e.g.,* no man's land); secondary, with free graft (includes obtaining graft), each tendon.	12.13		12.60	No.
271X1	Closed treatment of posterior pelvic ring fracture(s), dislocation(s), diastasis or subluxation of the ilium, sacroiliac joint, and/or sacrum, with or without anterior pelvic ring fracture(s) and/or dislocation(s) of the pubic symphysis and/or superior/inferior rami, unilateral or bilateral; without manipulation.	NEW	5.50	1.53	Yes.
271X2	Closed treatment of posterior pelvic ring fracture(s), dislocation(s), diastasis or subluxation of the ilium, sacroiliac joint, and/or sacrum, with or without anterior pelvic ring fracture(s) and/or dislocation(s) of the pubic symphysis and/or superior/inferior rami, unilateral or bilateral; with manipulation, requiring more than local anesthesia (*i.e.,* general anesthesia, moderate sedation, spinal/epidural).	NEW	9.00	4.75	Yes.
28289	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint.	8.31	6.90	6.90	No.
28292	Correction, hallux valgus (bunion), with or without sesamoidectomy; Keller, McBride, or Mayo type procedure.	9.05	7.44	7.44	No.
28296	Correction, hallux valgus (bunion), with or without sesamoidectomy; with metatarsal osteotomy (*e.g.,* Mitchell, Chevron, or concentric type procedures).	8.35	8.25	8.25	No.
28297	Correction, hallux valgus (bunion), with or without sesamoidectomy; Lapidus-type procedure.	9.43	9.29	9.29	No.
28298	Correction, hallux valgus (bunion), with or without sesamoidectomy; by phalanx osteotomy.	8.13	7.75	7.75	No.
28299	Correction, hallux valgus (bunion), with or without sesamoidectomy; by double osteotomy.	11.57	9.29	9.29	No.
282X1	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; with implant.	NEW	8.01	7.81	No.
282X2	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal metatarsal osteotomy, any method.	NEW	8.57	8.25	No.
31500	Intubation, endotracheal, emergency procedure	2.33	3.00	2.66	No.
31575	Laryngoscopy, flexible fiberoptic; diagnostic	1.10	1.00	0.94	No.
31576	Laryngoscopy, flexible fiberoptic; with biopsy	1.97	1.95	1.89	No.
31577	Laryngoscopy, flexible fiberoptic; with removal of foreign body.	2.47	2.25	2.19	No.
31578	Laryngoscopy, flexible fiberoptic; with removal of lesion	2.84	2.49	2.43	No.
31579	Laryngoscopy, flexible or rigid fiberoptic, with stroboscopy	2.26	1.94	1.88	No.
317X1	Laryngoscopy, flexible; with ablation or destruction of lesion(s) with laser, unilateral.	NEW	3.07	3.01	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
317X2	Laryngoscopy, flexible; with therapeutic injection(s) (*e.g.,* chemodenervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral.	NEW	2.49	2.43	No.
317X3	Laryngoscopy, flexible; with injection(s) for augmentation (*e.g.,* percutaneous, transoral), unilateral.	NEW	2.49	2.43	No.
31580	Laryngoplasty; for laryngeal web, 2-stage, with keel insertion and removal.	14.66	14.60	14.60	No.
31584	Laryngoplasty; with open reduction of fracture	20.47	20.00	17.58	No.
31587	Laryngoplasty, cricoid split	15.27	15.27	15.27	No.
315X1	Laryngoplasty; for laryngeal stenosis, with graft, without indwelling stent placement, younger than 12 years of age.	NEW	21.50	21.50	No.
315X2	Laryngoplasty; for laryngeal stenosis, with graft, without indwelling stent placement, age 12 years or older.	NEW	20.50	20.50	No.
315X3	Laryngoplasty; for laryngeal stenosis, with graft, with indwelling stent placement, younger than 12 years of age.	NEW	22.00	22.00	No.
315X4	Laryngoplasty; for laryngeal stenosis, with graft, with indwelling stent placement, age 12 years or older.	NEW	22.00	22.00	No.
315X5	Laryngoplasty, medialization; unilateral	NEW	15.60	13.56	No.
315X6	Cricotracheal resection	NEW	25.00	25.00	No.
333X3	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation.	NEW	14.00	13.00	No.
334X1	Valvuloplasty, aortic valve, open, with cardiopulmonary bypass; simple (*i.e.,* valvotomy, debridement, debulking and/or simple commissural resuspension).	NEW	35.00	35.00	No.
334X2	Valvuloplasty, aortic valve, open, with cardiopulmonary bypass; complex (*e.g.,* leaflet extension, leaflet resection, leaflet reconstruction or annuloplasty).	NEW	44.00	41.50	No.
364X1	Partial exchange transfusion, blood, plasma or crystalloid necessitating the skill of a physician or other qualified health care professional, newborn.	NEW	2.00	2.00	No.
36440	Push transfusion, blood, 2 years or younger	1.03	1.03	1.03	No.
36450	Exchange transfusion, blood; newborn	2.23	3.50	3.50	No.
36455	Exchange transfusion, blood; other than newborn	2.43	2.43	2.43	No.
36X41	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated.	NEW	3.50	3.50	No.
364X2	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.	NEW	2.25	1.75	No.
369X1	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, radiologic supervision and interpretation and image documentation and report.	NEW	3.36	2.82	No.
369X2	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, radiologic 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.	NEW	4.83	4.24	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
369X3	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, radiologic 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.	NEW	6.39	5.85	No.
369X4	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).	NEW	7.50	6.73	No.
369X5	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.	NEW	9.00	8.46	No.
369X6	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 an intravascular stent(s), peripheral dialysis segment, including all imaging and radiological supervision and interpretation to perform the stenting and all angioplasty within the peripheral dialysis circuit.	NEW	10.42	9.88	No.
369X7	Transluminal balloon angioplasty, central dialysis segment, performed through dialysis circuit, including all imaging and radiological supervision and interpretation required to perform the angioplasty.	NEW	3.00	2.48	No.
369X8	Transcatheter placement of an intravascular stent(s), central dialysis segment, performed through dialysis circuit, including all imaging and radiological supervision and interpretation required to perform the stenting, and all angioplasty in the central dialysis segment.	NEW	4.25	3.73	No.
369X9	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.	NEW	4.12	3.48	No.
372X1	Transluminal balloon angioplasty (except lower extremity artery(s) for occlusive disease, intracranial, coronary, pulmonary, or dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same artery; initial artery.	NEW	7.00	7.00	No.
372X2	Transluminal balloon angioplasty (except lower extremity artery(s) for occlusive disease, intracranial, coronary, pulmonary, or dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same artery; each additional artery.	NEW	3.50	3.50	No.
372X3	Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; initial vein.	NEW	6.00	6.00	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
372X4	Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; each additional vein.	NEW	2.97	2.97	No.
41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session.	3.50		3.50	No.
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed.	7.75		7.75	No.
432X1	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (*i.e.,* magnetic band), including cruroplasty when performed.	NEW	10.13	9.03	No.
432X2	Removal of esophageal sphincter augmentation device	NEW	10.47	9.37	No.
47531	Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; existing access.	1.80	1.30	1.30	No.
47532	Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access (*e.g.,* percutaneous transhepatic cholangiogram).	4.25	4.32	4.25	No.
47533	Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (*e.g.,* ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation; external.	6.00	5.45	5.38	No.
47534	Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (*e.g.,* ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation; internal-external.	8.03	7.67	7.60	No.
47535	Conversion of external biliary drainage catheter to internal-external biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (*e.g.,* fluoroscopy), and all associated radiological supervision and interpretation.	4.50	4.02	3.95	No.
47536	Exchange of biliary drainage catheter (*e.g.,* external, internal-external, or conversion of internal-external to external only), percutaneous, including diagnostic cholangiography when performed, imaging guidance (*e.g.,* fluoroscopy), and all associated radiological supervision and interpretation.	2.88	2.68	2.61	No.
47537	Removal of biliary drainage catheter, percutaneous, requiring fluoroscopic guidance (*e.g.,* with concurrent indwelling biliary stents), including diagnostic cholangiography when performed, imaging guidance (*e.g.,* fluoroscopy), and all associated radiological supervision and interpretation.	1.83	1.84	1.84	No.
47538	Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (*e.g.,* fluoroscopy and/or ultrasound), balloon dilation, catheter exchange(s) and catheter removal(s) when performed, and all associated radiological supervision and interpretation, each stent; existing access.	6.60	4.82	4.75	No.
47539	Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (*e.g.,* fluoroscopy and/or ultrasound), balloon dilation, catheter exchange(s) and catheter removal(s) when performed, and all associated radiological supervision and interpretation, each stent; new access, without placement of separate biliary drainage catheter.	9.00	8.82	8.75	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
47540	Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (*e.g.,* fluoroscopy and/or ultrasound), balloon dilation, catheter exchange(s) and catheter removal(s) when performed, and all associated radiological supervision and interpretation, each stent; new access, with placement of separate biliary drainage catheter (*e.g.,* external or internal-external).	10.75	9.10	9.03	No.
47541	Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (*e.g.,* rendezvous procedure), percutaneous, including diagnostic cholangiography when performed, imaging guidance (*e.g.,* ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation, new access.	5.61	6.82	5.38	No.
47542	Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous, including imaging guidance (*e.g.,* fluoroscopy), and all associated radiological supervision and interpretation, each duct.	2.50	2.85	2.85	No.
47543	Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (*e.g.,* brush, forceps, and/or needle), including imaging guidance (*e.g.,* fluoroscopy), and all associated radiological supervision and interpretation, single or multiple.	3.07	3.00	3.00	No.
47544	Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (*e.g.,* mechanical, electrohydraulic, lithotripsy) when performed, imaging guidance (*e.g.,* fluoroscopy), and all associated radiological supervision and interpretation.	4.29	3.28	3.28	No.
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.	2.35	.....	2.35	No.
50606	Endoluminal biopsy of ureter and/or renal pelvis, non-endoscopic, including imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	3.16	.....	3.16	No.
50705	Ureteral embolization or occlusion, including imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	4.03	.....	4.03	No.
50706	Balloon dilation, ureteral stricture, including imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	3.80	.....	3.80	No.
51700	Bladder irrigation, simple, lavage and/or instillation	0.88	0.60	0.60	No.
51701	Insertion of non-indwelling bladder catheter (*e.g.,* straight catheterization for residual urine).	0.50	0.50	0.50	No.
51702	Insertion of temporary indwelling bladder catheter; simple (*e.g.,* Foley).	0.50	0.50	0.50	No.
51703	Insertion of temporary indwelling bladder catheter; complicated (*e.g.,* altered anatomy, fractured catheter/balloon).	1.47	1.47	1.47	No.
51720	Bladder instillation of anticarcinogenic agent (including retention time).	1.50	0.87	0.87	No.
51784	Electromyography studies (EMG) of anal or urethral sphincter, other than needle, any technique.	1.53	0.75	0.75	No.
52000	Cystourethroscopy (separate procedure)	2.23	1.75	1.53	No.
55700	Biopsy, prostate; needle or punch, single or multiple, any approach.	2.58	2.50	2.06	No.
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed.	21.36	.....	21.36	No.
58555	Hysteroscopy, diagnostic (separate procedure)	3.33	3.07	2.65	No.
58558	Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without D & C.	4.74	4.37	4.17	No.
58559	Hysteroscopy, surgical; with lysis of intrauterine adhesions (any method).	6.16	5.54	5.20	No.
58560	Hysteroscopy, surgical; with division or resection of intrauterine septum (any method).	6.99	6.15	5.75	No.
58561	Hysteroscopy, surgical; with removal of leiomyomata	9.99	7.00	6.60	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
58562	Hysteroscopy, surgical; with removal of impacted foreign body.	5.20	4.17	4.00	No.
58563	Hysteroscopy, surgical; with endometrial ablation (*e.g.,* endometrial resection, electrosurgical ablation, thermoablation).	6.16	4.62	4.47	No.
585X1	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency.	NEW	14.08	14.08	No.
61640	Balloon dilatation of intracranial vasospasm, percutaneous; initial vessel.	N	N	N	No.
61641	Balloon dilatation of intracranial vasospasm, percutaneous; each additional vessel in same vascular family.	N	N	N	No.
61642	Balloon dilatation of intracranial vasospasm, percutaneous; each additional vessel in different vascular family.	N	N	N	No.
61645	Percutaneous arterial transluminal mechanical thrombectomy and/or infusion for thrombolysis, intracranial, any method, including diagnostic angiography, fluoroscopic guidance, catheter placement, and intraprocedural pharmacological thrombolytic injection(s).	15.00		15.00	No.
61650	Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; initial vascular territory.	10.00		10.00	No.
61651	Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; each additional vascular territory.	4.25		4.25	No.
623X5	Injection(s), of diagnostic or therapeutic substance(s) (*e.g.,* anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance.	NEW	1.80	1.80	No.
623X6	Injection(s), of diagnostic or therapeutic substance(s) (*e.g.,* anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (*i.e.*, fluoroscopy or CT).	NEW	1.95	1.95	No.
623X7	Injection(s), of diagnostic or therapeutic substance(s) (*e.g.,* anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance.	NEW	1.55	1.55	No.
623X8	Injection(s), of diagnostic or therapeutic substance(s) (*e.g.,* anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT).	NEW	1.80	1.80	No.
623X9	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (*e.g.,* anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance.	NEW	1.89	1.89	No.
62X10	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (*e.g.,* anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT).	NEW	2.20	2.20	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
62X11	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (*e.g.,* anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance.	NEW	1.78	1.78	No.
62X12	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (*e.g.,* anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT).	NEW	1.90	1.90	No.
630X1	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar.	NEW	10.47	9.09	No.
64461	Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed).	1.75		1.75	No.
64462	Paravertebral block (PVB) (paraspinous block), thoracic; second and any additional injection site(s) (includes imaging guidance, when performed).	1.10		1.10	No.
64463	Paravertebral block (PVB) (paraspinous block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed).	1.81		1.81	No.
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve.	2.36		2.36	Yes.
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve).	2.32		2.32	Yes.
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming.	0.60		0.60	No.
65778	Placement of amniotic membrane on the ocular surface; without sutures.	1.00		1.00	No.
65779	Placement of amniotic membrane on the ocular surface; single layer, sutured.	2.50		2.50	No.
65780	Ocular surface reconstruction; amniotic membrane transplantation, multiple layers.	7.81		7.81	No.
65855	Trabeculoplasty by laser surgery	2.66		2.77	No.
66170	Fistulization of sclera for glaucoma; trabeculectomy ab externo in absence of previous surgery.	11.27		11.27	No.
66172	Fistulization of sclera for glaucoma; trabeculectomy ab externo with scarring from previous ocular surgery or trauma (includes injection of antifibrotic agents).	12.57		12.57	No.
67101	Repair of retinal detachment, 1 or more sessions; cryotherapy or diathermy, including drainage of subretinal fluid, when performed.	8.80	3.50	3.50	No.
67105	Repair of retinal detachment, 1 or more sessions; photocoagulation, including drainage of subretinal fluid, when performed.	8.53	3.84	3.39	No.
67107	Repair of retinal detachment; scleral buckling (such as lamellar scleral dissection, imbrication or encircling procedure), including, when performed, implant, cryotherapy, photocoagulation, and drainage of subretinal fluid.	14.06		14.06	No.
67108	Repair of retinal detachment; with vitrectomy, any method, including, when performed, air or gas tamponade, focal endolaser photocoagulation, cryotherapy, drainage of subretinal fluid, scleral buckling, and/or removal of lens by same technique.	15.19		15.19	No.
67110	Repair of retinal detachment; by injection of air or other gas (*e.g.,* pneumatic retinopexy).	8.31		8.31	No.
67113	Repair of complex retinal detachment (*e.g.,* proliferative vitreoretinopathy, stage C–1 or greater, diabetic traction retinal detachment, retinopathy of prematurity, retinal tear of greater than 90 degrees), with vitrectomy and membrane peeling, including, when performed, air, gas, or silicone oil tamponade, cryotherapy, endolaser photocoagulation, drainage of subretinal fluid, scleral buckling, and/or removal of lens.	19.00		19.00	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
67227	Destruction of extensive or progressive retinopathy (*e.g.,* diabetic retinopathy), cryotherapy, diathermy.	3.50		3.50	No.
67228	Treatment of extensive or progressive retinopathy (*e.g.,* diabetic retinopathy), photocoagulation.	4.39		4.39	No.
70540	Magnetic resonance (*e.g.,* proton) imaging, orbit, face, and/or neck; without contrast material(s).	1.35	1.35	1.35	No.
70542	Magnetic resonance (*e.g.,* proton) imaging, orbit, face, and/or neck; with contrast material(s).	1.62	1.62	1.62	No.
70543	Magnetic resonance (*e.g.,* proton) imaging, orbit, face, and/or neck; without contrast material(s), followed by contrast material(s) and further sequences.	2.15	2.15	2.15	No.
72170	Radiologic examination, pelvis; 1 or 2 views	0.17		0.17	No.
73501	Radiologic examination, hip, unilateral, with pelvis when performed; 1 view.	0.18		0.18	No.
73502	Radiologic examination, hip, unilateral, with pelvis when performed; 2–3 views.	0.22		0.22	No.
73503	Radiologic examination, hip, unilateral, with pelvis when performed; minimum of 4 views.	0.27		0.27	No.
73521	Radiologic examination, hips, bilateral, with pelvis when performed; 2 views.	0.22		0.22	No.
73522	Radiologic examination, hips, bilateral, with pelvis when performed; 3–4 views.	0.29		0.29	No.
73523	Radiologic examination, hips, bilateral, with pelvis when performed; minimum of 5 views.	0.31		0.31	No.
73551	Radiologic examination, femur; 1 view	0.16		0.16	No.
73552	Radiologic examination, femur; minimum 2 views	0.18		0.18	No.
74712	Magnetic resonance (*e.g.,* proton) imaging, fetal, including placental and maternal pelvic imaging when performed; single or first gestation.	3.00		3.00	No.
74713	Magnetic resonance (*e.g.,* proton) imaging, fetal, including placental and maternal pelvic imaging when performed; each additional gestation.	1.78		1.85	No.
767X1	Ultrasound, abdominal aorta, real time with image documentation, screening study for abdominal aortic aneurysm.	NEW	0.55	0.55	No.
77001	Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal (includes fluoroscopic guidance for vascular access and catheter manipulation, any necessary contrast injections through access site or catheter with related venography radiologic supervision and interpretation, and radiographic documentation of final catheter position).	0.38	0.38	0.38	No.
77002	Fluoroscopic guidance for needle placement (*e.g.,* biopsy, aspiration, injection, localization device).	0.54	0.54	0.38	No.
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid).	0.60	0.60	0.38	No.
770X1	Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal (includes fluoroscopic guidance for vascular access and catheter manipulation, any necessary contrast injections through access site or catheter with related venography radiologic supervision and interpretation, and radiographic documentation of final catheter position).	NEW	0.81	0.81	No.
770X2	Fluoroscopic guidance for needle placement (*e.g.,* biopsy, aspiration, injection, localization device).	NEW	1.00	1.00	No.
770X3	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid).	NEW	0.76	0.76	No.
77332	Treatment devices, design and construction; simple (simple block, simple bolus).	0.54	0.54	0.45	No.
77333	Treatment devices, design and construction; intermediate (multiple blocks, stents, bite blocks, special bolus).	0.84	0.84	0.75	No.
77334	Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts).	1.24	1.24	1.15	No.
77470	Special treatment procedure (*e.g.,* total body irradiation, hemibody radiation, per oral or endocavitary irradiation).	2.09	2.03	2.03	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
77778	Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed.	8.00		8.00	No.
77790	Supervision, handling, loading of radiation source	0.00		0.00	No.
78264	Gastric emptying imaging study (*e.g.,* solid, liquid, or both)	0.74		0.74	No.
78265	Gastric emptying imaging study (*e.g.,* solid, liquid, or both); with small bowel transit.	0.98		0.98	No.
78266	Gastric emptying imaging study (*e.g.,* solid, liquid, or both); with small bowel and colon transit, multiple days.	1.08		1.08	No.
88104	Cytopathology, fluids, washings or brushings, except cervical or vaginal; smears with interpretation.	0.56		0.56	No.
88106	Cytopathology, fluids, washings or brushings, except cervical or vaginal; simple filter method with interpretation.	0.37		0.37	No.
88108	Cytopathology, concentration technique, smears and interpretation (*e.g.,* Saccomanno technique).	0.44		0.44	No.
88112	Cytopathology, selective cellular enhancement technique with interpretation (*e.g.,* liquid based slide preparation method), except cervical or vaginal.	0.56		0.56	No.
88160	Cytopathology, smears, any other source; screening and interpretation.	0.50		0.50	No.
88161	Cytopathology, smears, any other source; preparation, screening and interpretation.	0.50		0.50	No.
88162	Cytopathology, smears, any other source; extended study involving over 5 slides and/or multiple stains.	0.76		0.76	No.
88184	Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker.	0.00	0.00	0.00	No.
88185	Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; each additional marker.	0.00	0.00	0.00	No.
88187	Flow cytometry, interpretation; 2 to 8 markers	1.36	0.74	0.74	No.
88188	Flow cytometry, interpretation; 9 to 15 markers	1.69	1.40	1.20	No.
88189	Flow cytometry, interpretation; 16 or more markers	2.23	1.70	1.70	No.
88321	Consultation and report on referred slides prepared elsewhere.	1.63	1.63	1.63	No.
88323	Consultation and report on referred material requiring preparation of slides.	1.83	1.83	1.83	No.
88325	Consultation, comprehensive, with review of records and specimens, with report on referred material.	2.50	2.85	2.85	No.
88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure).	0.53		0.56	No.
88364	In situ hybridization (*e.g.,* FISH), per specimen; each additional single probe stain procedure.	0.67		0.70	No.
88369	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each additional single probe stain procedure.	0.67		0.67	No.
91110	Gastrointestinal tract imaging, intraluminal (*e.g.,* capsule endoscopy), esophagus through ileum, with interpretation and report.	3.64	2.49	2.49	No.
91111	Gastrointestinal tract imaging, intraluminal (*e.g.,* capsule endoscopy), esophagus with interpretation and report.	1.00	1.00	1.00	No.
91200	Liver elastography, mechanically induced shear wave (*e.g.,* vibration), without imaging, with interpretation and report.	0.27		0.27	No.
92132	Scanning computerized ophthalmic diagnostic imaging, anterior segment, with interpretation and report, unilateral or bilateral.	0.35	0.30	0.30	No.
92133	Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; optic nerve.	0.50	0.40	0.40	No.
92134	Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; retina.	0.50	0.45	0.45	No.
92235	Fluorescein angiography (includes multiframe imaging) with interpretation and report.	0.81	0.75	0.75	No.
92240	Indocyanine-green angiography (includes multiframe imaging) with interpretation and report.	1.10	0.80	0.80	No.
92250	Fundus photography with interpretation and report	0.44	0.40	0.40	No.
922X4	Fluorescein angiography and indocyanine-green angiography (includes multiframe imaging) performed at the same patient encounter with interpretation and report, unilateral or bilateral.	NEW	0.95	0.95	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
93050	Arterial pressure waveform analysis for assessment of central arterial pressures, includes obtaining waveform(s), digitization and application of nonlinear mathematical transformations to determine central arterial pressures and augmentation index, with interpretation and report, upper extremity artery, non-invasive.	0.17		0.17	No.
935X1	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve.	NEW	21.70	18.23	No.
935X2	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve.	NEW	17.97	14.50	No.
935X3	Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (list separately in addition to code for primary service).	NEW	8.00	6.81	No.
95144	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy, single dose vial(s) (specify number of vials).	0.06	0.06	0.06	No.
95165	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses).	0.06	0.06	0.06	No.
95812	Electroencephalogram (EEG) extended monitoring; 41–60 minutes.	1.08	1.08	1.08	No.
95813	Electroencephalogram (EEG) extended monitoring; greater than 1 hour.	1.73	1.63	1.63	No.
95957	Digital analysis of electroencephalogram (EEG) (*e.g.,* for epileptic spike analysis).	1.98	1.98	1.98	No.
95971	Electronic analysis of implanted neurostimulator pulse generator system (*e.g.,* rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (*i.e.,* peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming.	0.78		0.78	No.
95972	Electronic analysis of implanted neurostimulator pulse generator system (*e.g.,* rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (*i.e*, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming.	0.80		0.80	No.
961X0	Administration of patient-focused health risk assessment instrument (*e.g.,* health hazard appraisal) with scoring and documentation, per standardized instrument.	NEW	0.00	0.00	No.
961X1	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.	NEW	0.00	0.00	No.
96931	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, first lesion.	0.00	0.80	0.75	No.
96932	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition only, first lesion.	0.00	0.00	0.00	No.
96933	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; interpretation and report only, first lesion.	0.00	0.80	0.75	No.
96934	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, each additional lesion.	0.00	0.76	0.71	No.
96935	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition only, each additional lesion.	0.00	0.00	0.00	No.
96936	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; interpretation and report only, each additional lesion.	0.00	0.76	0.71	No.
97X61	Physical therapy evaluation; low complexity	NEW	0.75	1.20	Yes.
97X62	Physical therapy evaluation; moderate complexity	NEW	1.18	1.20	No.
97X63	Physical therapy evaluation; high complexity	NEW	1.50	1.20	Yes.
97X64	Reevaluation of physical therapy established plan of care	NEW	0.75	0.60	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
97X65	Occupational therapy evaluation; low complexity	NEW	0.88	1.20	Yes.
97X66	Occupational therapy evaluation; moderate complexity	NEW	1.20	1.20	No.
97X67	Occupational therapy evaluation; high complexity	NEW	1.70	1.20	Yes.
97X68	Reevaluation of occupational therapy care/established plan of care.	NEW	0.80	0.60	No.
991X1	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time, patient younger than 5 years of age.	NEW	0.50	0.50	No.
991X2	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time, patient age 5 years or older.	NEW	0.25	0.25	No.
991X3	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 minutes of intra-service time, patient younger than 5 years of age.	NEW	1.90	1.90	No.
991X4	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 minutes of intra-service time, patient age 5 years or older.	NEW	1.84	1.65	No.
991X5	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; each additional 15 minutes of intra-service time.	NEW	0.00	0.00	No.
991X6	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; each additional 15 minutes intra-service time.	NEW	1.25	1.25	No.
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.	1.77		2.33	No.
99358	Prolonged evaluation and management service before and/or after direct patient care; first hour.	2.10		2.10	No.
99359	Prolonged evaluation and management service before and/or after direct patient care; each additional 30 minutes.	1.00		1.00	No.
99487	Complex chronic care management services, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, establishment or substantial revision of a comprehensive care plan, moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.	0.00		1.00	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
99489	Complex chronic care management services, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, establishment or substantial revision of a comprehensive care plan, moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.	0.00		0.50	No.
G0416	Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method.	3.09	4.00	3.60	No.
GDDD1	Resource-intensive services for patients for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient lift, and adjustable padded leg supports) is medically necessary and used during the provision of an office/outpatient E/M visit (Add-on code, list separately in addition to primary procedure).	NEW		0.48	No.
GMMM1	Moderate sedation services provided by the same physician or other qualified health care professional performing a gastrointestinal endoscopic service (excluding biliary procedures) that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intraservice time.	NEW		0.10	No.
GPPP1	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.	NEW		1.59	No.
GPPP2	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.	NEW		1.42	No.
GPPP3	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		0.71	No.
GPPP6	Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history obtained from patient and/or caregiver, in office or other outpatient setting or home or domiciliary or rest home.	NEW		3.30	No.
GPPP7	Comprehensive assessment of and care planning for patients requiring chronic care management services (billed separately from monthly care management services).	NEW		0.87	No.
GPPPX	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 time, per calendar month.	NEW		0.61	No.
GTTT1	Telehealth consultation, critical care, physicians typically spend 60 minutes communicating with the patient via telehealth (initial).	NEW		4.00	No.
GTTT2	Telehealth consultation, critical care, physicians typically spend 50 minutes communicating with the patient via telehealth (subsequent).	NEW		3.86	No.

TABLE 24—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITHOUT REFINEMENT

HCPCS code	Description
00740	Anesth upper gi visualize.
00810	Anesth low intestine scope.
10030	Guide cathet fluid drainage.
11730	Removal of nail plate.
19298	Place breast rad tube/caths.
20245	Bone biopsy excisional.
20550	Inj tendon sheath/ligament.
20552	Inj trigger point 1/2 muscl.
20553	Inject trigger points 3/>.
20982	Ablate bone tumor(s) perq.
20983	Ablate bone tumor(s) perq.
22510	Perq cervicothoracic inject.
22511	Perq lumbosacral injection.
22512	Vertebroplasty addl inject.
22513	Perq vertebral augmentation.
22514	Perq vertebral augmentation.
22515	Perq vertebral augmentation.
22526	Idet single level.
22527	Idet 1 or more levels.
228X1	Insj stablj dev w/dcmprn.
228X4	Insj stablj dev w/o dcmprn.
28289	Repair hallux rigidus.
28292	Correction of bunion.
28296	Correction of bunion.
28297	Correction of bunion.
28298	Correction of bunion.
28299	Correction of bunion.
282X1	Corrj halux rigdus w/implt.
31615	Visualization of windpipe.
31622	Dx bronchoscope/wash.
31623	Dx bronchoscope/brush.
31624	Dx bronchoscope/lavage.
31625	Bronchoscopy w/biopsy(s).
31626	Bronchoscopy w/markers.
31627	Navigational bronchoscopy.
31628	Bronchoscopy/lung bx each.
31629	Bronchoscopy/needle bx each.
31632	Bronchoscopy/lung bx addl.
31633	Bronchoscopy/needle bx addl.
31634	Bronch w/balloon occlusion.
31635	Bronchoscopy w/fb removal.
31645	Bronchoscopy clear airways.
31646	Bronchoscopy reclear airway.
31652	Bronch ebus samplng 1/2 node.
31653	Bronch ebus samplng 3/> node.
31654	Bronch ebus ivntj perph les.
32405	Percut bx lung/mediastinum.
32550	Insert pleural cath.
32553	Ins mark thor for rt perq.
333X3	Perq clsr tcat l atr apndge.
334X1	Valvuloplasty aortic valve.
334X2	Valvuloplasty aortic valve.
35471	Repair arterial blockage.
35472	Repair arterial blockage.
35475	Repair arterial blockage.
35476	Repair venous blockage.
36010	Place catheter in vein.
36140	Establish access to artery.
36147	Access av dial grft for eval.
36148	Access av dial grft for proc.
36200	Place catheter in aorta.
36221	Place cath thoracic aorta.
36222	Place cath carotid/inom art.
36223	Place cath carotid/inom art.
36224	Place cath carotid art.

TABLE 24—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITHOUT REFINEMENT—Continued

HCPCS code	Description
36225	Place cath subclavian art.
36226	Place cath vertebral art.
36227	Place cath xtrnl carotid.
36228	Place cath intracranial art.
36245	Ins cath abd/l-ext art 1st.
36246	Ins cath abd/l-ext art 2nd.
36247	Ins cath abd/l-ext art 3rd.
36248	Ins cath abd/l-ext art addl.
36251	Ins cath ren art 1st unilat.
36252	Ins cath ren art 1st bilat.
36253	Ins cath ren art 2nd+ unilat.
36254	Ins cath ren art 2nd+ bilat.
36481	Insertion of catheter vein.
36555	Insert non-tunnel cv cath.
36557	Insert tunneled cv cath.
36558	Insert tunneled cv cath.
36560	Insert tunneled cv cath.
36561	Insert tunneled cv cath.
36563	Insert tunneled cv cath.
36565	Insert tunneled cv cath.
36566	Insert tunneled cv cath.
36568	Insert picc cath.
36570	Insert picvad cath.
36571	Insert picvad cath.
36576	Repair tunneled cv cath.
36578	Replace tunneled cv cath.
36581	Replace tunneled cv cath.
36582	Replace tunneled cv cath.
36583	Replace tunneled cv cath.
36585	Replace picvad cath.
36590	Removal tunneled cv cath.
36870	Percut thrombect av fistula.
369X7	Balo angiop ctr dialysis seg.
369X8	Stent plmt ctr dialysis seg.
369X9	Dialysis circuit embolj.
37183	Remove hepatic shunt (tips).
37184	Prim art m-thrmbc 1st vsl.
37185	Prim art m-thrmbc sbsq vsl.
37186	Sec art thrombectomy add-on.
37187	Venous mech thrombectomy.
37188	Venous m-thrombectomy add-on.
37191	Ins endovas vena cava filtr.
37192	Redo endovas vena cava filtr.
37193	Rem endovas vena cava filter.
37197	Remove intrvas foreign body.
37220	Iliac revasc.
37221	Iliac revasc w/stent.
37222	Iliac revasc add-on.
37223	Iliac revasc w/stent add-on.
37224	Fem/popl revas w/tla.
37225	Fem/popl revas w/ather.
37226	Fem/popl revasc w/stent.
37227	Fem/popl revasc stnt & ather.
37228	Tib/per revasc w/tla.
37229	Tib/per revasc w/ather.
37230	Tib/per revasc w/stent.
37231	Tib/per revasc stent & ather.
37232	Tib/per revasc add-on.
37233	Tibper revasc w/ather add-on.
37234	Revsc opn/prq tib/pero stent.
37235	Tib/per revasc stnt & ather.
37236	Open/perq place stent 1st.
37237	Open/perq place stent ea add.
37238	Open/perq place stent same.

TABLE 24—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITHOUT REFINEMENT—Continued

HCPCS code	Description
37239	Open/perq place stent ea add.
37241	Vasc embolize/occlude venous.
37242	Vasc embolize/occlude artery.
37243	Vasc embolize/occlude organ.
37244	Vasc embolize/occlude bleed.
37252	Intrvasc us noncoronary 1st.
37253	Intrvasc us noncoronary addl.
372X2	Trluml balo angiop addl art.
372X4	Trluml balo angiop addl vein.
43200	Esophagoscopy flexible brush.
43201	Esoph scope w/submucous inj.
43202	Esophagoscopy flex biopsy.
43206	Esoph optical endomicroscopy.
43213	Esophagoscopy retro balloon.
43215	Esophagoscopy flex remove fb.
43216	Esophagoscopy lesion removal.
43217	Esophagoscopy snare les remv.
43220	Esophagoscopy balloon <30 mm.
43226	Esoph endoscopy dilation.
43227	Esophagoscopy control bleed.
43229	Esophagoscopy lesion ablate.
43231	Esophagoscop ultrasound exam.
43232	Esophagoscopy w/us needle bx.
43235	Egd diagnostic brush wash.
43236	Uppr gi scope w/submuc inj.
43239	Egd biopsy single/multiple.
43245	Egd dilate stricture.
43247	Egd remove foreign body.
43248	Egd guide wire insertion.
43249	Esoph egd dilation <30 mm.
43250	Egd cautery tumor polyp.
43251	Egd remove lesion snare.
43252	Egd optical endomicroscopy.
43255	Egd control bleeding any.
43270	Egd lesion ablation.
432X1	Laps esophgl sphnctr agmnt.
432X2	Rmvl esophgl sphnctr dev.
43450	Dilate esophagus 1/mult pass.
43453	Dilate esophagus.
44380	Small bowel endoscopy br/wa.
44381	Small bowel endoscopy br/wa.
44382	Small bowel endoscopy.
44385	Endoscopy of bowel pouch.
44386	Endoscopy bowel pouch/biop.
44388	Colonoscopy thru stoma spx.
44389	Colonoscopy with biopsy.
44390	Colonoscopy for foreign body.
44391	Colonoscopy for bleeding.
44392	Colonoscopy & polypectomy.
44394	Colonoscopy w/snare.
44401	Colonoscopy with ablation.
44404	Colonoscopy w/injection.
44405	Colonoscopy w/dilation.
45303	Proctosigmoidoscopy dilate.
45305	Proctosigmoidoscopy w/bx.

TABLE 24—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITHOUT REFINEMENT—Continued

HCPCS code	Description
45307	Proctosigmoidoscopy fb.
45308	Proctosigmoidoscopy removal.
45309	Proctosigmoidoscopy removal.
45315	Proctosigmoidoscopy removal.
45317	Proctosigmoidoscopy bleed.
45320	Proctosigmoidoscopy ablate.
45332	Sigmoidoscopy w/fb removal.
45333	Sigmoidoscopy & polypectomy.
45334	Sigmoidoscopy for bleeding.
45335	Sigmoidoscopy w/submuc inj.
45338	Sigmoidoscopy w/tumr remove.
45340	Sig w/tndsc balloon dilation.
45346	Sigmoidoscopy w/ablation.
45350	Sgmdsc w/band ligation.
45378	Diagnostic colonoscopy.
45379	Colonoscopy w/fb removal.
45380	Colonoscopy and biopsy.
45381	Colonoscopy submucous njx.
45382	Colonoscopy w/control bleed.
45384	Colonoscopy w/lesion removal.
45385	Colonoscopy w/lesion removal.
45386	Colonoscopy w/balloon dilat.
45388	Colonoscopy w/ablation.
45398	Colonoscopy w/band ligation.
47000	Needle biopsy of liver.
47382	Percut ablate liver rf.
47383	Perq abltj lvr cryoablation.
49405	Image cath fluid colxn visc.
49406	Image cath fluid peri/retro.
49407	Image cath fluid trns/vgnl.
49411	Ins mark abd/pel for rt perq.
49418	Insert tun ip cath perc.
49440	Place gastrostomy tube perc.
49441	Place duod/jej tube perc.
49442	Place cecostomy tube perc.
49446	Change g-tube to g-j perc.
50200	Renal biopsy perq.
50382	Change ureter stent percut.
50384	Remove ureter stent percut.
50385	Change stent via transureth.

TABLE 24—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITHOUT REFINEMENT—Continued

HCPCS code	Description
50386	Remove stent via transureth.
50387	Change nephroureteral cath.
50430	Njx px nfrosgrm &/urtrgrm.
50432	Plmt nephrostomy catheter.
50433	Plmt nephroureteral catheter.
50434	Convert nephrostomy catheter.
50592	Perc rf ablate renal tumor.
50593	Perc cryo ablate renal tum.
50693	Plmt ureteral stent prq.
50694	Plmt ureteral stent prq.
50695	Plmt ureteral stent prq.
51702	Insert temp bladder cath.
51703	Insert bladder cath complex.
51720	Treatment of bladder lesion.
51784	Anal/urinary muscle study.
55700	Biopsy of prostate.
57155	Insert uteri tandem/ovoids.
58558	Hysteroscopy biopsy.
58559	Hysteroscopy lysis.
58560	Hysteroscopy resect septum.
58561	Hysteroscopy remove myoma.
58563	Hysteroscopy ablation.
585X1	Laps abltj uterine fibroids.
630X1	Ndsc dcmprn 1 ntrspc lumbar.
66720	Destruction ciliary body.
67101	Repair detached retina.
67105	Repair detached retina.
69300	Revise external ear.
767X1	Us abdl aorta screen aaa.
77332	Radiation treatment aid(s).
77333	Radiation treatment aid(s).
77334	Radiation treatment aid(s).
77470	Special radiation treatment.
77600	Hyperthermia treatment.
77605	Hyperthermia treatment.
77610	Hyperthermia treatment.
77615	Hyperthermia treatment.
91110	Gi tract capsule endoscopy.
91111	Esophageal capsule endoscopy.
92132	Cmptr ophth dx img ant segmt.
92133	Cmptr ophth img optic nerve.
92134	Cptr ophth dx img post segmt.

TABLE 24—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITHOUT REFINEMENT—Continued

HCPCS code	Description
92235	Eye exam with photos.
92240	Icg angiography.
92250	Eye exam with photos.
922X4	Fluorescein icg angiography.
92960	Cardioversion electric ext.
93312	Echo transesophageal.
93314	Echo transesophageal.
93451	Right heart cath.
93452	Left hrt cath w/ventrclgrphy.
93453	R&l hrt cath w/ventriclgrphy.
93454	Coronary artery angio s&i.
93455	Coronary art/grft angio s&i.
93456	R hrt coronary artery angio.
93457	R hrt art/grft angio.
93458	L hrt artery/ventricle angio.
93459	L hrt art/grft angio.
93460	R&l hrt art/ventricle angio.
93461	R&l hrt art/ventricle angio.
93464	Exercise w/hemodynamic meas.
93505	Biopsy of heart lining.
93566	Inject r ventr/atrial angio.
93567	Inject suprvlv aortography.
93568	Inject pulm art hrt cath.
935X1	Perq transcath cls mitral.
935X2	Perq transcath cls aortic.
93642	Electrophysiology evaluation.
93644	Electrophysiology evaluation.
95144	Antigen therapy services.
95165	Antigen therapy services.
95957	Eeg digital analysis.
961X0	Pt-focused hlth risk assmt.
961X1	Caregiver health risk assmt.
96440	Chemotherapy intracavitary.
96931	Rcm celulr subcelulr img skn.
96932	Rcm celulr subcelulr img skn.
97X64	Pt re-eval est plan care.
97X68	Ot re-eval est plan care.
991X1	Mod sed same phys/qhp <5 yrs.
991X2	Mod sed same phys/qhp 5/>yrs.
991X5	Mod sed oth phys/qhp 5/>yrs.
G0341	Percutaneous islet celltrans.
GMMM1	

TABLE 25: CY 2016 Proposed Codes With Direct PE Input Recommendations Accepted With Refinement

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)
11732	Remove nail plate add-on	EF015	mayo stand	NF		0	8	See preamble text	$0.01
11732	Remove nail plate add-on	EF031	table, power	NF		7	8	Refined equipment time to conform to changes in clinical labor time	$0.02
11732	Remove nail plate add-on	EQ137	instrument pack, basic ($500-$1499)	NF		0	8	See preamble text	$0.02
11732	Remove nail plate add-on	EQ168	light, exam	NF		7	8	Refined equipment time to conform to changes in clinical labor time	$0.00
11732	Remove nail plate add-on	L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	7	8	See preamble text	$0.37
11732	Remove nail plate add-on	SC031	needle, 30g	NF		1	0	Add-on code. Additional supplies not typical; see preamble text	-$0.34
11732	Remove nail plate add-on	SC051	syringe 10-12ml	NF		1	0	Add-on code. Additional supplies not typical; see preamble text	-$0.18
11732	Remove nail plate add-on	SG067	penrose drain (0.25in x 4in)	NF		1	0	Add-on code. Additional supplies not typical; see preamble text	-$0.50

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)
11732	Remove nail plate add-on	SH047	lidocaine 1%-2% inj (Xylocaine)	NF		10	0	Add-on code. Additional supplies not typical; see preamble text	-$0.35
11732	Remove nail plate add-on	SH064	silver sulfadiazene cream (Silvadene)	NF		0.5	0	Add-on code. Additional supplies not typical; see preamble text	-$0.08
11732	Remove nail plate add-on	SJ053	swab-pad, alcohol	NF		2	1	Add-on code. Additional supplies not typical; see preamble text	-$0.01
271X1	Clsd tx pelvic ring fx	L037D	RN/LPN/MTA	F	99213 36 minutes	1	0	See preamble text	-$13.32
271X1	Clsd tx pelvic ring fx	L037D	RN/LPN/MTA	F	99212 27 minutes	2	0	See preamble text	-$19.98
271X2	Clsd tx pelvic ring fx	L037D	RN/LPN/MTA	F	99212 27 minutes	1	0	See preamble text	-$9.99
271X2	Clsd tx pelvic ring fx	L037D	RN/LPN/MTA	F	99213 36 minutes	2	0	See preamble text	-$26.64
31575	Diagnostic laryngoscopy	EF008	chair with headrest, exam, reclining	NF		23	20	Refined equipment time to conform to changes in clinical labor time	-$0.03
31575	Diagnostic laryngoscopy	EQ167	light source, xenon	NF		0	17	Refined equipment time to conform to established policies for scope accessories	$0.47
31575	Diagnostic laryngoscopy	EQ170	light, fiberoptic headlight w-source	NF		23	20	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)
31575	Diagnostic laryngoscopy	EQ234	suction and pressure cabinet, ENT (SMR)	NF		23	20	Refined equipment time to conform to changes in clinical labor time	-$0.03
31575	Diagnostic laryngoscopy	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		0	17	Refined equipment time to conform to established policies for scope accessories	$1.01
31575	Diagnostic laryngoscopy	ES060	Video-flexible laryngoscope system	NF		44	0	See preamble text	-$14.00
31575	Diagnostic laryngoscopy	ES063	rhinolaryngoscope, flexible, video, non-channeled	NF		0	47	Refined equipment time to conform to established policies for scopes	$2.18
31575	Diagnostic laryngoscopy	L037D	RN/LPN/MTA	NF	Clean room/equipment by physician staff	3	0	Clinical labor task redundant with clinical labor task "Assist physician in performing the procedure" (L041B)	-$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)
31576	Laryngoscopy with biopsy	EQ167	light source, xenon	NF		0	28	Refined equipment time to conform to established policies for scope accessories	$0.78
31576	Laryngoscopy with biopsy	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		0	28	Refined equipment time to conform to established policies for scope accessories	$1.67
31576	Laryngoscopy with biopsy	ES061	Video-flexible channeled laryngoscope system	NF		55	0	See preamble text	-$21.23
31576	Laryngoscopy with biopsy	ES064	rhinolaryngoscope, flexible, video, channeled	NF		0	55	Refined equipment time to conform to established policies for scopes	$2.87
31577	Remove foreign body larynx	EF008	chair with headrest, exam, reclining	NF		99	95	Refined equipment time to conform to changes in clinical labor time	-$0.04
31577	Remove foreign body larynx	EF015	mayo stand	NF		99	95	Refined equipment time to conform to changes in clinical labor time	$0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31577	Remove foreign body larynx	EQ137	instrument pack, basic ($500-$1499)	NF		40	39	Refined equipment time to conform to changes in clinical labor time	$0.00
31577	Remove foreign body larynx	EQ167	light source, xenon	NF		0	29	Refined equipment time to conform to established policies for scope accessories	$0.80
31577	Remove foreign body larynx	EQ170	light, fiberoptic headlight w-source	NF		99	95	Refined equipment time to conform to changes in clinical labor time	-$0.03
31577	Remove foreign body larynx	EQ234	suction and pressure cabinet, ENT (SMR)	NF		99	95	Refined equipment time to conform to changes in clinical labor time	-$0.04
31577	Remove foreign body larynx	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		0	29	Refined equipment time to conform to established policies for scope accessories	$1.73
31577	Remove foreign body larynx	ES061	Video-flexible channeled laryngoscope system	NF		54	0	See preamble text	-$20.84

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)
31577	Remove foreign body larynx	ES064	rhinolaryngoscope, flexible, video, channeled	NF		0	59	Refined equipment time to conform to established policies for scopes	$3.08
31577	Remove foreign body larynx	L037D	RN/LPN/MTA	NF	Clean room/equipment by physician staff	3	0	Clinical labor task redundant with clinical labor task "Assist physician in performing the procedure" (L041B)	-$1.11
31577	Remove foreign body larynx	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	2	Clinical labor task redundant with clinical labor task "Assist physician in performing the procedure" (L041B)	-$0.37
31578	Removal of larynx lesion	EQ167	light source, xenon	NF		0	33	Refined equipment time to conform to established policies for scope accessories	$0.92
31578	Removal of larynx lesion	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		0	33	Refined equipment time to conform to established policies for scope accessories	$1.97

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)
31578	Removal of larynx lesion	ES061	Video-flexible channeled laryngoscope system	NF		54	0	See preamble text	-$20.84
31578	Removal of larynx lesion	ES064	rhinolaryngoscope, flexible, video, channeled	NF		0	60	Refined equipment time to conform to established policies for scopes	$3.13
31579	Diagnostic laryngoscopy	EF008	chair with headrest, exam, reclining	NF		31	27	Refined equipment time to conform to changes in clinical labor time	-$0.04
31579	Diagnostic laryngoscopy	EF015	mayo stand	NF		31	27	Refined equipment time to conform to changes in clinical labor time	$0.00
31579	Diagnostic laryngoscopy	EQ167	light source, xenon	NF		0	24	Refined equipment time to conform to established policies for scope accessories	$0.67
31579	Diagnostic laryngoscopy	EQ170	light, fiberoptic headlight w-source	NF		31	27	Refined equipment time to conform to changes in clinical labor time	-$0.03

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31579	Diagnostic laryngoscopy	EQ234	suction and pressure cabinet, ENT (SMR)	NF		31	27	Refined equipment time to conform to changes in clinical labor time	-$0.04
31579	Diagnostic laryngoscopy	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		0	24	Refined equipment time to conform to established policies for scope accessories	$1.43
31579	Diagnostic laryngoscopy	ES063	rhinolaryngoscope, flexible, video, non-channeled	NF		0	54	Refined equipment time to conform to established policies for scopes	$2.50
31579	Diagnostic laryngoscopy	ES065	stroboscopy system	NF		49	44	Refined equipment time to conform to established policies for scope accessories	-$0.38
31579	Diagnostic laryngoscopy	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	2	Clinical labor task redundant with clinical labor task "Assist physician in performing the procedure" (L041B)	-$0.37

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31579	Diagnostic laryngoscopy	L037D	RN/LPN/MTA	NF	Clean room/equipment by physician staff	3	0	Clinical labor task redundant with clinical labor task "Assist physician in performing the procedure" (L041B)	-$1.11
31580	Revision of larynx	EQ137	instrument pack, basic ($500-$1499)	F		138	129	Refined equipment time to conform to established policies for surgical instrument packs	-$0.02
31580	Revision of larynx	EQ167	light source, xenon	F		0	108	Equipment item replaces another item; see preamble text EQ170	$3.00
31580	Revision of larynx	EQ170	light, fiberoptic headlight w-source	F		108	0	Equipment item replaced by another item; see preamble text EQ167	-$0.85
31580	Revision of larynx	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	F		0	108	Refined equipment time to conform to established policies for scope accessories	$6.44
31580	Revision of larynx	ES060	Video-flexible laryngoscope system	F		198	0	See preamble text	-$62.98

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)
31580	Revision of larynx	ES063	rhinolaryngoscope, flexible, video, non-channeled	F		0	189	Refined equipment time to conform to established policies for scopes	$8.76
31584	Treat larynx fracture	EQ137	instrument pack, basic ($500-$1499)	F		138	129	Refined equipment time to conform to established policies for surgical instrument packs	-$0.02
31584	Treat larynx fracture	EQ167	light source, xenon	F		0	108	Equipment item replaces another item; see preamble text EQ170	$3.00
31584	Treat larynx fracture	EQ170	light, fiberoptic headlight w-source	F		108	0	Equipment item replaced by another item; see preamble text EQ167	-$0.85
31584	Treat larynx fracture	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	F		0	108	Refined equipment time to conform to established policies for scope accessories	$6.44
31584	Treat larynx fracture	ES060	Video-flexible laryngoscope system	F		198	0	See preamble text	-$62.98

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)
31584	Treat larynx fracture	ES063	rhinolaryngoscope, flexible, video, non-channeled	F		0	189	Refined equipment time to conform to established policies for scopes	$8.76
31587	Revision of larynx	EQ137	instrument pack, basic ($500-$1499)	F		138	129	Refined equipment time to conform to established policies for surgical instrument packs	-$0.02
31587	Revision of larynx	EQ167	light source, xenon	F		0	108	Equipment item replaces another item; see preamble text EQ170	$3.00
31587	Revision of larynx	EQ170	light, fiberoptic headlight w-source	F		108	0	Equipment item replaced by another item; see preamble text EQ167	-$0.85
31587	Revision of larynx	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	F		0	108	Refined equipment time to conform to established policies for scope accessories	$6.44
31587	Revision of larynx	ES060	Video-flexible laryngoscope system	F		198	0	See preamble text	-$62.98

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)
31587	Revision of larynx	ES063	rhinolaryngoscope, flexible, video, non-channeled	F		0	189	Refined equipment time to conform to established policies for scopes	$8.76
317X1	Largsc w/laser dstrj les	EQ167	light source, xenon	NF		0	38	Refined equipment time to conform to established policies for scope accessories	$1.05
317X1	Largsc w/laser dstrj les	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		0	38	Refined equipment time to conform to established policies for scope accessories	$2.27
317X1	Largsc w/laser dstrj les	ES061	Video-flexible channeled laryngoscope system	NF		59	0	See preamble text	-$22.77
317X1	Largsc w/laser dstrj les	ES064	rhinolaryngoscope, flexible, video, channeled	NF		0	65	Refined equipment time to conform to established policies for scopes	$3.39
317X1	Largsc w/laser dstrj les	SF029	laser tip, bare (single use)	NF		0	1	Supply item replaces another item; see preamble SF030	$150.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
317X1	Largsc w/laser dstrj les	SF030	laser tip, diffuser fiber	NF		1	0	Supply item replaced by another item; see preamble SF029	-$197.50
317X2	Largsc w/ther injection	EQ167	light source, xenon	NF		0	33	Refined equipment time to conform to established policies for scope accessories	$0.92
317X2	Largsc w/ther injection	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		0	33	Refined equipment time to conform to established policies for scope accessories	$1.97
317X2	Largsc w/ther injection	ES061	Video-flexible channeled laryngoscope system	NF		54	0	See preamble text	-$20.84
317X2	Largsc w/ther injection	ES064	rhinolaryngoscope, flexible, video, channeled	NF		0	60	Refined equipment time to conform to established policies for scopes	$3.13
317X3	Largsc w/njx augmentation	EQ167	light source, xenon	NF		0	33	Refined equipment time to conform to established policies for scope accessories	$0.92

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)
317X3	Largsc w/njx augmentation	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		0	33	Refined equipment time to conform to established policies for scope accessories	$1.97
317X3	Largsc w/njx augmentation	ES060	Video-flexible laryngoscope system	NF		60	0	See preamble text	-$19.09
317X3	Largsc w/njx augmentation	ES063	rhinolaryngoscope, flexible, video, non-channeled	NF		0	60	Refined equipment time to conform to established policies for scopes	$2.78
315X1	Laryngoplasty laryngeal sten	EQ137	instrument pack, basic ($500-$1499)	F		138	129	Refined equipment time to conform to established policies for surgical instrument packs	-$0.02
315X1	Laryngoplasty laryngeal sten	EQ167	light source, xenon	F		0	108	Equipment item replaces another item; see preamble text EQ170	$3.00
315X1	Laryngoplasty laryngeal sten	EQ170	light, fiberoptic headlight w-source	F		108	0	Equipment item replaced by another item; see preamble text EQ167	-$0.85

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)
315X1	Laryngoplasty laryngeal sten	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	F		0	108	Refined equipment time to conform to established policies for scope accessories	$6.44
315X1	Laryngoplasty laryngeal sten	ES060	Video-flexible laryngoscope system	F		198	0	See preamble text	-$62.98
315X1	Laryngoplasty laryngeal sten	ES063	rhinolaryngoscope, flexible, video, non-channeled	F		0	189	Refined equipment time to conform to established policies for scopes	$8.76
315X2	Laryngoplasty laryngeal sten	EQ137	instrument pack, basic ($500-$1499)	F		138	129	Refined equipment time to conform to established policies for surgical instrument packs	-$0.02
315X2	Laryngoplasty laryngeal sten	EQ167	light source, xenon	F		0	108	Equipment item replaces another item; see preamble text EQ170	$3.00
315X2	Laryngoplasty laryngeal sten	EQ170	light, fiberoptic headlight w-source	F		108	0	Equipment item replaced by another item; see preamble text EQ167	-$0.85
315X2	Laryngoplasty laryngeal sten	ES031	video system, endoscopy (processor, digital capture, monitor,	F		0	108	Refined equipment time to conform to established policies for scope accessories	$6.44

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)
			printer, cart)						
315X2	Laryngoplasty laryngeal sten	ES060	Video-flexible laryngoscope system	F		198	0	See preamble text	-$62.98
315X2	Laryngoplasty laryngeal sten	ES063	rhinolaryngoscope, flexible, video, non-channeled	F		0	189	Refined equipment time to conform to established policies for scopes	$8.76
315X3	Laryngoplasty laryngeal sten	EQ137	instrument pack, basic ($500-$1499)	F		138	129	Refined equipment time to conform to established policies for surgical instrument packs	-$0.02
315X3	Laryngoplasty laryngeal sten	EQ167	light source, xenon	F		0	108	Equipment item replaces another item; see preamble text EQ170	$3.00
315X3	Laryngoplasty laryngeal sten	EQ170	light, fiberoptic headlight w-source	F		108	0	Equipment item replaced by another item; see preamble text EQ167	-$0.85

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)
315X3	Laryngoplasty laryngeal sten	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	F		0	108	Refined equipment time to conform to established policies for scope accessories	$6.44
315X3	Laryngoplasty laryngeal sten	ES060	Video-flexible laryngoscope system	F		198	0	See preamble text	-$62.98
315X3	Laryngoplasty laryngeal sten	ES063	rhinolaryngoscope, flexible, video, non-channeled	F		0	189	Refined equipment time to conform to established policies for scopes	$8.76
315X4	Laryngoplasty laryngeal sten	EQ137	instrument pack, basic ($500-$1499)	F		138	129	Refined equipment time to conform to established policies for surgical instrument packs	-$0.02
315X4	Laryngoplasty laryngeal sten	EQ167	light source, xenon	F		0	108	Equipment item replaces another item; see preamble text EQ170	$3.00
315X4	Laryngoplasty laryngeal sten	EQ170	light, fiberoptic headlight w-source	F		108	0	Equipment item replaced by another item; see preamble text EQ167	-$0.85
315X4	Laryngoplasty laryngeal sten	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	F		0	108	Refined equipment time to conform to established policies for scope accessories	$6.44

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)
315X4	Laryngoplasty laryngeal sten	ES060	Video-flexible laryngoscope system	F		198	0	See preamble text	-$62.98
315X4	Laryngoplasty laryngeal sten	ES063	rhinolaryngoscope, flexible, video, non-channeled	F		0	189	Refined equipment time to conform to established policies for scopes	$8.76
315X5	Laryngoplasty medialization	EQ137	instrument pack, basic ($500-$1499)	F		138	129	Refined equipment time to conform to established policies for surgical instrument packs	-$0.02
315X5	Laryngoplasty medialization	EQ167	light source, xenon	F		0	108	Equipment item replaces another item; see preamble text EQ170	$3.00
315X5	Laryngoplasty medialization	EQ170	light, fiberoptic headlight w-source	F		108	0	Equipment item replaced by another item; see preamble text EQ167	-$0.85
315X5	Laryngoplasty medialization	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	F		0	108	Refined equipment time to conform to established policies for scope accessories	$6.44
315X5	Laryngoplasty medialization	ES060	Video-flexible laryngoscope system	F		198	0	See preamble text	-$62.98
315X5	Laryngoplasty medialization	ES063	rhinolaryngoscope, flexible, video, non-channeled	F		0	189	Refined equipment time to conform to established policies for scopes	$8.76
315X6	Cricotracheal resection	EQ137	instrument pack, basic ($500-$1499)	F		138	129	Refined equipment time to conform to established policies for surgical instrument packs	-$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)
315X6	Cricotracheal resection	EQ167	light source, xenon	F		0	108	Equipment item replaces another item; see preamble text EQ170	$3.00
315X6	Cricotracheal resection	EQ170	light, fiberoptic headlight w-source	F		108	0	Equipment item replaced by another item; see preamble text EQ167	-$0.85
315X6	Cricotracheal resection	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	F		0	108	Refined equipment time to conform to established policies for scope accessories	$6.44
315X6	Cricotracheal resection	ES060	Video-flexible laryngoscope system	F		198	0	See preamble text	-$62.98
315X6	Cricotracheal resection	ES063	rhinolaryngoscope, flexible, video, non-channeled	F		0	189	Refined equipment time to conform to established policies for scopes	$8.76
364X2	Endovenous mchnchem add-on	EF014	light, surgical	NF		0	30	Equipment item replaces another item; see preamble text EL015	$0.30
364X2	Endovenous mchnchem add-on	EF031	table, power	NF		0	30	Equipment item replaces another item; see preamble text EL015	$0.49

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)
364X2	Endovenous mchnchem add-on	EL015	room, ultrasound, general	NF		30	0	Equipment item replaced by another item; see preamble text EQ250	-$42.05
364X2	Endovenous mchnchem add-on	EQ250	ultrasound unit, portable	NF		0	30	Equipment item replaces another item; see preamble text EL015	$3.49
364X2	Endovenous mchnchem add-on	SH108	Sotradecol Sclerosing Agent	NF		2	1	Refined supply quantity to what is typical for the procedure	-$110.20
369X1	Intro cath dialysis circuit	ED050	PACS Workstation Proxy	NF		54	52	Refined equipment time to conform to changes in clinical labor time	-$0.04
369X1	Intro cath dialysis circuit	EL011	room, angiography	NF		37	35	Refined equipment time to conform to changes in clinical labor time	-$10.51
369X1	Intro cath dialysis circuit	L037D	RN/LPN/MTA	NF	Prepare and position pt/ monitor pt/ set up IV	5	3	See preamble text	-$0.74
369X2	Intro cath dialysis circuit	ED050	PACS Workstation Proxy	NF		69	67	Refined equipment time to conform to changes in clinical labor time	-$0.04
369X2	Intro cath dialysis circuit	EL011	room, angiography	NF		52	50	Refined equipment time to conform to changes in clinical labor time	-$10.51
369X2	Intro cath dialysis circuit	L037D	RN/LPN/MTA	NF	Prepare and position pt/	5	3	See preamble text	-$0.74

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)
					monitor pt/ set up IV				
369X3	Intro cath dialysis circuit	ED050	PACS Workstation Proxy	NF		79	77	Refined equipment time to conform to changes in clinical labor time	-$0.04
369X3	Intro cath dialysis circuit	EL011	room, angiography	NF		62	60	Refined equipment time to conform to changes in clinical labor time	-$10.51
369X3	Intro cath dialysis circuit	L037D	RN/LPN/MTA	NF	Prepare and position pt/ monitor pt/ set up IV	5	3	See preamble text	-$0.74
369X3	Intro cath dialysis circuit	SA103	stent, vascular, deployment system, Cordis SMART	NF		0	1	Supply item replaces another item; see preamble SD254	$1,645.00
369X3	Intro cath dialysis circuit	SD254	covered stent (VIABAHN, Gore)	NF		1	0	Supply item replaced by another item; see preamble SA103	-$3,768.00
369X4	Thrmbc/nfs dialysis circuit	ED050	PACS Workstation Proxy	NF		89	87	Refined equipment time to conform to changes in clinical labor time	-$0.04
369X4	Thrmbc/nfs dialysis circuit	EL011	room, angiography	NF		72	70	Refined equipment time to conform to changes in clinical labor time	-$10.51

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)
369X4	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X4	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Complete preservice diagnostic and referral forms	3	0	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X4	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Follow-up phone calls and prescriptions	6	0	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$2.22
369X4	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Prepare and position pt/ monitor pt/ set up IV	5	3	See preamble text	-$0.74
369X4	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Follow-up phone calls and prescriptions	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X4	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$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)
369X4	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X4	Thrmbc/nfs dialysis circuit	SA015	kit, for percutaneous thrombolytic device (Trerotola)	NF		1	0	Supply removed due to redundancy when used together with supply SD032	-$487.50
369X4	Thrmbc/nfs dialysis circuit	SG095	Hemostatic patch	NF		2	1	Refined supply quantity to what is typical for the procedure	-$35.75
369X5	Thrmbc/nfs dialysis circuit	ED050	PACS Workstation Proxy	NF		104	102	Refined equipment time to conform to changes in clinical labor time	-$0.04
369X5	Thrmbc/nfs dialysis circuit	EL011	room, angiography	NF		87	85	Refined equipment time to conform to changes in clinical labor time	-$10.51
369X5	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Follow-up phone calls and prescriptions	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X5	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$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)
369X5	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X5	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Follow-up phone calls and prescriptions	6	0	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$2.22
369X5	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Complete preservice diagnostic and referral forms	3	0	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X5	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X5	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Prepare and position pt/ monitor pt/ set up IV	5	3	See preamble text	-$0.74
369X5	Thrmbc/nfs dialysis circuit	SA015	kit, for percutaneous thrombolytic device (Trerotola)	NF		1	0	Supply removed due to redundancy when used together with supply SD032	-$487.50

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)
369X5	Thrmbc/nfs dialysis circuit	SG095	Hemostatic patch	NF		2	1	Refined supply quantity to what is typical for the procedure	-$35.75
369X6	Thrmbc/nfs dialysis circuit	ED050	PACS Workstation Proxy	NF		119	117	Refined equipment time to conform to changes in clinical labor time	-$0.04
369X6	Thrmbc/nfs dialysis circuit	EL011	room, angiography	NF		102	100	Refined equipment time to conform to changes in clinical labor time	-$10.51
369X6	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Follow-up phone calls and prescriptions	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X6	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$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)
369X6	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X6	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Complete preservice diagnostic and referral forms	3	0	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X6	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Follow-up phone calls and prescriptions	6	0	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$2.22
369X6	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X6	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Prepare and position pt/ monitor pt/ set up IV	5	3	See preamble text	-$0.74
369X6	Thrmbc/nfs dialysis circuit	SA015	kit, for percutaneous thrombolytic device (Trerotola)	NF		1	0	Supply removed due to redundancy when used together with supply SD032	-$487.50
369X6	Thrmbc/nfs dialysis circuit	SA103	stent, vascular, deployment system, Cordis SMART	NF		0	1	Supply item replaces another item; see preamble SD254	$1,645.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
369X6	Thrmbc/nfs dialysis circuit	SD254	covered stent (VIABAHN, Gore)	NF		1	0	Supply item replaced by another item; see preamble SA103	-$3,768.00
369X6	Thrmbc/nfs dialysis circuit	SG095	Hemostatic patch	NF		2	1	Refined supply quantity to what is typical for the procedure	-$35.75
36X41	Endovenous mchnchem 1st vein	EF014	light, surgical	NF		0	48	Equipment item replaces another item; see preamble text EL015	$0.48
36X41	Endovenous mchnchem 1st vein	EF031	table, power	NF		0	48	Equipment item replaces another item; see preamble text EL015	$0.78
36X41	Endovenous mchnchem 1st vein	EL015	room, ultrasound, general	NF		39	0	Equipment item replaced by another item; see preamble text EQ250	-$54.67
36X41	Endovenous mchnchem 1st vein	EQ250	ultrasound unit, portable	NF		0	48	Equipment item replaces another item; see preamble text EL015	$5.58
36X41	Endovenous mchnchem 1st vein	L037D	RN/LPN/MTA	NF	Prepare room, equipment, supplies	2	0	See preamble text	-$0.74

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)
36X41	Endovenous mchnchem 1st vein	L054A	Vascular Technologist	NF	Exam documents scanned into U/S machinc. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	1	0	See preamble text	-$0.54
36X41	Endovenous mchnchem 1st vein	L054A	Vascular Technologist	NF	Review examination with interpreting MD	2	0	See preamble text	-$1.08
36X41	Endovenous mchnchem 1st vein	L054A	Vascular Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	2	0	See preamble text	-$1.08

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36X41	Endovenous mchnchem 1st vein	L054A	Vascular Technologist	NF	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	2	0	See preamble text	-$1.08
36X41	Endovenous mchnchem 1st vein	L054A	Vascular Technologist	NF	Availability of prior images confirmed	2	0	See preamble text	-$1.08
36X41	Endovenous mchnchem 1st vein	SA016	kit, guidewire introducer (Micro-Stick)	NF		1	0	Supply not typically used in this service	-$23.00
36X41	Endovcnous mchnchem 1st vein	SH108	Sotradccol Sclerosing Agent	NF		2	1	Rcfincd supply quantity to what is typical for the procedure	-$110.20

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)
372X1	Trluml balo angiop 1st art	ED050	PACS Workstation Proxy	NF		91	89	Refined equipment time to conform to changes in clinical labor time	-$0.04
372X1	Trluml balo angiop 1st art	EL011	room, angiography	NF		72	70	Refined equipment time to conform to changes in clinical labor time	-$10.51
372X1	Trluml balo angiop 1st art	L037D	RN/LPN/MTA	NF	Prepare and position patient/ monitor patient/ set up IV	5	3	See preamble text	-$0.74
372X1	Trluml balo angiop 1st art	SB009	drape, sterile, femoral	NF		1	0	Supply item replaced by another item; see preamble SB011	-$15.95
372X1	Trluml balo angiop 1st art	SB011	drape, sterile, fenestrated 16in x 29in	NF		0	1	Supply item replaces another item; see preamble SB009	$0.56

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)
372X3	Trluml balo angiop 1st vein	ED050	PACS Workstation Proxy	NF		91	89	Refined equipment time to conform to changes in clinical labor time	-$0.04
372X3	Trluml balo angiop 1st vein	EL011	room, angiography	NF		72	70	Refined equipment time to conform to changes in clinical labor time	-$10.51
372X3	Trluml balo angiop 1st vein	L037D	RN/LPN/MTA	NF	Prepare and position patient/ monitor patient/ set up IV	5	3	See preamble text	-$0.74
372X3	Trluml balo angiop 1st vein	SB009	drape, sterile, femoral	NF		1	0	Supply item replaced by another item; see preamble	-$15.95
372X3	Trluml balo angiop 1st vein	SB011	drape, sterile, fenestrated 16in x 29in	NF		0	1	Supply item replaces another item; see preamble	$0.56

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)
47531	Injection for cholangiogram	ED050	PACS Workstation Proxy	NF		51	46	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11
47531	Injection for cholangiogram	EF018	stretcher	NF		87	82	Refined equipment time to conform to established policies for equipment with 4x monitoring time	-$0.03
47531	Injection for cholangiogram	EF027	table, instrument, mobile	NF		87	82	Refined equipment time to conform to established policies for equipment with 4x monitoring time	-$0.01
47531	Injection for cholangiogram	EL011	room, angiography	NF		27	24	Refined equipment time to conform to changes in clinical labor time	-$15.76
47531	Injection for cholangiogram	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		87	82	Refined equipment time to conform to established policies for equipment with 4x monitoring time	-$0.07
47531	Injection for cholangiogram	EQ032	IV infusion pump	NF		87	82	Refined equipment time to conform to established policies for equipment with 4x	-$0.03

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								monitoring time	
47531	Injection for cholangiogram	EQ168	light, exam	NF		51	40	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
47531	Injection for cholangiogram	L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	15	0	Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure	-$5.55
47531	Injection for cholangiogram	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23
47531	Injection for cholangiogram	L051A	RN	NF	Sedate/Apply anesthesia	2	0	Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure	-$1.02

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)
47532	Injection for cholangiogram	ED050	PACS Workstation Proxy	NF		81	76	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11
47532	Injection for cholangiogram	EF018	stretcher	NF		297	187	See preamble text MS minutes backed out input	-$0.56
47532	Injection for cholangiogram	EF027	table, instrument, mobile	NF		297	187	See preamble text MS minutes backed out input	-$0.16
47532	Injection for cholangiogram	EL011	room, angiography	NF		57	54	Refined equipment time to conform to changes in clinical labor time	-$15.76
47532	Injection for cholangiogram	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		297	187	See preamble text MS minutes backed out input	-$1.53
47532	Injection for cholangiogram	EQ032	IV infusion pump	NF		297	187	See preamble text MS minutes backed out input	-$0.70

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)
47532	Injection for cholangiogram	EQ168	light, exam	NF		81	70	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
47532	Injection for cholangiogram	EQ250	ultrasound unit, portable	NF		81	70	Refined equipment time to conform to established policies for non-highly technical equipment	-$1.28
47532	Injection for cholangiogram	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23
47532	Injection for cholangiogram	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	45	0	See preamble text MS minutes backed out input	-$22.95
47532	Injection for cholangiogram	L051A	RN	NF	Monitor pt. following moderate sedation	15	0	See preamble text MS minutes backed out input	-$7.65

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47532	Injection for cholangiogram	L051A	RN	NF	Sedate/Apply anesthesia	2	0	See preamble text MS minutes backed out input	-$1.02
47532	Injection for cholangiogram	SA044	pack, conscious sedation	NF		1	0	See preamble text MS supply backed out input	-$17.31
47533	Plmt biliary drainage cath	ED050	PACS Workstation Proxy	NF		96	91	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11
47533	Plmt biliary drainage cath	EF018	stretcher	NF		312	187	See preamble text MS minutes backed out input	-$0.64
47533	Plmt biliary drainage cath	EF027	table, instrument, mobile	NF		312	187	See preamble text MS minutes backed out input	-$0.18

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)
47533	Plmt biliary drainage cath	EL011	room, angiography	NF		72	69	Refined equipment time to conform to changes in clinical labor time	-$15.76
47533	Plmt biliary drainage cath	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		312	187	See preamble text MS minutes backed out input	-$1.74
47533	Plmt biliary drainage cath	EQ032	IV infusion pump	NF		312	187	See preamble text MS minutes backed out input	-$0.79
47533	Plmt biliary drainage cath	EQ168	light, exam	NF		96	85	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
47533	Plmt biliary drainage cath	EQ250	ultrasound unit, portable	NF		96	85	Refined equipment time to conform to established policies for non-highly technical equipment	-$1.28
47533	Plmt biliary drainage cath	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23

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)
47533	Plmt biliary drainage cath	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	60	0	See preamble text MS minutes backed out input	-$30.60
47533	Plmt biliary drainage cath	L051A	RN	NF	Monitor pt. following moderate sedation	15	0	See preamble text MS minutes backed out input	-$7.65
47533	Plmt biliary drainage cath	L051A	RN	NF	Sedate/Apply anesthesia	2	0	See preamble text MS minutes backed out input	-$1.02
47533	Plmt biliary drainage cath	SA044	pack, conscious sedation	NF		1	0	See preamble text MS supply backed out input	-$17.31
47534	Plmt biliary drainage cath	ED050	PACS Workstation Proxy	NF		104	99	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11
47534	Plmt biliary drainage cath	EF018	stretcher	NF		320	187	See preamble text MS minutes backed out input	-$0.68
47534	Plmt biliary drainage cath	EF027	table, instrument, mobile	NF		320	187	See preamble text MS minutes backed out input	-$0.19

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)
47534	Plmt biliary drainage cath	EL011	room, angiography	NF		80	77	Refined equipment time to conform to changes in clinical labor time	-$15.76
47534	Plmt biliary drainage cath	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		320	187	See preamble text MS minutes backed out input	-$1.86
47534	Plmt biliary drainage cath	EQ032	IV infusion pump	NF		320	187	See preamble text MS minutes backed out input	-$0.84
47534	Plmt biliary drainage cath	EQ168	light, exam	NF		104	93	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
47534	Plmt biliary drainage cath	EQ250	ultrasound unit, portable	NF		104	93	Refined equipment time to conform to established policies for non-highly technical equipment	-$1.28

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47534	Plmt biliary drainage cath	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23
47534	Plmt biliary drainage cath	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	68	0	See preamble text MS minutes backed out input	-$34.68
47534	Plmt biliary drainage cath	L051A	RN	NF	Monitor pt. following moderate sedation	15	0	See preamble text MS minutes backed out input	-$7.65
47534	Plmt biliary drainage cath	L051A	RN	NF	Sedate/Apply anesthesia	2	0	See preamble text MS minutes backed out input	-$1.02
47534	Plmt biliary drainage cath	SA044	pack, conscious sedation	NF		1	0	See preamble text MS supply backed out input	-$17.31
47535	Conversion ext bil drg cath	ED050	PACS Workstation Proxy	NF		81	76	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11

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)
47535	Conversion ext bil drg cath	EF018	stretcher	NF		297	187	See preamble text MS minutes backed out input	-$0.56
47535	Conversion ext bil drg cath	EF027	table, instrument, mobile	NF		297	187	See preamble text MS minutes backed out input	-$0.16
47535	Conversion ext bil drg cath	EL011	room, angiography	NF		57	54	Refined equipment time to conform to changes in clinical labor time	-$15.76
47535	Conversion ext bil drg cath	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		297	187	See preamble text MS minutes backed out input	-$1.53
47535	Conversion ext bil drg cath	EQ032	IV infusion pump	NF		297	187	See preamble text MS minutes backed out input	-$0.70
47535	Conversion ext bil drg cath	EQ168	light, exam	NF		81	70	Refined equipment time to conform to established policies for non-highly technical equipment	-$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)
47535	Conversion ext bil drg cath	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23
47535	Conversion ext bil drg cath	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	45	0	See preamble text MS minutes backed out input	-$22.95
47535	Conversion ext bil drg cath	L051A	RN	NF	Monitor pt. following moderate sedation	15	0	See preamble text MS minutes backed out input	-$7.65
47535	Conversion ext bil drg cath	L051A	RN	NF	Sedate/Apply anesthesia	2	0	See preamble text MS minutes backed out input	-$1.02
47535	Conversion ext bil drg cath	SA044	pack, conscious sedation	NF		1	0	See preamble text MS supply backed out input	-$17.31
47536	Exchange biliary drg cath	ED050	PACS Workstation Proxy	NF		56	51	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11

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)
47536	Exchange biliary drg cath	EF018	stretcher	NF		152	67	See preamble text MS minutes backed out input	-$0.43
47536	Exchange biliary drg cath	EF027	table, instrument, mobile	NF		152	67	See preamble text MS minutes backed out input	-$0.12
47536	Exchange biliary drg cath	EL011	room, angiography	NF		32	29	Refined equipment time to conform to changes in clinical labor time	-$15.76
47536	Exchange biliary drg cath	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		152	67	See preamble text MS minutes backed out input	-$1.19
47536	Exchange biliary drg cath	EQ032	IV infusion pump	NF		152	67	See preamble text MS minutes backed out input	-$0.54
47536	Exchange biliary drg cath	EQ168	light, exam	NF		56	45	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
47536	Exchange biliary drg cath	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23

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)
47536	Exchange biliary drg cath	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	20	0	See preamble text MS minutes backed out input	-$10.20
47536	Exchange biliary drg cath	L051A	RN	NF	Monitor pt. following moderate sedation	15	0	See preamble text MS minutes backed out input	-$7.65
47536	Exchange biliary drg cath	L051A	RN	NF	Sedate/Apply anesthesia	2	0	See preamble text MS minutes backed out input	-$1.02
47536	Exchange biliary drg cath	SA044	pack, conscious sedation	NF		1	0	See preamble text MS supply backed out input	-$17.31
47537	Removal biliary drg cath	ED050	PACS Workstation Proxy	NF		51	46	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11

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)
47537	Removal biliary drg cath	EF018	stretcher	NF		87	82	Refined equipment time to conform to established policies for equipment with 4x monitoring time	-$0.03
47537	Removal biliary drg cath	EF027	table, instrument, mobile	NF		87	82	Refined equipment time to conform to established policies for equipment with 4x monitoring time	-$0.01
47537	Removal biliary drg cath	EL011	room, angiography	NF		27	24	Refined equipment time to conform to changes in clinical labor time	-$15.76
47537	Removal biliary drg cath	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		87	82	Refined equipment time to conform to established policies for equipment with 4x monitoring time	-$0.07
47537	Removal biliary drg cath	EQ032	IV infusion pump	NF		87	82	Refined equipment time to conform to established policies for equipment with 4x monitoring time	-$0.03
47537	Removal biliary drg cath	EQ168	light, exam	NF		51	40	Refined equipment time to conform to established policies for non-highly technical equipment	-$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)
47537	Removal biliary drg cath	L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	15	0	Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure	-$5.55
47537	Removal biliary drg cath	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23
47537	Removal biliary drg cath	L051A	RN	NF	Sedate/Apply anesthesia	2	0	Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure	-$1.02
47538	Perq plmt bile duct stent	ED050	PACS Workstation Proxy	NF		89	84	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11
47538	Perq plmt bile duct stent	EF018	stretcher	NF		305	187	See preamble text MS minutes backed out input	-$0.60
47538	Perq plmt bile duct stent	EF027	table, instrument, mobile	NF		305	187	See preamble text MS minutes backed out input	-$0.17

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)
47538	Perq plmt bile duct stent	EL011	room, angiography	NF		65	62	Refined equipment time to conform to changes in clinical labor time	-$15.76
47538	Perq plmt bile duct stent	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		305	187	See preamble text MS minutes backed out input	-$1.65
47538	Perq plmt bile duct stent	EQ032	IV infusion pump	NF		305	187	See preamble text MS minutes backed out input	-$0.75
47538	Perq plmt bile duct stent	EQ168	light, exam	NF		89	78	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
47538	Perq plmt bile duct stent	L041B	Radiologic Technologist	NF	Clean room/equip ment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23
47538	Perq plmt bile duct stent	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	53	0	See preamble text MS minutes backed out input	-$27.03
47538	Perq plmt bile duct stent	L051A	RN	NF	Monitor pt. following moderate sedation	15	0	See preamble text MS minutes backed out input	-$7.65
47538	Perq plmt bile duct stent	L051A	RN	NF	Sedate/App ly anesthesia	2	0	See preamble text MS minutes backed out input	-$1.02

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)
47538	Perq plmt bile duct stent	SA044	pack, conscious sedation	NF		1	0	See preamble text MS supply backed out input	-$17.31
47538	Perq plmt bile duct stent	SD150	catheter, balloon ureteral (Dowd)	NF		0	2	Supply item replaces another item; see preamble SD152	$130.00
47538	Perq plmt bile duct stent	SD152	catheter, balloon, PTA	NF		2	0	Supply item replaced by another item; see preamble SD150	-$487.00
47539	Perq plmt bile duct stent	ED050	PACS Workstation Proxy	NF		111	106	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11
47539	Perq plmt bile duct stent	EF018	stretcher	NF		327	187	See preamble text MS minutes backed out input	-$0.71
47539	Perq plmt bile duct stent	EF027	table, instrument, mobile	NF		327	187	See preamble text MS minutes backed out input	-$0.20
47539	Perq plmt bile duct stent	EL011	room, angiography	NF		87	84	Refined equipment time to conform to changes in clinical labor time	-$15.76
47539	Perq plmt bile duct stent	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		327	187	See preamble text MS minutes backed out input	-$1.95
47539	Perq plmt bile duct stent	EQ032	IV infusion pump	NF		327	187	See preamble text MS minutes backed out input	-$0.89

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)
47539	Perq plmt bilc duct stent	EQ168	light, exam	NF		111	100	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
47539	Perq plmt bile duct stent	EQ250	ultrasound unit, portable	NF		111	100	Refined equipment time to conform to established policies for non-highly technical equipment	-$1.28
47539	Perq plmt bile duct stent	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23
47539	Perq plmt bile duct stent	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	75	0	See preamble text MS minutes backed out input	-$38.25
47539	Perq plmt bile duct stent	L051A	RN	NF	Monitor pt. following moderate sedation	15	0	See preamble text MS minutes backed out input	-$7.65
47539	Perq plmt bile duct stent	L051A	RN	NF	Sedate/Apply anesthesia	2	0	See preamble text MS minutes backed out input	-$1.02
47539	Perq plmt bile duct stent	SA044	pack, conscious sedation	NF		1	0	See preamble text MS supply backed out input	-$17.31

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)
47539	Perq plmt bile duct stent	SD150	catheter, balloon ureteral (Dowd)	NF		0	2	Supply item replaces another item; see preamble SD152	$130.00
47539	Perq plmt bile duct stent	SD152	catheter, balloon, PTA	NF		2	0	Supply item replaced by another item; see preamble SD150	-$487.00
47540	Perq plmt bile duct stent	ED050	PACS Workstation Proxy	NF		121	116	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11
47540	Perq plmt bile duct stent	EF018	stretcher	NF		337	187	See preamble text MS minutes backed out input	-$0.76
47540	Perq plmt bile duct stent	EF027	table, instrument, mobile	NF		337	187	See preamble text MS minutes backed out input	-$0.21
47540	Perq plmt bile duct stent	EL011	room, angiography	NF		97	94	Refined equipment time to conform to changes in clinical labor time	-$15.76
47540	Perq plmt bile duct stent	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		337	187	See preamble text MS minutes backed out input	-$2.09
47540	Perq plmt bile duct stent	EQ032	IV infusion pump	NF		337	187	See preamble text MS minutes backed out input	-$0.95

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47540	Perq plmt bile duct stent	EQ168	light, exam	NF		121	110	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
47540	Perq plmt bile duct stent	EQ250	ultrasound unit, portable	NF		121	110	Refined equipment time to conform to established policies for non-highly technical equipment	-$1.28
47540	Perq plmt bile duct stent	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23
47540	Perq plmt bile duct stent	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	85	0	See preamble text MS minutes backed out input	-$43.35
47540	Perq plmt bile duct stent	L051A	RN	NF	Monitor pt. following moderate sedation	15	0	See preamble text MS minutes backed out input	-$7.65
47540	Perq plmt bile duct stent	L051A	RN	NF	Sedate/Apply anesthesia	2	0	See preamble text MS minutes backed out input	-$1.02
47540	Perq plmt bile duct stent	SA044	pack, conscious sedation	NF		1	0	See preamble text MS supply backed out input	-$17.31
47540	Perq plmt bile duct stent	SD150	catheter, balloon ureteral (Dowd)	NF		0	2	Supply item replaces another item; see preamble SD152	$130.00

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47540	Perq plmt bile duct stent	SD152	catheter, balloon, PTA	NF		2	0	Supply item replaced by another item; see preamble SD150	-$487.00
47541	Plmt access bil tree sm bwl	ED050	PACS Workstation Proxy	NF		96	91	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11
47541	Plmt access bil tree sm bwl	EF018	stretcher	NF		312	187	See preamble text MS minutes backed out input	-$0.64
47541	Plmt access bil tree sm bwl	EF027	table, instrument, mobile	NF		312	187	See preamble text MS minutes backed out input	-$0.18
47541	Plmt access bil tree sm bwl	EL011	room, angiography	NF		72	69	Refined equipment time to conform to changes in clinical labor time	-$15.76
47541	Plmt access bil tree sm bwl	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		312	187	See preamble text MS minutes backed out input	-$1.74
47541	Plmt access bil tree sm bwl	EQ032	IV infusion pump	NF		312	187	See preamble text MS minutes backed out input	-$0.79
47541	Plmt access bil tree sm bwl	EQ168	light, exam	NF		96	85	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05

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47541	Plmt access bil tree sm bwl	EQ250	ultrasound unit, portable	NF		96	85	Refined equipment time to conform to established policies for non-highly technical equipment	-$1.28
47541	Plmt access bil tree sm bwl	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23
47541	Plmt access bil tree sm bwl	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	85	0	See preamble text MS minutes backed out input	-$43.35
47541	Plmt access bil tree sm bwl	L051A	RN	NF	Monitor pt. following moderate sedation	15	0	See preamble text MS minutes backed out input	-$7.65
47541	Plmt access bil tree sm bwl	L051A	RN	NF	Sedate/Apply anesthesia	2	0	See preamble text MS minutes backed out input	-$1.02
47541	Plmt access bil tree sm bwl	SA044	pack, conscious sedation	NF		1	0	See preamble text MS supply backed out input	-$17.31
47542	Dilate biliary duct/ampulla	ED050	PACS Workstation Proxy	NF		30	0	Refined equipment time to conform to changes in clinical labor time	-$0.66

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47542	Dilate biliary duct/ampulla	EF018	stretcher	NF		30	0	See preamble text MS minutes backed out input	-$0.15
47542	Dilate biliary duct/ampulla	EF027	table, instrument, mobile	NF		30	0	See preamble text MS minutes backed out input	-$0.04
47542	Dilate biliary duct/ampulla	EQ011	ECG, 3-channel (with Sp02, NIBP, temp, resp)	NF		30	0	See preamble text MS minutes backed out input	-$0.42
47542	Dilate biliary duct/ampulla	EQ032	IV infusion pump	NF		30	0	See preamble text MS minutes backed out input	-$0.19
47542	Dilate biliary duct/ampulla	EQ168	light, exam	NF		30	0	Refined equipment time to conform to changes in clinical labor time	-$0.13
47542	Dilate biliary duct/ampulla	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	30	0	See preamble text MS minutes backed out input	-$15.30
47542	Dilate biliary duct/ampulla	SD150	catheter, balloon ureteral (Dowd)	NF		0	1	Supply item replaces another item; see preamble SD152	$65.00
47542	Dilate biliary duct/ampulla	SD152	catheter, balloon, PTA	NF		1	0	Supply item replaced by another item; see preamble SD150	-$243.50
47543	Endoluminal bx biliary tree	ED050	PACS Workstation Proxy	NF		30	0	Refined equipment time to conform to changes in clinical labor time	-$0.66

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47543	Endoluminal bx biliary tree	EF018	stretcher	NF		30	0	See preamble text MS minutes backed out input	-$0.15
47543	Endoluminal bx biliary tree	EF027	table, instrument, mobile	NF		30	0	See preamble text MS minutes backed out input	-$0.04
47543	Endoluminal bx biliary tree	EQ011	ECG, 3-channel (with Sp02, NIBP, temp, resp)	NF		30	0	See preamble text MS minutes backed out input	-$0.42
47543	Endoluminal bx biliary tree	EQ032	IV infusion pump	NF		30	0	See preamble text MS minutes backed out input	-$0.19
47543	Endoluminal bx biliary tree	EQ168	light, exam	NF		30	0	Refined equipment time to conform to changes in clinical labor time	-$0.13
47543	Endoluminal bx biliary tree	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	30	0	See preamble text MS minutes backed out input	-$15.30
47543	Endoluminal bx biliary tree	SD315	Stone basket	NF		1	0	See preamble text	-$417.00
47544	Removal duct glbldr calculi	ED050	PACS Workstation Proxy	NF		45	0	Refined equipment time to conform to changes in clinical labor time	-$0.99

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47544	Removal duct glbldr calculi	EF018	stretcher	NF		45	0	See preamble text MS minutes backed out input	-$0.23
47544	Removal duct glbldr calculi	EF027	table, instrument, mobile	NF		45	0	See preamble text MS minutes backed out input	-$0.06
47544	Removal duct glbldr calculi	EQ011	ECG, 3-channel (with Sp02, NIBP, temp, resp)	NF		45	0	See preamble text MS minutes backed out input	-$0.63
47544	Removal duct glbldr calculi	EQ032	IV infusion pump	NF		45	0	See preamble text MS minutes backed out input	-$0.28
47544	Removal duct glbldr calculi	EQ168	light, exam	NF		45	0	Refined equipment time to conform to changes in clinical labor time	-$0.19
47544	Removal duct glbldr calculi	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	45	0	See preamble text MS minutes backed out input	-$22.95
47544	Removal duct glbldr calculi	SD150	catheter, balloon ureteral (Dowd)	NF		0	1	Supply item replaces another item; see preamble SD152	$65.00

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47544	Removal duct glbldr calculi	SD152	catheter, balloon, PTA	NF		1	0	Supply item replaced by another item; see preamble SD150	-$243.50
47544	Removal duct glbldr calculi	SD315	Stone basket	NF		0	1	See preamble text	$417.00
50606	Endoluminal bx urtr rnl plvs	EL014	room, radiographic-fluoroscopic	NF		47	0	Equipment item replaced by another item; see preamble text	-$65.48
50606	Endoluminal bx urtr rnl plvs	EL029	100 KW at 100 kV (DIN6822) generator (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL030	C-arm single plane system, ceiling mounted, integrated multispace (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL031	T motorized rotation, multiple operating modes (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00

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50606	Endoluminal bx urtr rnl plvs	EL032	real-time digital imaging (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL033	40 cm image intensifier at 40/28/20/14 cm (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL034	30 x 38 image intensifier dynamic flat panel detector (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL035	floor-mounted patient table with floating tabletop designed for angiographic exams and interventions (with peistepping for image intensifiers 13in+)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL036	18 in TFT monitor (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL037	network interface (DICOM) (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00

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50606	Endoluminal bx urtr rnl plvs	EL038	Careposition: radiation free positionong of collimators (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL039	Carewatch: acquisition and monitoring of configurable dose area product (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL040	Carefilter: Cu-prefiltration (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL041	DICOM HIS / RIS (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL042	Control room interface (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL043	Shields, lower body and mavig (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00

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50606	Endoluminal bx urtr rnl plvs	EL044	Leonardo software (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL045	Fujitsu-Siemens high performance computers (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL046	Color monitors (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL047	Singo modules for dynamic replay and full format images (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL048	Prepared for internal networking and Siemens remote servicing, both hardware and software (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00

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50705	Ureteral embolization/occl	EL014	room, radiographic-fluoroscopic	NF		62	0	Equipment item replaced by another item; see preamble text	-$86.37
50705	Ureteral embolization/occl	EL029	100 KW at 100 kV (DIN6822) generator (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL030	C-arm single plane system, ceiling mounted, integrated multispace (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL031	T motorized rotation, multiple operating modes (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL032	real-time digital imaging (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL033	40 cm image intensifier at 40/28/20/14 cm (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
50705	Ureteral embolization/occl	EL034	30 x 38 image intensifier dynamic flat panel detector (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL035	floor-mounted patient table with floating tabletop designed for angiographic exams and interventions (with pcistcpping for image intensifiers 13in+)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL036	18 in TFT monitor (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL037	network interface (DICOM) (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL038	Careposition: radiation free positionong of collimators (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL039	Carewatch: acquisition and monitoring of configurable dose area product (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
50705	Ureteral embolization/occl	EL040	Carefilter: Cu-prefiltration (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL041	DICOM HIS / RIS (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL042	Control room interface (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL043	Shields, lower body and mavig (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL044	Leonardo software (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL045	Fujitsu-Siemens high performance computers (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL046	Color monitors (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL047	Singo modules for dynamic replay and full format images (for angiography	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			room)						
50705	Ureteral embolization/occl	EL048	Prepared for internal networking and Siemens remote servicing, both hardware and software (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL014	room, radiographic-fluoroscopic	NF		62	0	Equipment item replaced by another item; see preamble text	-$86.37
50706	Balloon dilate urtrl strix	EL029	100 KW at 100 kV (DIN6822) generator (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL030	C-arm single plane system, ceiling mounted, integrated multispace (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL031	T motorized rotation, multiple operating modes (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL032	real-time digital imaging (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00

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50706	Balloon dilate urtrl strix	EL033	40 cm image intensifier at 40/28/20/14 cm (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL034	30 x 38 image intensifier dynamic flat panel detector (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL035	floor-mounted patient table with floating tabletop designed for angiographic exams and interventions (with peistepping for image intensifiers 13in+)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL036	18 in TFT monitor (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL037	network interface (DICOM) (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL038	Careposition: radiation free positionong of collimators (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00

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50706	Balloon dilate urtrl strix	EL039	Carewatch: acquisition and monitoring of configurable dose area product (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL040	Carefilter: Cu-prefiltration (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL041	DICOM HIS / RIS (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL042	Control room interface (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL043	Shields, lower body and mavig (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL044	Leonardo software (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL045	Fujitsu-Siemens high performance computers (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00

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50706	Balloon dilate urtrl strix	EL046	Color monitors (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL047	Singo modules for dynamic replay and full format images (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL048	Prepared for internal networking and Siemens remote servicing, both hardware and software (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
51700	Irrigation of bladder	SD024	catheter, Foley	NF		0	1	Supply item replaces another item; see preamble SD030	$7.82
51700	Irrigation of bladder	SD030	catheter, straight	NF		1	0	Supply item replaced by another item; see preamble SD024	-$1.70
51700	Irrigation of bladder	SJ031	leg or urinary drainage bag	NF		0	1	Supply item replaces another item; see preamble SD030	$3.08
51701	Insert bladder catheter	SD024	catheter, Foley	NF		1	0	Supply item replaced by another item; see preamble SD030	-$7.82
51701	Insert bladder catheter	SD030	catheter, straight	NF		0	1	Supply item replaces another item; see preamble SD024	$1.70

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)
51701	Insert bladder catheter	SJ031	leg or urinary drainage bag	NF		1	0	Supply item replaced by another item; see preamble SD030	-$3.08
52000	Cystoscopy	EF027	table, instrument, mobile	NF		17	22	Refined equipment time to conform to established policies for scopes	$0.01
52000	Cystoscopy	EF031	table, power	NF		17	22	Refined equipment time to conform to established policies for scopes	$0.08
52000	Cystoscopy	EQ167	light source, xenon	NF		17	22	Refined equipment time to conform to established policies for scopes	$0.14
52000	Cystoscopy	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		17	22	Refined equipment time to conform to established policies for scopes	$0.30
58555	Hysteroscopy dx sep proc	L037D	RN/LPN/MTA	F	Conduct phone calls/call in prescriptions	0	3	Refined time to standard for this clinical labor task	$1.11

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58562	Hysteroscopy remove fb	L037D	RN/LPN/MTA	F	Conduct phone calls/call in prescriptions	0	3	Refined time to standard for this clinical labor task	$1.11
623X5	Njx interlaminar crv/thrc	SC038	needle, epidural (RK)	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$10.00
623X5	Njx interlaminar crv/thrc	SC051	syringe 10-12ml	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$0.18
623X6	Njx interlaminar crv/thrc	EF018	stretcher	NF		73	75	Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
623X6	Njx interlaminar crv/thrc	EQ211	pulse oximeter w-printer	NF		73	75	Refined equipment time to conform to established policies for non-highly technical equipment	$0.01

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623X6	Njx interlaminar crv/thrc	SC038	needle, epidural (RK)	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$10.00
623X6	Njx interlaminar crv/thrc	SC051	syringe 10-12ml	NF		2	0	Duplicative; supply is included in conscious sedation pack	-$0.37
623X7	Njx interlaminar lmbr/sac	SC038	needle, epidural (RK)	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$10.00
623X7	Njx interlaminar lmbr/sac	SC051	syringe 10-12ml	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$0.18
623X8	Njx interlaminar lmbr/sac	EF018	stretcher	NF		73	75	Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
623X8	Njx interlaminar lmbr/sac	EQ211	pulse oximeter w-printer	NF		73	75	Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
623X8	Njx interlaminar lmbr/sac	SC038	needle, epidural (RK)	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$10.00

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623X8	Njx interlaminar lmbr/sac	SC051	syringe 10-12ml	NF		2	0	Duplicative; supply is included in conscious sedation pack	-$0.37
623X9	Njx interlaminar crv/thrc	SC038	needle, epidural (RK)	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$10.00
623X9	Njx interlaminar crv/thrc	SC051	syringe 10-12ml	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$0.18
62X10	Njx interlaminar crv/thrc	EF018	stretcher	NF		73	75	Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
62X10	Njx interlaminar crv/thrc	EQ211	pulse oximeter w-printer	NF		73	75	Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
62X10	Njx interlaminar crv/thrc	SC038	needle, epidural (RK)	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$10.00
62X10	Njx interlaminar crv/thrc	SC051	syringe 10-12ml	NF		2	0	Duplicative; supply is included in conscious sedation pack	-$0.37

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62X11	Njx interlaminar lmbr/sac	SC038	needle, epidural (RK)	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$10.00
62X11	Njx interlaminar lmbr/sac	SC051	syringe 10-12ml	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$0.18
62X12	Njx interlaminar lmbr/sac	EF018	stretcher	NF		73	75	Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
62X12	Njx interlaminar lmbr/sac	EQ211	pulse oximeter w-printer	NF		73	75	Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
62X12	Njx interlaminar lmbr/sac	SC038	needle, epidural (RK)	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$10.00
62X12	Njx interlaminar lmbr/sac	SC051	syringe 10-12ml	NF		2	0	Duplicative; supply is included in conscious sedation pack	-$0.37

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70540	Mri orbit/face/neck w/o dye	ED053	Professional PACS Workstation	NF		24	22	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.14
70542	Mri orbit/face/neck w/dye	ED053	Professional PACS Workstation	NF		25	23	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.14
70543	Mri orbt/fac/nck w/o &w/dye	ED053	Professional PACS Workstation	NF		30	28	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.14
77001	Fluoroguide for vein device	ED050	PACS Workstation Proxy	NF		27	25	Refined equipment time to conform to changes in clinical labor time	-$0.04
77001	Fluoroguide for vein device	EL014	room, radiographic-fluoroscopic	NF		24	22	Refined equipment time to conform to changes in clinical labor time	-$2.79

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77001	Fluoroguidc for vein device	L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies	2	0	Add-on codc. Additional time for clinical labor task not typical; see preamble text	-$0.82
77002	Needle localization by xray	ED050	PACS Workstation Proxy	NF		27	25	Refined equipment time to conform to changes in clinical labor time	-$0.04
77002	Needle localization by xray	EL014	room, radiographic-fluoroscopic	NF		24	22	Refined equipment time to conform to changes in clinical labor time	-$2.79
77002	Needle localization by xray	L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies	2	0	Add-on code. Additional time for clinical labor task not typical; see preamble text	-$0.82
77003	Fluoroguide for spine inject	ED050	PACS Workstation Proxy	NF		27	25	Refined equipment time to conform to changes in clinical labor time	-$0.04
77003	Fluoroguidc for spine inject	EL014	room, radiographic-fluoroscopic	NF		24	22	Refined cquipment time to conform to changes in clinical labor time	-$2.79

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77003	Fluoroguide for spine inject	L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies	2	0	Add-on code. Additional time for clinical labor task not typical; see preamble text	-$0.82
88184	Flowcytometry/ tc 1 marker	ED031	printer, dye sublimation (photo, color)	NF		5	2	Refined equipment time to conform to changes in clinical labor time	-$0.03
88184	Flowcytometry/ tc 1 marker	L033A	Lab Technician	NF	Enter data into laboratory information system, multiparameter analyses and field data entry, complete quality assurance documentation	4	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-$1.32
88184	Flowcytometry/ tc 1 marker	L033A	Lab Technician	NF	Clean room/equipment following	2	1	Refined time to standard for this clinical labor task	-$0.33

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					procedure (including any equipment maintenance that must be done after the procedure)				
88184	Flowcytometry/ tc 1 marker	L045A	Cytotechnologist	NF	Load specimen into flow cytometer, run specimen, monitor data acquisition, and data modeling, and unload flow cytometer	10	7	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.35
88184	Flowcytometry/ tc 1 marker	L045A	Cytotechnologist	NF	Print out histograms, assemble materials with paperwork to pathologists	5	2	Refined time to standard for this clinical labor task	-$1.35

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88184	Flowcytometry/ tc 1 marker	L045A	Cytotechnologist	NF	Instrument start-up, quality control functions, calibration, centrifugation, maintaining specimen tracking, logs and labeling	15	13	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$0.90
88184	Flowcytometry/ tc 1 marker	SL186	antibody, flow cytometry (each test)	NF		1.6	1	See preamble text	-$5.10
88185	Flowcytometry/tc add-on	ED031	printer, dye sublimation (photo, color)	NF		2	1	Refined equipment time to conform to changes in clinical labor time	-$0.01
88185	Flowcytometry/tc add-on	L033A	Lab Technician	NF	Enter data into laboratory information system, multiparameter analyses	1	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-$0.33

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					and field data entry, complete quality assurance documentation				
88185	Flowcytometry/tc add-on	SL089	lysing reagent (FACS)	NF		3	2	See preamble text	-$4.49
88185	Flowcytometry/tc add-on	SL186	antibody, flow cytometry (each test)	NF		1.6	1	See preamble text	-$5.10
88321	Microslide consultation	L037B	Histotechnologist	NF	Assemble and deliver slides with paperwork to pathologists	1	0	Clinical labor task redundant with clinical labor task	-$0.37
88323	Microslide consultation	L037B	Histotechnologist	NF	Complete workload recording logs. Collate slides and paperwork. Deliver to pathologist.	0	1	See preamble text	$0.37

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
88323	Microslide consultation	L037B	Histotechnologist	NF	Assemble and deliver slides with paperwork to pathologists	1	0	Clinical labor task redundant with clinical labor task	-$0.37
88323	Microslide consultation	L037B	Histotechnologist	NF	Clean equipment while performing service	1	0	Clinical labor task redundant with clinical labor task	-$0.37
88323	Microslide consultation	SL135	stain, hematoxylin	NF		32	16	See preamble text	-$0.70
88325	Comprehensive review of data	L037B	Histotechnologist	NF	Assemble and deliver slides with paperwork to pathologists	1	0	Clinical labor task redundant with clinical labor task	-$0.37
88325	Comprehensive review of data	L037B	Histotechnologist	NF	Clean Equipment while performing service	1	0	Clinical labor task redundant with clinical labor task	-$0.37

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
88325	Comprehensive review of data	L037B	Histotechnologist	NF	Complete workload recording logs. Collate slides and paperwork. Deliver to pathologist.	0	1	See preamble text	$0.37
88325	Comprehensive review of data	SL135	stain, hematoxylin	NF		32	16	See preamble text	-$0.70
95812	EEG 41-60 minutes	EF003	bedroom furniture (hospital bed, table, reclining chair)	NF		108	99	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
95812	EEG 41-60 minutes	EQ017	EEG, digital, prolonged testing system (computer w-remote camera)	NF		108	99	Refined equipment time to conform to established policies for non-highly technical equipment	-$1.32
95812	EEG 41-60 minutes	L047B	REEGT	NF	Perform procedure	62	50	See preamble text	-$5.64
95813	EEG over 1 hour	EF003	bedroom furniture (hospital bed, table, reclining chair)	NF		142	129	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.08

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)
95813	EEG over 1 hour	EQ017	EEG, digital, prolonged testing system (computer w-remote camera)	NF		142	129	Refined equipment time to conform to established policies for non-highly technical equipment	-$1.91
95813	EEG over 1 hour	L047B	REEGT	NF	Perform procedure	96	80	See preamble text	-$7.52
96933	Rcm celulr subcelulr img skn	L042A	RN/LPN	NF	Review imaging with interpreting physician	2	0	See preamble text	-$0.84
96934	Rcm celulr subcelulr img skn	EF031	table, power	NF		32	31	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.02
96934	Rcm celulr subcelulr img skn	EQ168	light, exam	NF		32	31	Refined equipment time to conform to established policies for non-highly technical equipment	$0.00
96934	Rcm celulr subcelulr img skn	ES056	reflectance confocal imaging system	NF		32	31	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.37

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
96934	Rcm celulr subcelulr img skn	L042A	RN/LPN	NF	Review imaging with interpreting physician	2	1	See preamble text	-$0.42
96934	Rcm celulr subcelulr img skn	L042A	RN/LPN	NF	Prepare and position pt/ monitor pt/ set up IV	2	1	Add-on code. Additional time for clinical labor task not typical; see preamble text	-$0.42
96934	Rcm celulr subcelulr img skn	L042A	RN/LPN	NF	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	2	0	Add-on code. Additional time for clinical labor task not typical; see preamble text	-$0.84
96935	Rcm celulr subcelulr img skn	EF031	table, power	NF		32	31	Refined equipment time to conform to established policies for non-highly technical equipment	-$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)
96935	Rcm celulr subcelulr img skn	EQ168	light, exam	NF		32	31	Refined equipment time to conform to established policies for non-highly technical equipment	$0.00
96935	Rcm celulr subcelulr img skn	ES056	reflectance confocal imaging system	NF		32	31	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.37
96935	Rcm celulr subcelulr img skn	L042A	RN/LPN	NF	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	2	0	Add-on code. Additional time for clinical labor task not typical; see preamble text	-$0.84
96935	Rcm celulr subcelulr img skn	L042A	RN/LPN	NF	Prepare and position pt/ monitor pt/ set up IV	2	1	Add-on code. Additional time for clinical labor task not typical; see preamble text	-$0.42

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)
96935	Rcm celulr subcelulr img skn	L042A	RN/LPN	NF	Review imaging with interpreting physician	2	0	See preamble text	-$0.84
97X61	Pt eval low complex 20 min	EF028	table, mat, hi-lo, 6 x 8 platform	NF		13	20	Refined equipment time to conform with other codes in the family	$0.07
97X61	Pt eval low complex 20 min	EQ219	rehab and testing system (BTE primus)	NF		5	10	Refined equipment time to conform with other codes in the family	$0.89
97X61	Pt eval low complex 20 min	EQ243	treadmill	NF		5	3	Refined equipment time to conform with other codes in the family	-$0.03
97X61	Pt eval low complex 20 min	L023A	Physical Therapy Aide	NF	Prepare and position pt/ monitor pt/ set up IV	0	2	Refined clinical labor time to conform with identical labor activity in other codes in the family	$0.46
97X61	Pt eval low complex 20 min	L039B	Physical Therapy Assistant	NF	Obtain vital signs	3	5	Refined clinical labor time to conform with identical labor activity in other codes in the family	$0.78
97X61	Pt eval low complex 20 min	L039B	Physical Therapy Assistant	NF	Assist physical therapist with exam/evaluation,	5	10	Refined clinical labor time to conform with identical labor activity in other codes in the family	$1.95

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)
					obtain records/measures				
97X61	Pt eval low complex 20 min	L039B	Physical Therapy Assistant	NF	Conduct phone calls/call in prescriptions	0	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	$1.17
97X61	Pt eval low complex 20 min	L039B	Physical Therapy Assistant	NF	Obtain/record medical and medication history, self assessment tools, and fall screening for PT review	5	8	Refined clinical labor time to conform with identical labor activity in other codes in the family	$1.17
97X62	Pt eval mod complex 30 min	L039B	Physical Therapy Assistant	NF	Obtain/record medical and medication history, self assessment tools, and fall screening for PT review	10	8	See preamble text	-$0.78
97X63	Pt eval high complex 45 min	EF028	table, mat, hi-lo, 6 x 8 platform	NF		30	20	Refined equipment time to conform with other codes in the family	-$0.10

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97X63	Pt eval high complex 45 min	EQ148	kit, hand dexterity, sensory, strength	NF		5	2	Refined equipment time to conform with other codes in the family	-$0.01
97X63	Pt eval high complex 45 min	EQ201	parallel bars, platform mounted	NF		5	0	Refined equipment time to conform with other codes in the family	-$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)
97X63	Pt eval high complex 45 min	EQ243	treadmill	NF		0	3	Refined equipment time to conform with other codes in the family	$0.04
97X63	Pt eval high complex 45 min	L039B	Physical Therapy Assistant	NF	Assist physical therapist with exam/evaluation, obtain records/measures	15	10	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.95
97X63	Pt eval high complex 45 min	L039B	Physical Therapy Assistant	NF	Obtain/record medical and medication history, self assessment tools, and fall screening for PT review	12	8	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.56
97X63	Pt eval high complex 45 min	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		6	5	Refined supply quantity to conform with other codes in the family	-$0.05
97X64	Pt re-eval est plan care	L039B	Physical Therapy Assistant	NF	Obtain/record medical and medication history, self assessment	5	4	See preamble text	-$0.39

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)
					tools, and fall screening for PT review				
97X65	Ot eval low complex 20 min	EF033	table, treatment, hi-lo	NF		0	10	Refined equipment time to conform with other codes in the family	$0.05
97X65	Ot eval low complex 20 min	EL002	environmental module - kitchen	NF		10	11	Refined equipment time to conform with other codes in the family	$0.11
97X65	Ot eval low complex 20 min	EQ068	balance assessment-retraining system (Balance Master)	NF		0	8	Refined equipment time to conform with other codes in the family	$0.43
97X65	Ot eval low complex 20 min	EQ143	kit, ADL	NF		8	11	Refined equipment time to conform with other codes in the family	$0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97X65	Ot eval low complex 20 min	EQ151	kit, motor coordination	NF		2	3	Refined equipment time to conform with other codes in the family	$0.00
97X65	Ot eval low complex 20 min	EQ152	kit, sensory	NF		2	3	Refined equipment time to conform with other codes in the family	$0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97X65	Ot eval low complex 20 min	ES057	environmental module - bathroom	NF		0	10	Refined equipment time to conform with other codes in the family	$0.64
97X65	Ot eval low complex 20 min	ES058	kit, vision	NF		0	3	Refined equipment time to conform with other codes in the family	$0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97X65	Ot eval low complex 20 min	L039B	Physical Therapy Assistant	NF	Obtain vital signs	3	5	Refined clinical labor time to conform with identical labor activity in other codes in the family	$0.78
97X65	Ot eval low complex 20 min	L039B	Physical Therapy Assistant	NF	Obtain measurements	4	6	Refined clinical labor time to conform with identical labor activity in other codes in the family	$0.78
97X65	Ot eval low complex 20 min	L039B	Physical Therapy Assistant	NF	Assist physician in performing procedure (15%)	5	7	Refined clinical labor time to conform with identical labor activity in other codes in the family	$0.78
97X66	Ot eval mod complex 30 min	L039B	Physical Therapy Assistant	NF	Obtain measurements	8	6	See preamble text	-$0.78
97X67	Ot eval high complex 45 min	EF033	table, treatment, hi-lo	NF		15	10	Refined equipment time to conform with other codes in the family	-$0.03

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97X67	Ot eval high complex 45 min	EL002	environmental module - kitchen	NF		14	11	Refined equipment time to conform with other codes in the family	-$0.34
97X67	Ot eval high complex 45 min	EQ068	balance assessment-retraining system (Balance Master)	NF		0	8	Refined equipment time to conform with other codes in the family	$0.43
97X67	Ot eval high complex 45 min	EQ117	evaluation system for upper extremity-hand (Greenleaf)	NF		5	4	Refined equipment time to conform with other codes in the family	-$0.07
97X67	Ot eval high complex 45 min	EQ143	kit, ADL	NF		15	11	Refined equipment time to conform with other codes in the family	-$0.01
97X67	Ot eval high complex 45 min	EQ185	neurobehavioral status instrument	NF		11	0	Refined equipment time to conform with other codes in the family	-$0.59

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)
97X67	Ot eval high complex 45 min	EQ219	rehab and testing system (BTE primus)	NF		5	3	Refined equipment time to conform with other codes in the family	-$0.36
97X67	Ot eval high complex 45 min	ES057	environmental module - bathroom	NF		14	10	Refined equipment time to conform with other codes in the family	-$0.26

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)
97X67	Ot eval high complex 45 min	L039B	Physical Therapy Assistant	NF	Obtain measurements	12	6	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$2.34
97X67	Ot eval high complex 45 min	L039B	Physical Therapy Assistant	NF	Assist physician in performing procedure (15%)	9	7	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$0.78

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)
97X68	Ot re-eval est plan care	L039B	Physical Therapy Assistant	NF	Obtain measurements	3	2	See preamble text	-$0.39
G0416	Prostate biopsy, any mthd	SL063	eosin y	NF		48	0	Supply item replaced by another item; see preamble SL201	-$38.45

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)
G0416	Prostate biopsy, any mthd	SL201	stain, eosin	NF		0	48	Supply item replaces another item; see preamble SL063	$3.24

TABLE 26—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
19030, 19081, 19082, 19281, 19282, 19283, 19284, 77053, 77054, 770X1, 770X2, 770X3.	room, digital mammography.	EL013	168,214.00	362,935.00	116	10	2,294,862
31575, 31576, 31577, 31578, 31579, 317X1, 317X2, 317X3, 31580, 31584, 31587, 315X1, 315X2, 315X3, 315X4, 315X5, 315X6, 190+ other codes.	video system, endoscopy (processor, digital capture, monitor, printer, cart).	ES031	33,232.50	15,045.00	−55	1	1,497,130
58555, 58562, 58563, 58565.	endoscope, rigid, hysteroscopy.	ES009	4,990.50	6,207.50	24	1	672
88323, 88355, 88380, 88381.	stain, eosin	SL201	0.04	0.07	55	5	45,393
88360, 88361	Antibody Estrogen Receptor monoclonal.	SL493	3.19	14.00	339	4	216,208
91110	kit, capsule endoscopy w-application supplies (M2A).	SA005	450.00	520.00	16	1	30,464
91110, 91111	video system, capsule endoscopy (software, computer, monitor, printer).	ES029	17,000.00	12,450.00	−27	1	30,586
91111	kit, capsule, ESO, endoscopy w-application supplies (ESO).	SA094	450.00	472.80	5	1	122
95145, 95146, 95148, 95149.	antigen, venom	SH009	16.67	20.14	21	4	50,772
95147, 95148, 95149	antigen, venom, tri-vespid	SH010	30.22	44.05	46	3	37,955
122 codes	light source, xenon	EQ167	6,723.33	7,000.00	4	1	2,149,616
59 codes	fiberscope, flexible, rhinolaryngoscopy.	ES020	6,301.93	4,250.00	−33	1	581,924

TABLE 27—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
31575, 31579, 317X3, 31580, 31584, 31587, 315X1, 315X2, 315X3, 315X4, 315X5, 315X6.	rhinolaryngoscope, flexible, video, non-channeled.	ES063	8,000.00	1	541,537
31576, 31577, 31578, 317X1, 317X2	rhinolaryngoscope, flexible, video, channeled.	ES064	9,000.00	1	756
31576, 31577, 31578	Disposable biopsy forceps	SD318	26.84	1	574
31579	stroboscopy system	ES065	19,100.00	1	54,466
317X3	Voice Augmentation Gel	SJ090	575.00	1	99
36X41	Claravein Kit	SA122	890.00	1	264
36X41, 364X2	Sotradecol Sclerosing Agent	SH108	110.20	1	528
55700	Biopsy Guide	EQ375	7,000.00	0	85,731
58558	BLADE INCSR 2.9MM	SF059	599.00	1	2,677
58558	Hysteroscopic fluid management system.	EQ378	14,698.38	1	2,677
58558	Hysteroscopic Resection System	EQ379	19,857.50	1	2,677
770X1, 770X2, 770X3	PACS Mammography Workstation	ED054	103,616.47	8	2,274,249
70540, 70542, 70543; over 400 additional codes.	Professional PACS Workstation	ED053	14,616.93	9	32,571,650

TABLE 27—INVOICES RECEIVED FOR NEW DIRECT PE INPUTS—Continued

CPT/HCPCS codes	Item name	CMS code	Average price	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
77332	knee wedge/foot block system	EQ376	3,290.00	1	48,831
77333	Thermoplastic tissue bolus 30X30X0.3cm.	SD321	23.90	1	3,493
77333	water bath, digital control	EP120	2,350.00	1	3,493
77333, 77334	Supine Breast/Lung Board	EQ377	5,773.15	1	290,969
77334	Urethane Foaming Agent	SL519	53.50	1	287,476
88184, 88185	flow cytometry analytics software	EQ380	14,000.00	1	1,680,252
95144, 95165	antigen vial transport envelope	SK127	1.50	2	6,464,311
961X1	Beck Depression Inventory, Second Edition (BDI–II).	SK128	2.26	1	1
96416	IV infusion pump, ambulatory	EQ381	2384.45	1	117,248
96931, 96932	Imaging Tray	SA121	34.75	1	5
96931, 96932	adhesive ruler	SK125	9.95	1	5
96931, 96932, 96934, 96935	reflectance confocal imaging system	ES056	98,500.00	1	9
97X66, 97X67, 97X68	environmental module—bathroom	ES057	25,000.00	1	115,107
97X66, 97X67	kit, vision	ES058	410.00	1	86,912
GDDD1	patient lift system	EF045	2,824.33	3	15,115,789
GDDD1	wheelchair accessible scale	EF046	875.92	3	15,115,789
GDDD1	leg positioning system	EF047	1,076.50	3	15,115,789

III. Other Provisions of the Proposed Rule for PFS

A. Chronic Care Management (CCM) and Transitional Care Management (TCM) Supervision Requirements in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In the CY 2016 PFS final rule with comment period (80 FR 71080 through 71088), 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. Payment is made when CPT code 99490 is billed alone or with other payable services on a RHC or FQHC claim, and the rate is based on the PFS national average non-facility payment rate. The requirement that RHC or FQHC services be furnished face-to-face was waived for CCM services furnished to a RHC or FQHC patient because CCM services are not required to be furnished face-to-face.

Medicare payment for TCM services furnished by a RHC or FQHC practitioner was effective January 1, 2013, consistent with the effective date of payment for TCM services under the PFS (77 FR 68978 through 68994; also, see CMS-Pub. 100–02, Medicare Benefit Policy Manual, chapter 13, section 110.4).

TCM services are billable only when furnished within 30 days of the date of the patient's discharge from a hospital (including outpatient observation or partial hospitalization), skilled nursing facility, or community mental health center. Communication (direct contact, telephone, or electronic) with the patient or caregiver must commence within 2 business days of discharge, and a face-to-face visit must occur within 14 days of discharge for moderate complexity decision making (CPT code 99495), or within 7 days of discharge for high complexity decision making (CPT code 99496). The TCM visit is billed on the day that the TCM visit takes place, and only one TCM visit may be paid per beneficiary for services furnished during that 30 day post-discharge period. If the TCM visit occurs on the same day as another billable visit, only one visit may be billed. TCM and CCM cannot be billed during the same time period for the same patient.

In the CY 2016 PFS final rule with comment period (80 FR 71087), we responded to comments requesting that we make an exception to the supervision requirements for auxiliary staff furnishing CCM and TCM services incident to physician services in RHCs and FQHCs (80 FR 71087). Auxiliary staff in RHCs and FQHCs furnish services incident to a RHC or FQHC visit and include nurses, medical assistants, and other clinical staff who work under the direct supervision of a RHC or FQHC practitioner. The commenters suggested that the regulatory language be amended to be consistent with the provision in § 410.26(b)(5) for CCM and TCM services under the PFS, which states that services and supplies furnished incident to CCM and TCM services can be furnished under general supervision of the physician (or other practitioner) when they are provided by clinical staff. It further specifies that the physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based, but only the supervising physician (or other practitioner) may bill Medicare for incident to services. We responded that due to the differences between physician offices and RHCs and FQHCs in their models of care and payment structures, we believe that the direct supervision requirement for services furnished by auxiliary staff is appropriate for RHCs and FQHCs, but that we would consider changing this in future rulemaking if RHCs and FQHCs find that requiring direct supervision presents a barrier to furnishing CCM services.

Since payment for CCM in RHCs and FQHCs began on January 1, 2016, some RHCs and FQHCs have informed us that, in their view, the direct supervision requirement for auxiliary

staff has limited their ability to furnish CCM services. Specifically, these RHCs and FQHCs have stated that the direct supervision requirement has prevented them from entering into contracts with third party companies to provide CCM services, especially during hours that they are not open, and that they are unable to meet the CCM requirements within their current staffing and budget constraints.

To bill for CCM services, RHCs and FQHCs must ensure that there is access to care management services on a 24 hour a day, 7 day a week basis. This includes providing the patient with a means to make timely contact with RHC or FQHC practitioners who have access to the patient's electronic care plan to address his or her urgent chronic care needs. The RHC or FQHC must ensure the care plan is available electronically at all times to anyone within the RHC or FQHC who is providing CCM services.

Once the RHC or FQHC practitioner has initiated CCM services and the patient has consented to receiving this service, CCM services can be furnished by a RHC or FQHC practitioner, or by auxiliary personnel, as defined in § 410.26(a)(1), which includes nurses, medical assistants, and other staff working under physician supervision who meet the requirements to provide incident to services. Auxiliary personnel in RHCs and FQHCs must furnish services under direct supervision, which requires that a RHC or FQHC practitioner be present in the RHC or FQHC and immediately available to furnish assistance and direction. The RHC or FQHC practitioner does not need to be present in the room when the service is furnished.

Although many RHCs and FQHCs prefer to furnish CCM and TCM services utilizing existing staff, some RHCs and FQHCs would like to contract with a third party to furnish aspects of their CCM and TCM services, but cannot do so because of the direct supervision requirement. Without the ability to contract with a third party, these RHCs and FQHCs have stated that they find it difficult to meet the CCM requirements for 24 hours a day, 7 days a week access to services.

To enable RHCs and FQHCs to effectively contract with third parties to furnish aspects of CCM and TCM services, we propose to revise § 405.2413(a)(5) and § 405.2415(a)(5) to state that services and supplies furnished incident to TCM and CCM services can be furnished under general supervision of a RHC or FQHC practitioner. The proposed exception to the direct supervision requirement would apply only to auxiliary personnel furnishing TCM or CCM incident to services, and would not apply to any other RHC or FQHC services. The proposed revisions for CCM and TCM services and supplies furnished by RHCs and FQHCs are 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.

B. FQHC-Specific Market Basket

1. Background

Section 10501(i)(3)(A) of the Affordable Care Act (Pub. L. 111–148 and Pub. L. 111–152) added section 1834(o) of the Act to establish a payment system for the costs of FQHC services under Medicare Part B based on prospectively set rates. In the Prospective Payment System (PPS) for FQHC Final Rule published in the May 2, 2014 **Federal Register** (79 FR 25436), we implemented a methodology and payment rates for the FQHC PPS. The FQHC PPS base payment rate was determined using FQHC cost report and claims data and was effective for FQHC payments from October 1, 2014, through December 31, 2015 (implementation year). The adjusted base payment rate for the implementation year was $158.85 (79 FR 25455). When calculating the FQHC PPS payment, the base payment rate is multiplied by the FQHC geographic adjustment factor (GAF) based on the location of the FQHC, and adjusted for new patients or when an initial preventive physical examination or annual wellness visit are furnished. Beginning on October 1, 2014, FQHCs began to transition to the FQHC PPS based on their cost reporting periods. As of January 1, 2016, all FQHCs are paid under the FQHC PPS.

Section 1834(o)(2)(B)(ii) of the Act requires that the payment for the first year after the implementation year be increased by the percentage increase in the MEI. Therefore, in CY 2016, the FQHC PPS base payment rate was increased by the MEI. The MEI was based on 2006 data from the American Medical Association (AMA) for self-employed physicians and was used in the PFS Sustainable Growth Rate (SGR) formula to determine the conversion factor for physician service payments. (See the CY 2014 PFS final rule (78 FR 74264) for a complete discussion of the 2006-based MEI). Section 1834(o)(2)(B)(ii) of the Act also requires that beginning in CY 2017, the FQHC PPS base payment rate will be increased by the percentage increase in a market basket of FQHC goods and services, or if such an index is not available, by the percentage increase in the MEI.

For CY 2017, we are proposing to create a 2013-based FQHC market basket. The proposed market basket uses Medicare cost report (MCR) data submitted by freestanding FQHCs. In the following discussion, we provide an overview of the proposed market basket and describe the methodologies used to determine the cost categories, cost weights, and price proxies. In addition, we compare the growth rates of the proposed FQHC market basket to the growth rates of the MEI.

2. Overview of the FQHC Market Basket

The 2013-based FQHC market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time relative to a base period are not measured.

The index itself is constructed in three steps. First, a base period is selected (in this proposed rule, the base period is CY 2013), total base period costs are estimated for a set of mutually exclusive and exhaustive cost categories, and the proportion of total costs that each cost category represents is calculated. These proportions are called cost weights. Second, each cost category is matched to an appropriate price or wage variable, referred to as a price proxy. These price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the cost weight for each cost category is multiplied by the established price proxy index level. The sum of these products (that is, the cost weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket for the given time period. Repeating this step for other periods produces a series of market basket levels over time. Dividing the composite index level of one period by the composite index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As previously noted, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish FQHC services. The effects on total costs resulting from changes in the mix of goods and services purchased subsequent to the base period are not

measured. For example, a FQHC hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the FQHC, but would not be factored into the price change measured by a fixed-weight FQHC market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market baskets periodically so that the cost weights reflect a current mix of goods and services purchased (FQHC inputs) to furnish FQHC services.

3. Creating a FQHC Market Basket

In 2015, we began researching the possibility of creating a FQHC market basket that would be used in place of the MEI to update the FQHC PPS base payment rate annually. An FQHC market basket should reflect the cost structures of FQHCs while the MEI reflects the cost structures of self-employed physician offices. At the time of implementation of the FQHC PPS, a FQHC market basket had not been developed, and therefore, the law stipulated that the FQHC PPS base payment rate be updated by the MEI for the first year after implementation (CY 2016). In subsequent years, the FQHC PPS base payment rate should be annually updated by a FQHC market basket, if available.

The MEI cost weights were derived from data collected by the AMA on the Physician Practice Expense Information Survey (PPIS), since physicians, unlike other Medicare providers, are not required to complete and submit a Medicare Cost Report. FQHCs submit expense data annually on the Medicare Cost Report form CMS–222–92 (OMB No: 0938–0107), ''Independent Rural Health Clinic and Freestanding Federally Qualified Health Center Cost Report''; therefore, we were able to estimate relative cost weights specific to FQHCs. We define a ''major cost weight'' as one calculated using the Medicare cost reports (for example, FQHC practitioner compensation). However, the Medicare cost report data allows multiple methods for reporting detailed expenses, either in detailed cost center lines or more broadly reported in general categories of expenses. An alternative data source is used to disaggregate further residual costs that could not be classified into a major cost category directly using only the Medicare Cost Report data. We estimated the cost weights for each year 2009 through 2013 and found the cost weights from each year to be similar, which provided confidence in the derived cost weights.

In summary, our research over the past year allowed us to evaluate the appropriateness of using freestanding FQHC Medicare cost report data to calculate the major cost weights for a FQHC market basket. We believe that the proposed methodologies described below create a FQHC market basket that reflects the cost structure of FQHCs. Therefore, we believe that the use of this proposed 2013-based FQHC market basket to update FQHC PPS base payment rate would more accurately reflect the actual costs and scope of services that FQHCs furnish compared to the 2006-based MEI.

4. Development of Cost Categories and Cost Weights for the Proposed 2013-Based FQHC Market Basket

a. Use of Medicare Cost Report Data

The proposed 2013-based FQHC market basket consists of eight major cost categories, which were derived from the CY 2013 Medicare cost reports for freestanding FQHCs. These categories are FQHC-Practitioner Compensation, Other Clinical Compensation, Non-Health Compensation, Fringe Benefits, Pharmaceuticals, Fixed Capital, Moveable Capital, and an All Other (Residual) cost category. The All Other (Residual) cost category reflects the costs not captured in the other seven cost categories. The CY 2013 Medicare cost reports include all FQHCs whose cost reporting period began on or after January 1, 2013, and prior to or on December 31, 2013. We selected CY 2013 as the base year because the Medicare cost reports for that year were the most recent, complete set of Medicare cost report data available for FQHCs at the time of development of the cost share weights and proposed 2013-based FQHC market basket. As stated above, we compared the cost share weights from the MCR for CY 2009 through CY 2013 and the CY 2013 weights were consistent with the weights from prior years.

We began with all FQHCs with reporting periods in CY 2013 (that is, between and including January 1, 2013, and December 31, 2013). We then excluded FQHCs missing ''total costs'' (that is, any FQHC that did not report expenses on Worksheet A, Column 7, Line 62). This edit removed 83 providers from our analysis. Next, we compared the total Medicare allowable costs (that is, total costs eligible for reimbursement under the FQHC PPS) to total costs reported on the Medicare cost report. We kept FQHCs whose Medicare-allowable costs accounted for 60 percent or more of total costs to remove FQHCs whose costs were primarily driven by services not covered under the FQHC benefit. For example, FQHCs that reported a majority of costs for dental services were excluded from the sample. This edit removed 33 FQHCs from our analysis. We used the remaining Medicare cost reports to calculate the costs for the eight major cost categories (FQHC Practitioner Compensation, Other Clinical Compensation, Non-Health Compensation, Fringe Benefits, Pharmaceuticals, Fixed Capital, Moveable Capital, and All Other (Residual) costs).

The resulting 2013-based FQHC market basket cost weights reflect Medicare allowable costs. We propose to define Medicare allowable costs for freestanding FQHC facilities as: Worksheet A, Columns 1 and 2, cost centers lines 1 through 51 but excluding line 20, which is professional liability insurance (PLI). We exclude PLI costs from the total Medicare allowable costs because FQHCs that receive section 330 grant funds also are eligible to apply for medical malpractice coverage under Federally Supported Health Centers Assistance Act (FSHCAA) of 1992 (Pub. L. 102–501) and FSHCAA of 1995 (Pub. L. 104–73 amending section 224 of the Public Health Service Act). Below we derive the eight major cost categories.

(1) *FQHC Practitioner Compensation:* A FQHC practitioner is defined as one of the following occupations: Physicians, NPs, PAs, CNMs, Clinical Psychologist (CPs), and Clinical Social Worker (CSWs). Under certain conditions, a FQHC visit also may be provided by qualified practitioners of outpatient DSMT and MNT when the FQHC meets the relevant program requirements for provision of these services. FQHC Practitioner Compensation costs are derived as the sum of compensation and other costs as reported on Worksheet A; columns 1 and 2; lines 1, 2, 3, 6, 7, 13, 14. The Medicare cost reports also captures ''Other'' compensation costs (the sum of costs reported on Worksheet A; columns 1 and 2; lines 9, 10, 11, and 15). We allocate a portion of these compensation costs to FQHC Practitioner compensation by multiplying this amount by the ratio of FQHC Practitioner compensation costs to the sum of FQHC Practitioner compensation costs and Other Clinical compensation costs. We believe that the assumption of distributing the costs proportionally is reasonable since there is no additional detail on the specific occupations these compensation costs represent. We also include a proportion of Fringe Benefit

costs as described in section III.B.1.a.iv of this proposed rule.

(2) *Other Clinical Compensation:* Other Clinical Compensation includes any health-related clinical staff who does not fall under the definition of a FQHC practitioner from paragraph (1) (FQHC Practitioner Compensation). Other Clinical Compensation costs are derived as the sum of compensation and other costs as reported on Worksheet A; columns 1 and 2; lines 4, 5, and 8. Similar to the FQHC Practitioner compensation, we also allocate a proportion of the ''Other'' Clinical compensation costs by multiplying this amount by the ratio of Other Clinical Compensation costs to the sum of FQHC Practitioner Compensation costs and Other Clinical compensation costs. Given the ambiguity in the costs reported on these lines, we believe that the assumption of distributing the costs proportionally is reasonable since there is no additional detail on the specific occupations these compensation costs represent. We also include a proportion of Fringe Benefit costs as described in section III.B.1.a.iv of this proposed rule.

(3) *Non-Health Compensation:* Non-Health Compensation includes compensation costs for Office Staff, Housekeeping & Maintenance, and Pharmacy. Non-Health Compensation costs are derived as the sum of compensation costs as reported on Worksheet A; column 1 only for lines 32 and 51; and Worksheet A; both columns 1 and 2 for line 38. We only use the costs from column 1 for housekeeping and maintenance and pharmacy since we believe that there are considerable costs other than compensation that could be reported for these categories. We use the costs from both column 1 and column 2 for office salaries (line 38) since only salaries or compensation should be reported on this line. We also include a proportion of Fringe Benefit costs as described in section III.B.1.a.iv of this proposed rule.

(4) *Fringe Benefits:* Worksheet A; columns 1 and 2; line 45 of the Medicare cost report captures fringe benefits and payroll tax expenses. We proposed to estimate the fringe benefit cost weight as the fringe benefits costs divided by total Medicare allowable costs. We propose to allocate the Fringe Benefits cost weight to the three compensation cost categories (FQHC practitioner compensation, other clinical compensation, and non-health compensation) based on their relative proportions. The fringe benefits ratio is equal to the compensation cost weight as a percent of the sum of the compensation cost weights for all three types of workers. These allocation ratios are 46 percent, 14 percent, and 40 percent, respectively. Therefore, we propose to allocate 46 percent of the fringe benefits cost weight to the FQHC practitioner cost weight, 14 percent of the fringe benefits cost weight to the clinical compensation cost weight, and 40 percent of the fringe benefits cost weight to the non-health compensation cost weight. Table 28 shows the three compensation category cost weights after the fringe benefit cost weight is allocated for the proposed 2013-based FQHC market basket.

TABLE 28—COMPENSATION CATEGORY COST WEIGHTS AFTER FRINGE BENEFITS ALLOCATION

Cost category	Before fringe benefits allocation (%)	After fringe benefits allocation (%)
FQHC Practitioner Compensation	26.8	31.8
Other Clinical Compensation	8.1	9.5
Non-Health Compensation	23.1	27.4
Fringe Benefits (distribute to comp)	10.7	0.0

We believe that distributing the fringe benefit expenses reported on line 45 using the provider-specific compensation ratios is reasonable.

(5) *Pharmaceuticals:* Drugs and biologicals that are not usually self-administered, and certain Medicare-covered preventive injectable drugs are paid incident to a FQHC visit. Therefore, pharmaceutical costs include the non-compensation costs reported on Worksheet A, column 2, for the pharmacy cost center (line 51). We note that pharmaceutical costs are not included in the MEI since pharmaceutical costs are paid outside of the PFS.

(6) *Fixed Capital:* Fixed capital costs are equal to the sum of costs for rent, interest on mortgage loans, depreciation on buildings and fixtures, and property tax as reported on Worksheet A; columns 1 and 2; lines 26, 28, 30, and 33.

(7) *Moveable Capital:* Moveable capital costs are equal to the sum of costs for depreciation of medical equipment, office equipment, and other equipment as reported on Worksheet A; column 1 and 2; lines 19, 31, and 39.

(8) *All Other (Residual):* After estimating the expenses for the seven cost categories listed above, we summed all remaining costs together for each FQHC to come up with All Other (Residual) costs. The costs included in the All Other (Residual) category include all costs reported for medical supplies, transportation, allowable GME pass through costs, facility insurance, utilities, office supplies, legal, accounting, administrative insurance, telephone, housekeeping & maintenance, nondescript healthcare costs, nondescript facility costs, and nondescript administrative costs.

Although a cost weight for these categories could be obtained directly from the costs reported in that cost center's respective line on the cost report form, some FQHCs reported significant costs in other (specify), or ''free form,'' lines which made it difficult to determine the accuracy of these costs. For example, some FQHCs reported costs only in the free form lines and not in the cost center specific lines, while other FQHCs reported costs in both the cost center specific lines and the free form lines. Since a majority of FQHCs used the free form lines, relying solely on the costs reported in the cost center specific lines for costs could lead to an inaccurate cost weights in the market basket. For example, if a FQHC reported all other healthcare costs in line 21 rather than breaking the healthcare costs into the detailed cost centers (lines 17 through 20.50), then the cost weight for medical supplies could be lower than it should be if we did not allocate the costs reported in the free form lines to medical supplies.

Section III.B.1.b explains the method used to allocate the residual costs to more detailed cost categories.

After we derived costs for the eight major cost categories for each FQHC using the Medicare cost report data as previously described, we addressed data outliers using the following steps. First,

we divided the costs for each of the eight categories by total Medicare allowable costs for each FQHC. We then removed those FQHCs whose derived cost weights fell in the top and bottom 5 percent of provider specific derived cost weights. Five percent is the standard trim applied for all CMS market basket cost weights. After these outliers were removed, we summed the costs for each category across all remaining FQHCs. We then divided this by the sum of total Medicare allowable costs across all remaining FQHCs to obtain a cost weight for the proposed 2013-based FQHC market basket for the given category. See Table 29 for the resulting cost weights for these major cost categories that we obtained from the Medicare cost reports.

TABLE 29—MAJOR COST CATEGORIES AS DERIVED FROM MEDICARE COST REPORTS

Cost category	2013 FQHC weight (%)
FQHC Practitioner Compensation	26.8
Other Clinical Compensation	8.1
Non-Health Compensation	23.1
Fringe Benefits (distribute to compensation)	10.7
Fixed Capital	4.5
Moveable Capital	1.7
Non Salary Pharmaceuticals	5.1
All Other (Residual)	20.1

Totals may not sum to 100.0% due to rounding.

b. Derivation of Detailed Cost Categories From the All Other (Residual) Cost Weight

The All Other Residual cost weight was derived from summing all expenses reported on the Medicare cost report Worksheet A, columns 1 and 2 for medical supplies (line 17), transportation (line 18), allowable GME pass through costs (line 20.50), facility insurance (line 27), utilities (line 29), office supplies (line 40), legal (line 41), accounting (line 42), administrative insurance (line 43), telephone (line 44), non-compensation housekeeping & maintenance (line 32, column 2 only), nondescript healthcare costs (lines 21–23), nondescript facility costs (lines 34–36), and nondescript administrative costs (lines 54–56).

To further divide the ''All Other'' residual cost weight (20.1 percent) estimated from the CY 2013 Medicare cost report data into more detailed cost categories, we propose to use the relative cost shares from the 2006-based MEI for nine detailed cost categories: Utilities; Miscellaneous Office Expenses; Telephone; Postage; Medical Equipment; Medical Supplies; Professional, Scientific, & Technical Services; Administrative & Facility Services; and Other Services. For example, the Utilities cost represents 7 percent of the sum of the 2006-based MEI ''All Other'' cost category weights; therefore, the Utilities cost weight would represent 7 percent of the proposed 2013-based FQHC market basket's ''All Other'' cost category (20.066 percent), yielding a ''final'' Utilities proposed cost weight of 1.4 percent in the proposed 2013-based LTCH market basket (7 percent * 20.1 percent = 1.4 percent).

Table 30 shows the cost weight for each matching category from the 2006-based MEI, the percent each cost category represents of the 2006-based MEI ''All Other'' cost weight, and the resulting proposed 2013-based FQHC market basket cost weights for detailed cost categories.

TABLE 30—PROPOSED DETAILED FQHC COST CATEGORY WEIGHTS

Proposed FQHC detailed cost categories	2006-based MEI cost weights (%)	Percent of the 2006-based MEI ''All Other'' cost weight (%)	Proposed 2013-based FQHC detailed cost weights (%)
Total All Other (Residual)	17.976	100.000	20.1
Utilities	1.266	7.0	1.4
Miscellaneous Office Expenses	2.478	13.8	2.8
Telephone	1.501	8.4	1.7
Postage	0.898	5.0	1.0
Medical Equipment	1.978	11.0	2.2
Medical supplies	1.760	9.8	2.0
Professional, Scientific, & Tech. Services	2.592	14.4	2.9
Administrative & Facility Services	3.052	17.0	3.4
Other Services	2.451	13.6	2.7

FQHCs have liberty in how and where certain costs are reported on the Medicare cost report form. We believe that, given the ambiguity in how the data are reported for these overhead cost centers on the FQHC cost report form, relying on the relative shares determined from the MEI is reasonable. We hope that future cost data from the upcoming revised FQHC cost report form will allow us to better estimate the detailed cost weights for these categories directly. All FQHCs will report costs on the new forms for cost report periods for CY 2016 expenses. For details regarding how the 2006-based MEI cost categories were derived, see the CY 2011 PFS final rule with comment period (75 FR 73262 through 73267). The following is a description of the types of expenses included in detailed cost categories derived from the All Other (Residual) cost category:

- *Utilities:* Includes expenses classified in the fuel, oil and gas, water and sewage, and electricity industries. These types of industries are classified in NAICS and include NAICS 2211 (Electric power generation, transmission, and distribution), 2212 (Natural gas distribution), and 2213 (Water, sewage, and other systems).
- *Miscellaneous Office Expense:* Includes expenses for office expenses not reported in other categories, miscellaneous expenses, included but not limited to, paper (such as paper towels), printing (such as toner for printers), miscellaneous chemicals (such as soap and hand sanitizer).
- *Telephone:* Includes expenses classified in NAICS 517

(Telecommunications) and NAICS 518 (Internet service providers), and NAICS 515 (Cable and other subscription programming). Telephone service, which is one component of the Telecommunications expenses, accounts for the majority of the expenditures in this cost category.

- *Postage:* Includes expenses classified in NAICS 491 (Postal services) and NAICS 492 (Courier services).
- *Medical Equipment Expenses:* Includes the expenses related to maintenance contracts, and the leases or rental of medical equipment used in diagnosis or treatment of patients. It would also include the expenses for any medical equipment that was purchased in a single year and not financed.
- *Medical Supplies Expenses:* Includes the expenses related to medical supplies such as sterile gloves, needles, bandages, specimen containers, and catheters. We note that the Medical Supply cost category does not include expenses related to pharmaceuticals (drugs and biologicals).
- *Professional, Scientific, & Technical Services:* Includes the expenses for any professional services purchased from an outside agency or party and could include fees including but not limited to, legal, marketing, professional association memberships, licensure fees, journal fees, continuing education.
- *Administrative & Facility Services:* Includes the expenses for any administrative and facility services purchased from an outside agency or party and could include fees including but not limited to, accounting, billing, office management services, security services, transportation services, landscaping, or professional car upkeep.
- *Other Services:* Includes other service expenses including, but not limited to, nonresidential maintenance and repair, machinery repair, janitorial, and security services.

Table 31 shows the proposed cost categories and weights for the 2013-based FQHC market basket. The resulting cost weights include combining the cost weights derived from the Medicare Cost Report Data (shown in Table 29), distributing the fringe benefits weight across the three compensation cost categories (shown in Table 28), and disaggregating the residual cost weight into detailed cost categories (shown in Table 30). Additionally, we compare the cost weights of the proposed 2013-based FQHC market basket to the cost weights in the 2006-based MEI, where we have grouped the cost weights from the MEI to align with the FQHC proposed cost categories.

TABLE 31—PROPOSED FQHC MARKET BASKET AND MEI, COST CATEGORIES, COST WEIGHTS

FQHC cost category	2013 FQHC weight (percent)	2006 MEI weight (percent)	MEI cost category
FQHC Market Basket	100.0	100.000	MEI.
Total Compensation	68.7	67.419	Total Compensation.
FQHC Practitioner Compensation	31.7	50.866	Physician Compensation.
Other Clinical Compensation	9.5	6.503	Other Clinical Compensation.
Non-health Compensation	27.4	10.050	Non-health Compensation.
All Other Products	16.1	14.176	All Other Products.
Utilities	1.4	1.266	Utilities.
Miscellaneous Office Expenses	2.8	2.478	Miscellaneous Office Expenses.
Telephone	1.7	1.501	Telephone.
Postage	1.0	0.898	Postage.
Medical Equipment	2.2	1.978	Medical Equipment.
Medical Supplies	2.0	1.760	Medical Supplies.
Professional Liability Insurance	.....	4.295	Professional Liability Insurance.
Pharmaceuticals	5.1	.....	Pharmaceuticals.
All Other Services	9.0	8.095	All Other Services.
Professional, Scientific & Technical Services	2.9	2.592	Professional, Scientific & Technical Services.
Administrative & Facility Services	3.4	3.052	Administrative & Facility Services.
Other Services	2.7	2.451	Other Services.
Capital	6.1	10.310	Capital.
Fixed Capital	4.5	8.957	Fixed Capital.
Moveable Capital	1.7	1.353	Moveable Capital.

Although the overall cost structure of the MEI, the index currently used to update the FQHC PPS base payment, is similar to the proposed FQHC cost structure, there are a few key differences.

First, though total compensation costs in the proposed FQHC market basket and the MEI are each approximately 67–68 percent of total costs, non-health compensation accounts for a larger share of compensation costs in the FQHC setting than in the self-employed physician office. Likewise, physician compensation accounts for a larger percentage of costs in the MEI than FQHC practitioner compensation accounts for in the proposed FQHC market basket.

Second, the proposed FQHC market basket includes a cost category for pharmaceuticals, while drug costs are excluded from the MEI. Drug costs are an expense in the FQHC PPS base payment rate since drugs and biologicals that are not usually self-administered, and certain Medicare-covered preventive injectable drugs are paid incident to a visit while drug costs are reimbursed separately under the PFS.

Third, as mentioned previously, PLI expenditures are excluded from the proposed FQHC market basket since most FQHCs PLI costs are covered under the Federal Tort Claims Act, while in the MEI the PLI costs are a significant expense for self-employed physicians. Finally, fixed capital expenses, which include costs such as office rent and depreciation, are about half of the share in the FQHC market basket as they are in the MEI.

c. Selection of Price Proxies for the Proposed 2013-Based FQHC Market Basket

After establishing the 2013 cost weights for the proposed FQHC market basket, an appropriate price proxy was selected for each cost category. The proposed price proxies are chosen from a set of publicly available price indexes

that best reflect the rate of price change for each cost category in the FQHC market basket. All of the proxies for the proposed 2013-based FQHC market basket are based on indexes published by the Bureau of Labor Statistics (BLS) and are grouped into one of the following BLS categories:

- *Producer Price Indexes:* Producer Price Indexes (PPIs) measure price changes for goods sold in markets other than the retail market. PPIs are preferable price proxies for goods and services that businesses purchase as inputs. For example, we are proposing to use a PPI for prescription drugs, rather than the Consumer Price Index (CPI) for prescription drugs, because healthcare providers generally purchase drugs directly from a wholesaler. The PPIs that we are proposing to use measure price changes at the final stage of production.
- *Consumer Price Indexes:* CPIs measure change in the prices of final goods and services bought by the typical consumer. Because they may not represent the price encountered by a producer, we are proposing to use CPIs only if an appropriate PPI is not available, or if the expenditures are more like those faced by retail consumers in general rather than by purchasers of goods at the wholesale level.
- *Employment Cost Indexes:* Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. Appropriately, they are not affected by shifts in employment mix.

We evaluate the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. Availability means that the proxy is publicly available. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. We believe the proposed PPIs, CPIs, and ECIs selected meet these criteria.

Table 32 lists all price proxies that we are proposing to use for the 2013-based FQHC market basket. Below is a detailed explanation of the price proxies that we are proposing for each cost category weight. We note that many of the proxies that we are proposing for the 2013-based FQHC market basket are the same as those used for the 2006-based MEI.

(1) *FQHC Practitioner Compensation:* We are proposing to use the ECI for Total Compensation for Private Industry Workers in Professional and Related) (BLS series code CIU2010000120000I) to measure price growth of this category. There is no specific ECI for physicians and, therefore, similar to the MEI, we are proposing to use an index that is based on professionals that receive advanced training. We note that the 2006-based MEI has a separate cost category for Physician Wages and Salaries and Physician Benefits. For these cost categories, the MEI uses the ECI for Wages and Salaries and ECI for Benefits for Professional and Related Occupations.

(2) *Other Clinical Compensation:* We are proposing to use the ECI for Total Compensation for all Civilian Workers in Health Care and Social Assistance (BLS series code CIU1016200000000I) to measure the price growth of this cost category. This cost category consists of compensation costs for Nurses, Laboratory Technicians, and all other health staff not included in the FQHC practitioner compensation category. Based on the clinical composition of these workers, we believe that the ECI for health-related workers is an appropriate proxy to measure compensation price pressures for these workers. The MEI uses the ECI for Wages and Salaries and benefits for Hospitals.

(3) *Non-Health Compensation:* We are proposing to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this cost category. The Non-health compensation cost weight is predominately attributable to administrative and facility type occupations, as reported in the data from the Medicare cost reports. We note the MEI has a composite index of four price proxies, with the majority of the composite index accounted for by administrative occupations, proxied by the ECI for Wages & Salaries of Office and Administrative Support (Private).

(4) *Utilities:* We are proposing to use the CPI for Fuel and Utilities (BLS series code CUUR0000SAH2) to measure the price growth of this cost category. This is the same proxy used in the 2006-based MEI.

(5) *Miscellaneous Office Expenses:* We are proposing to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. We believe that using the CPI for All Items Less Food and Energy avoids double counting of changes in food and energy prices already captured elsewhere in the market basket. We note the MEI does not have a separate cost category for miscellaneous office expenses.

(6) *Telephone Services:* We are proposing to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same price proxy used in the 2006-based MEI.

(7) *Postage:* We are proposing to use the CPI for Postage (BLS series code CUUR0000SEEC01) to measure the price growth of this cost category. This is the same proxy used in the 2006-based MEI.

(8) *Medical Equipment:* We are proposing to use the PPI Commodities for Surgical and Medical Instruments (BLS series code WPU1562) as the price proxy for this category. This is the same proxy used in the current 2006-based MEI.

(9) *Medical Supplies:* We are proposing to use a 50/50 blended index comprised of the PPI Commodities for Medical and Surgical Appliances and Supplies (BLS series code WPU156301) and the CPI–U for Medical Equipment and Supplies (BLS series code CUUR0000SEMG). The 50/50 blend is used in all market baskets where we do not have an accurate split available. We believe FQHCs purchase the types of supplies contained within these proxies, including such items as bandages, dressings, catheters, intravenous equipment, syringes, and other general disposable medical supplies, via wholesale purchase, as well as at the retail level. Consequently, we are proposing to combine the two aforementioned indexes to reflect those modes of purchase. This is the same proxy used in the 2006-based MEI.

(10) *Pharmaceuticals:* We are proposing to use the PPI Commodities for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. We note the MEI does not have a separate cost category for Pharmaceuticals. This price proxy is used to measure prices of Pharmaceuticals in other CMS market baskets, such as 2010-based Inpatient Prospective Payment System and 2010-based Skilled Nursing Facility market baskets.

(11) *Professional, Scientific, & Technical Services:* We are proposing to use the ECI for Total Compensation for Private Industry Workers in Professional, Scientific, and Technical Services (BLS series code CIU2015400000000I) to measure the price growth of this cost category. This

is the same proxy used in the 2006-based MEI.

(12) *Administrative & Facility Services:* We are proposing to use the ECI Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this cost category. This is the same price proxy used in the 2006-based MEI.

(13) *Other Services:* We are proposing to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same price proxy used in the 2006-based MEI.

(14) *Fixed Capital:* We are proposing to use the PPI Industry for Lessors of Nonresidential Buildings (BLS series code PCU531120531120) to measure the price growth of this cost category. This is the same price proxy used in the 2006-based MEI. We believe this is an appropriate proxy since fixed capital expenses in FQHCs should reflect inflation for the rental and purchase of business office space.

(15) *Moveable Capital:* We are proposing to use the PPI Commodities for Machinery and Equipment (series code WPU11) to measure the price growth of this cost category as this cost category represents nonmedical moveable equipment. This is the same proxy used in the 2006-based MEI.

Table 32 lists the proposed price proxies for each cost category in the proposed FQHC market basket.

TABLE 32—PROPOSED COST CATEGORIES AND PRICE PROXIES FOR THE FQHC MARKET BASKET

Cost category	FQHC price proxies
FQHC Practitioner Compensation	ECI—for Total Compensation for Private Industry Workers in Professional and Related.
Other Clinical Compensation	ECI—for Total Compensation for all Civilian Workers in Health Care and Social Assistance.
Non-health Compensation	ECI—for Total Compensation for Private Industry Workers in Office and Administrative Support.
Utilities	CPI–U for Fuels and Utilities.
Miscellaneous Office Expense	CPI–U for All Items Less Food And Energy.
Telephone	CPI–U for Telephone.
Postage	CP–U for Postage.
Medical Equipment	PPI Commodities for Surgical and Medical Instruments.
Medical supplies	Blend: PPI Commodities for Medical and Surgical Appliances and Supplies and CPI for Medical Equipment and Supplies.
Pharmaceuticals	PPI Commodities for Pharmaceuticals for Human Use, Prescription.
Professional, Scientific, and Technical Services	ECI—for Total Compensation for Private Industry Workers in Professional, Scientific, and Technical Services.
Administrative & Facility Services	ECI—for Total Compensation for Private Industry Workers in Office and Administrative Support.
Other Services	ECI—for Total compensation for Private industry workers in Service Occupations.
Fixed Capital	PPI Industry—for Lessors of nonresidential buildings.
Moveable Capital	PPI Commodities—for Machinery and Equipment.

d. Inclusion of Multi-Factor Productivity in the Proposed FQHC Market Basket

Section 1834(o)(2)(B)(ii) of the Act describes the methods for determining updates to FQHC PPS payment. After the first year of implementation, the FQHC PPS base payment rate must be increased by the percentage increase in the MEI. In subsequent years, the FQHC PPS base payment rate shall be increased by the percentage increase in a market basket of FQHC goods and services as established through regulations or, if not available, the MEI published in the PFS final rule.

The MEI published in the PFS final rule has a productivity adjustment. The MEI has been adjusted for changes in productivity since its inception. In the CY 2003 PFS final rule with comment period (67 FR 80019), we implemented a change in the way the MEI was adjusted to account for changes in productivity. The MEI used for the 2003 physician payment update incorporated changes in the 10-year moving average of private nonfarm business (economy-wide) multifactor productivity. Previously, the index incorporated changes in productivity by adjusting the labor portions of the index by the 10-year moving average of private nonfarm business (economy-wide) labor productivity.

In 2012, we convened the MEI Technical Panel to review all aspects of the MEI including inputs, input weights, price-measurement proxies, and productivity adjustment. For more information regarding the MEI Technical Panel, see the CY 2014 PFS final rule with comment period (78 FR 74264). The MEI Technical Panel was asked to review the approach of adjusting the MEI by the 10-year moving average of private nonfarm business productivity. As described in the CY 2014 PFS final rule with comment period (78 FR 74271), the MEI Technical Panel concluded in Finding 5.1 that ''such an adjustment continues to be appropriate. This adjustment prevents 'double counting' of the effects of productivity improvements, which would otherwise be reflected in both (i) the increase in compensation and other input price proxies underlying the MEI, and (ii) the growth in the number of physician services performed per unit of input resources, which results from advances in productivity by individual physician practices.''

We are proposing to include a productivity adjustment similar to the MEI in the proposed FQHC market basket. We believe that applying a productivity adjustment is appropriate because this would be consistent with the MEI, which has an embedded productivity adjustment. We note that the MEI Technical Panel concluded that a productivity adjustment is appropriate for the MEI given the type of services performed in physician's offices. Specifically, the MEI Technical Panel report states that ''The input price increases within the MEI are reflected in the price proxies, such as changes in wages and benefits. Wages increase, in part, due to the ability of workers to increase the amount of output per unit of input. Absent a productivity

adjustment in the MEI, physicians would be receiving increased payments resulting both from their ability to increase their individual outputs and from the productivity gains already reflected in the wage proxies used in the index. The productivity adjustment used in the MEI ensures the productivity gains reflected in increased outputs are not double counted, or paid for twice. Currently, the productivity adjustment in the MEI is based on changes in economy-wide productivity based on the rationale that the price proxy for physician income reflects changes in economy-wide wages. Implicitly, this assumes physicians can achieve the same level of productivity as the average general wage earner.'' We believe that the services performed in FQHC facilities are similar to those covered by the MEI, and therefore, a productivity adjustment is appropriate to avoid double counting of the effects of productivity improvements.

We propose to use the most recent estimate of the 10-year moving average of changes in annual private nonfarm business (economy-wide) multifactor productivity (MFP), which is the same measure of MFP used in the MEI. The BLS publishes the official measure of private nonfarm business MFP. (See *http://www.bls.gov/mfp* for the published BLS historical MFP data). For the final FQHC market basket update, we propose to use the most recent historical estimate of annual MFP as published by the BLS. Generally, the most recent historical MFP estimate is lagged two years from the payment year. Therefore, we propose to use the 2015 MFP as published by BLS in the CY2017 FQHC market basket update.

We note that MFP is derived by subtracting the contribution of labor and capital input growth from output growth. Since at the time of the proposed rule the 2015 MFP has not been published by BLS, we rely on a projection of MFP. The projection of MFP is currently produced by IHS Global Insight (IGI), a national economic forecasting firm with which CMS contracts to forecast the components of the market basket and MFP. A complete description of the MFP projection methodology is available at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html*.

Using IGI's first quarter 2016 forecast, the productivity adjustment for CY 2017 (the 10-year moving average of MFP for the period ending CY 2015) is projected to be 0.4 percent. If more recent data are subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data to determine the CY 2017 increase in the proposed FQHC market basket in the final rule.

5. CY 2017 Proposed Market Basket Update: Proposed CY 2017 FQHC Market Basket Update Compared to the MEI Update for CY 2017

For CY 2017, we are proposing to use the proposed 2013-based FQHC market basket increase factor to update the FQHC PPS base payment rate. Consistent with CMS practice, we estimated the market basket update for the FQHC PPS based on the most recent forecast from IGI. Identical to the MEI, we are proposing to use the update based on the most recent historical data available at the time of publication of the final rule. For example, the final CY 2017 FQHC update would be based on the four-quarter moving-average percent change of the FQHC market basket through the second quarter of 2016 (based on the final rule's statutory publication schedule). For the proposed rule, we do not have the second quarter of 2016 historical data and, therefore, we will use the most recent projection available.

Based on IGI's first quarter 2016 forecast with historical data through the fourth quarter of 2015, the projected proposed FQHC market basket increase factor for CY 2017 would be 1.7 percent. This reflects a 2.1-percent increase of FQHC input prices and a 0.4-percent adjustment for productivity. We are also proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket or MFP) we would use such data, to determine the CY 2017 update in the final rule.

For comparison, the 2006-based MEI is projected to be 1.3 percent in CY 2017; this estimate is based on IGI's first quarter 2016 forecast (with historical data through the fourth quarter of 2015). Table 33 compares the proposed 2013-based FQHC market basket updates and the 2006-based MEI market basket updates for CY 2017.

TABLE 33—FQHC MARKET BASKET AND MEI, COST CATEGORIES, COST WEIGHTS, MFP, AND CY 2017 UPDATE

FQHC cost category	CY 2017 Update		MEI cost category
	(percent)	(percent)	
FQHC Market Basket	1.7	1.3	MEI.
Productivity adjustment	0.4	0.4	Productivity adjustment.
FQHC Market Basket (unadjusted)	2.1	1.7	MEI (unadjusted).
Total Compensation	2.1	2.0	Total Compensation.
FQHC Practitioner Comp.	1.9	2.0	Physician Compensation.
Other Clinical Compensation	1.9	2.0	Other Clinical Compensation.
Non-health Compensation	2.4	2.4	Non-health Compensation.
All Other Products	2.6	−0.6	All Other Products.
Utilities	−3.9	−3.9	Utilities.
Miscellaneous Office Expenses	2.0	−1.7	Miscellaneous Office Expenses.
Telephone	0.4	0.4	Telephone.
Postage	0.3	0.3	Postage.
Medical Equipment	1.2	1.2	Medical Equipment.
Medical Supplies	−0.4	−0.4	Medical Supplies.
Professional Liability Insurance	.....	−0.4	Professional Liability Insurance.
Pharmaceuticals	7.8	.....	Pharmaceuticals.
All Other Services	2.0	2.0	All Other Services.
Professional, Scientific & Technical Services	1.5	1.5	Professional, Scientific & Technical Services.
Administrative & Facility Services	2.4	2.4	Administrative & Facility Services.
Other Services	1.9	1.9	Other Services.
Capital	1.6	1.9	Capital.
Fixed Capital	2.1	2.1	Fixed Capital.
Moveable Capital	0.1	0.1	Moveable Capital.

For CY 2017, the proposed 2013-based FQHC market basket update (1.7 percent) is 0.4 percent higher than the 2006-based MEI (1.3 percent). The 0.4 percentage point difference stems mostly from the inclusion of pharmaceuticals in the proposed FQHC market basket. Prices for pharmaceuticals are projected to grow 7.8 percent, faster than the other components in the market basket. This cost category and associated price pressures are not included in the MEI.

We propose to update the FQHC PPS base payment rate by 1.7 percent for CY 2017 based on the proposed 2013-based FQHC market basket. The proposed FQHC market basket would more accurately reflect the actual costs and scope of services that FQHCs furnish compared to the 2006-based MEI. We invite public comment on all aspects of the FQHC market basket proposals.

C. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of the 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 we established 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 are expected to be posted on the CMS Web site by the end of June 2016 at which time their AUC libraries will be considered to be specified AUC for purposes of section 1834(q)(2)(A) of the Act.

This rule proposes requirements and processes for specification of qualified clinical decision support mechanisms (CDSMs) under the Medicare AUC program; the initial list of priority clinical areas; and exceptions to the requirement that ordering professionals consult specified applicable AUC when ordering applicable imaging services.

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 are 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 and/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 would 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 definitions of CDSM 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. Previous CDSM Experience

In the CY 2016 PFS final rule with comment period, we included a discussion of the Medicare Imaging Demonstration (MID), which was required by section 135(b) of the MIPPA, in addition to independent experiences of implementing AUC by several healthcare systems and academic medical centers. Two key aspects of that discussion remain relevant to the CDSM component of this program. First, AUC, and the CDSMs through which clinicians access AUC, must be integrated into the clinical workflow and facilitate, not obstruct, evidence-based care delivery. For instance, a CDSM external to a provider's primary user interface could utilize an application program interface (API), a set of protocols and tools specifying how software components should interact, to pull relevant information into the decision support application. By adhering to common interoperability standards, such as the national standards advanced through certified health IT (see 2015 edition of criteria available in the **Federal Register** (80 FR 62601) and described in the Interoperability Standards Advisory at *https://www.healthit.gov/standards-advisory*), CDSMs could both ensure integration of patient-specific data from EHRs, and allow clinicians to optimize the time spent using the tool.

Second, the ideal AUC is an evidence-based guide that starts with a patient's specific clinical condition or presentation (symptoms) and assists the clinician in the overall patient workup, treatment, and follow-up. Imaging would appear as key nodes within the clinical management decision tree.

Other options outside of certified EHR technology exist to access AUC through CDSMs. Stand-alone, internet-based CDSMs are available and, although they will not interact with EHR data, can nonetheless search for and present AUC relevant to a patient's presenting symptoms or condition.

In communicating an appropriateness rating to the ordering practitioner, some CDSMs provide a scale with numeric ratings, some output a red, yellow, or green light while others provide a dichotomous yes or no. At this time, we do not believe there is one correct approach to communicating the level of appropriateness to the ordering professional. However, section 1834(q)(4)(B) of the Act requires that information be reported on the claim form as to whether the service would or would not adhere to the specified AUC consulted through a particular CDSM, or whether the AUC was not applicable to the service. We are requesting feedback from commenters regarding how appropriateness ratings provided by CDSMs could be interpreted and recorded for the purposes of this program.

There are different views about the comprehensiveness of AUC that should be accessible within CDSMs. Some stakeholders believe that the CDSM should contain as comprehensive a collection of AUC as possible, incorporating individual criteria from across all specified AUC libraries. The intent would be for ordering professionals to avoid the frustration, experienced and voiced by many clinicians participating in the MID, of spending time navigating the CDSM only to find that no criterion for their patient's specific clinical condition exists.

Other stakeholders believe, based on decades of experience rolling out AUC in the context of robust quality improvement programs that it is best to

start with a CDSM that contains AUC for a few clinical areas where impact is large and evidence is strong. This would ensure that quality AUC are developed, and that clinicians and entire care teams could fully understand the AUC they are using, including when they do not apply to a particular patient.

As we stated in the CY 2016 PFS final rule with comment period, we believe there is merit to both approaches, and it has been suggested to us that the best approach may depend on the particular care setting. The second, ''focused'' approach may work better for a large health system that produces and uses its own AUC. The first, ''comprehensive'' approach may in turn work better for a smaller practice with broad image ordering patterns and fewer resources that wants to simply adopt and start using a complete AUC system developed elsewhere. We believe a successful program would allow flexibility, and under section 1834(q) of the Act, we foresee a number of sets of AUC developed by different PLEs, and an array of CDSMs from which clinicians may choose.

3. Priority Clinical Areas

We established in the CY 2016 PFS final rule with comment period that we would identify priority clinical areas through rulemaking, and that these may be used in the determination of outlier ordering professionals (a future phase of the Medicare AUC program). The concept of priority clinical areas allows us to implement an AUC program that combines the focused and comprehensive approaches to implementation discussed above. Although potentially large volumes of AUC (as some PLEs have large libraries of AUC) would become specified across clinical conditions and advanced imaging technologies, we believe this rapid and comprehensive roll out of specified AUC should be balanced with a more focused approach when identifying outlier ordering professionals. We believe this will provide an opportunity for physicians and practitioners to become familiar with AUC in identified priority clinical areas prior to Medicare claims for those services being part of the input for calculating outlier ordering professionals.

As we describe earlier, CDSMs are the access point for ordering professionals to consult AUC. We believe the combination of the comprehensive and focused approaches should be applied to CDSM requirements as we consider a minimum floor of AUC that must be made available to ordering professionals through qualified CDSMs. AUC that reasonably address the entire clinical scope of priority clinical areas could establish a minimum floor of AUC to be included in qualified CDSMs, and the number of priority clinical areas could be expanded through annual rulemaking and in consultation with physicians and other stakeholders. This allows priority clinical areas to roll out judiciously, and build over time.

4. 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)(3)(A) of the Act requires the Secretary to specify qualified CDSMs that could be used by ordering professionals to consult with specified applicable AUC for applicable imaging services.

5. Discussion of Statutory Requirements

There are four major components of the AUC program under section 1834(q) of the Act, each with its own implementation date: (1) Establishment of AUC by November 15, 2015 (section 1834(q)(2)); (2) identification of mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3)); (3) AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017 (section 1834(q)(4)); and (4) annual identification of outlier ordering professionals for services furnished after January 1, 2017 (section 1834(q)(5)). As we will discuss later in this preamble, we did not identify mechanisms for consultation by April 1, 2016 and will not have specified or published the list of qualified CDSMs by January 1, 2017; therefore, ordering professionals will not be required to consult CDSMs, and furnishing professionals will not be able to report information on the consultation, by this date.

a. Establishment of AUC

In the CY 2016 PFS final rule with comment period, we addressed the first component 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.

A timeline and process was established for PLEs to apply to become qualified with the first list of qualified PLEs expected to be published at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html* by June 30, 2016.

b. Mechanism for AUC Consultation

The second major component of the Medicare AUC program is the specification of qualified CDSMs that could be used by ordering professionals for consultation with specified applicable AUC under section 1834(q)(3) of the Act. We envision a CDSM as an interactive tool that communicates AUC information to the user. Information regarding the clinical presentation of the patient would be incorporated into the CDSM from another health IT system or through data entry by the ordering professional. At a minimum, the tool would provide immediate feedback to the ordering professional on the appropriateness of one or more imaging services. Ideally, CDSMs would be integrated within or seamlessly interoperable with existing health IT systems and would automatically receive patient data from the EHR or through an API or other connection. Such integration would minimize burden on practitioners and avoid duplicate documentation. Also useful to clinicians would be the ability to switch between CDSMs that can interoperate based on common standards.

Section 1834(q)(3)(A) of the Act states that the Secretary must specify qualified CDSMs in consultation with physicians, practitioners, health care technology experts, and other stakeholders. This

paragraph authorizes the Secretary to specify mechanisms that could include: CDS modules within certified EHR technology; private sector CDSMs that are independent of certified EHR technology; and a CDSM established by the Secretary. The Secretary does not propose to establish a CDSM at this time.

All CDSMs must meet the requirements under section 1834(q)(3)(B) of the Act, which specifies that a mechanism must: Make available to the ordering professional applicable AUC and the documentation supporting the appropriateness of the applicable imaging service that is ordered; where there is more than one applicable appropriate use criterion specified for an applicable imaging service, indicate the criteria it uses for the service; determine the extent to which an applicable imaging service that is ordered is consistent with the applicable AUC; generate and provide to the ordering professional documentation to demonstrate that the qualified CDSM was consulted by the ordering professional; be updated on a timely basis to reflect revisions to the specification of applicable AUC; meet applicable privacy and security standards; and perform such other functions as specified by the Secretary (which may include a requirement to provide aggregate feedback to the ordering professional). Section 1834(q)(3)(C) of the Act specifies that the Secretary must publish an initial list of specified mechanisms no later than April 1, 2016, and that the Secretary must identify on an annual basis the list of specified qualified CDSMs.

As we explained in the CY 2016 PFS proposed and final rules with comment period, implementation of many aspects of the amendments made by section 218(b) of the PAMA requires consultation with physicians, practitioners, and other stakeholders, and notice and comment rulemaking. We continue to believe the PFS calendar year rulemaking process is the most appropriate and administratively feasible implementation vehicle. Given the timing of the PFS rulemaking process, we were not able to include proposals in the PFS proposed rule to begin implementation in the same year the PAMA was enacted, as we would have had to interpret and analyze the new statutory language, and develop proposed plans for implementation in under one month. As we did prior to the CY 2016 PFS proposed rule when we met extensively with stakeholders to gain insight and hear their comments and concerns about the AUC program, we have used the time prior to the CY 2017 PFS proposed rule to meet with many of the same stakeholders but also a new group of stakeholders specifically related to CDSMs. In addition, we are continuing our stepwise approach to implementing this AUC program. The first phase of the AUC program (specifying AUC including defining what AUC are and specifying the process for developing them) was accomplished through last year's CY 2016 PFS final rule with comment period. For this second phase, we will use this CY 2017 PFS rulemaking process as the vehicle to establish requirements for CDSMs, and the process to specify qualified CDSMs, in a transparent manner that allows for stakeholder and public involvement. Therefore, the final CDSM requirements and process for CDSMs to become qualified would be published in the CY 2017 PFS final rule with comment period on or about November 1, 2016.

c. AUC Consultation and Reporting

The third major component of the 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. 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. Section 1834(q)(4)(D) of the Act specifies that the applicable payment systems for the AUC consultation and reporting requirements are the PFS, hospital outpatient prospective payment system, and the ambulatory surgical center payment systems.

Since a list of qualified CDSMs is not yet available and will not be available by January 1, 2017, we will not require ordering professionals to meet this requirement by that date.

d. Identification of Outliers

The fourth component of the 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. Although we are not proposing to implement these sections in the CY 2017 PFS proposed rule, we propose below a list of priority clinical areas which may serve as part of the basis for identifying outlier ordering professionals.

6. Proposals for Implementation

We propose to amend our regulations at § 414.94, ''Appropriate Use Criteria for Certain Imaging Services.''

a. Definitions

In § 414.94(b), we propose to codify and add language to clarify some of the definitions provided in section 1834(q) of the Act, as well as define terms that were not defined in statute but for which a definition would be helpful for program implementation. In this section, we provide a description of the terms we propose to codify to facilitate understanding and encourage public comment on the AUC program.

We propose to define CDSM under § 414.94(b) 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. A CDSM would incorporate specified applicable AUC sets from which an ordering professional could select. A CDSM may be a module 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. If within or available through certified EHR technology, a qualified CDSM would incorporate relevant patient-specific information into the assessment of the appropriateness of an applicable imaging service.

As prescribed in section 1834(q) of the Act and § 414.94(b) of our regulations, the Medicare AUC program imposes requirements only for applicable imaging services furnished in applicable settings. Further, as specified in section 1834(q)(4)(D) of the Act, we propose to amend our regulation at § 414.94(b) to state that the applicable payment systems for the Medicare AUC program are the PFS under section

1848(b) of the Act, the prospective payment system for hospital outpatient department services under section 1833(t) of the Act, and the ambulatory surgical center payment systems under section 1833(i) of the Act. Applicable payment systems are relevant to implementation of section 1834(q)(4)(B) of the Act, entitled ''Reporting by Furnishing Professionals.''

We remind readers that in PFS rulemaking for CY 2016 we defined applicable imaging service in § 414.94(b) as an advanced diagnostic imaging service as defined in 1834(e)(1)(B) of the Act for which the Secretary determines (i) One or more applicable appropriate use criteria apply; (ii) There are one or more qualified clinical decision support mechanisms listed; and (iii) One or more of such mechanisms is available free of charge.

b. Priority Clinical Areas

We propose to establish a new § 414.94(e)(5) to set forth the initial list of priority clinical areas.

To compile this proposed list we performed an analysis of Medicare claims data using the CMS Chronic Conditions Data Warehouse (CCW) as the primary data source. The CCW contains 100 percent of Medicare claims for beneficiaries who are enrolled in the fee-for-service (FFS) program. Data were derived from the CCW's 2014 Part B non-institutional claim line file, which includes Part B services furnished during CY 2014. This is the main file containing final action claims data for non-institutional health care providers, including physicians, physician assistants, clinical social workers, nurse practitioners, independent clinical laboratories, and freestanding ambulatory surgical centers. The Part B non-institutional claim line file contains the individual line level information from the claim and includes Healthcare Common Procedure Coding System (HCPCS) code(s), diagnosis code(s) using the International Classification of Diseases, Ninth Revision (ICD–9), service dates, and Medicare payment amount. A publicly available version of this dataset can be downloaded from the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html*. We encourage stakeholders to review this dataset as a source that may help inform public comments related to the proposed priority clinical areas.

In the CY 2016 PFS final rule with comment period, we stated that when identifying priority clinical areas we may consider factors such as incidence and prevalence of disease, the volume and variability of utilization of imaging services, the strength of evidence for their use, and applicability of the clinical area to the Medicare population and to a variety of care settings.

Using the 2014 Medicare claims data referenced above, we ranked ICD–9 codes by the frequency with which they were used as the primary indication for specific imaging procedures, which in turn were identified by the volume of individual Current Procedural Terminology (CPT) codes for which payments were made in 2014. We extracted the top 135 ICD–9 codes from this list and formed clinically-related categories. Next, we searched manually through an electronic list of all ICD–9 codes to find others that would plausibly fit into each clinical grouping. This process required subjective clinical judgment on whether a particular ICD–9 code should be included in a given clinical group. The top eight clinical groupings (by volume of procedures) are what we are proposing as the initial list of priority clinical areas. The eight clinical areas account for roughly 40 percent of part B advanced diagnostic imaging services paid for by Medicare in 2014. We are aware that some stakeholders have suggested beginning the AUC program with no more than five priority clinical areas while others have suggested a far greater number. We believe the proposed eight priority clinical areas strike a reasonable balance that allows us to focus on a significant range and volume of advanced diagnostic imaging services.

We also considered extracting pulmonary embolism as a separate priority clinical area from the chest pain grouping based on stakeholder consultation and feedback. However, we decided not to identify pulmonary embolism separately, but are asking for public comment on whether pulmonary embolism should be included as a stand-alone priority clinical area. Based on our consultations with physicians, practitioners and other stakeholders, as required by section 218(b) of the PAMA, we attempted to be inclusive when grouping ICD–9 codes into cohesive clinical areas. As an example of how we derived the priority clinical area for low back pain, we grouped together 10 ICD–9 codes, incorporating six from the top 135 and four from the manual search of all ICD–9 codes. Included in this grouping are the ICD–9 codes for displacement of lumbar intervertebral disc without myelopathy (722.10), degeneration of lumbar of lumbosacral intervertebral disc (722.52), intervertebral disc disorder with myelopathy lumbar region (722.73), post-laminectomy syndrome of lumbar region (722.83), lumbago (724.2), sciatica (724.3), thoracic or lumbosacral neuritis or radiculitis unspecified (724.4), spinal stenosis, lumbar region, without neurogenic claudication (724.02), lumbosacral spondylosis without myelopathy (721.3), and spondylosis with myelopathy lumbar region (721.42) which resulted in 1,883,617 services. To see all of the priority clinical area groupings of diagnosis codes, a table is available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html*.

Using the above methodology, we developed and are proposing eight priority clinical areas. These reflect both the significance and the high prevalence of some of the most disruptive diseases in the Medicare population.

TABLE 34—PROPOSED PRIORITY CLINICAL AREAS WITH CORRESPONDING CLAIMS DATA

Proposed priority clinical area	Total services	% Total services [1]	Total payments	% Total payments/1
Chest Pain (includes angina, suspected myocardial infarction, and suspected pulmonary embolism)	4,435,240.00	12	$ 470,395,545	14
Abdominal Pain (any locations and flank pain)	2,973,331.00	8	235,424,592	7
Headache, traumatic and non-traumatic	2,107,868.00	6	89,382,087	3
Low back pain	1,883,617.00	5	180,063,352	5
Suspected stroke	1,810,514.00	5	119,574,141	4
Altered mental status	1,782,794.00	5	83,296,007	3
Cancer of the lung (primary or metastatic, suspected or diagnosed)	1,114,303.00	3	154,872,814	5

TABLE 34—PROPOSED PRIORITY CLINICAL AREAS WITH CORRESPONDING CLAIMS DATA—Continued

Proposed priority clinical area	Total services	% Total services [1]	Total payments	% Total payments/1
Cervical or neck pain	1,045,381.00	3	83,899,299	3

[1] Percentage of 2014 Part B non-institutional claim line file for advanced imaging services from Medicare claims for beneficiaries who are enrolled in the fee-for-service (FFS) program (source: CMS Chronic Conditions Data Warehouse).

CMS also engaged the CMS Alliance to Modernize Healthcare (CAMH) Federally Funded Research and Development Center (FFRDC), the MITRE Corporation (MITRE), to begin developing efficient and effective processes for managing current and future health technology assessments. MITRE generated an independent report that presents a summary of findings from claims data from the Medicare population and their utilization of advanced imaging procedures. Coupled with our internal analysis, this report has assisted in identification of proposed priority clinical areas for the Medicare AUC program for advanced diagnostic imaging services. Analysis and methods for this report are available at *https://www.mitre.org/publications/technical-papers/claims-data-analysis-to-define-priority-clinical-areas-for-advanced*.

While this year we are proposing priority clinical areas based on an analysis of claims data alone, we may use a different approach in future rulemaking cycles. As we provided in § 414.94(e) of our regulations, we may consider factors other than volume when proposing priority clinical areas including incidence and prevalence of disease, variability of use of particular imaging services, strength of evidence supporting particular imaging services and the applicability of a clinical area to a variety of care settings and to the Medicare population.

We encourage public comments on this proposed initial list of priority clinical areas, including recommendations for other clinical areas that we should include among our list of priority clinical areas. In particular, we are interested in comments on the above methodology or alternate options; whether the proposed priority clinical areas are appropriate including information on the extent to which these proposed priority clinical areas may be represented by clinical guidelines or AUC in the future. Furthermore, we are interested in public comments, supported by published information, with respect to varying levels of evidence that exist across as well as within priority clinical areas.

c. CDSM Qualifications and Requirements

We are proposing to add a new § 414.94(g)(1) to our regulations to establish requirements for qualified CDSMs. Section 1834(q)(3)(A)(iii) of the Act provides relative flexibility for qualified CDSMs, and states that they may include mechanisms that are within certified EHR technology, private sector mechanisms that are independent from certified EHR technology or mechanisms that are established by the Secretary.

We believe that, at least initially, it is in the best interest of the program to establish CDSM requirements that are not prescriptive about specific IT standards. Rather, we are proposing an approach that focuses on the functionality and capabilities of qualified CDSMs. The CDSM, EHR and health IT environments are constantly changing and improving and we want to allow room for growth and innovation. However, in the future, as more stakeholders and other entities including the ONC, AHRQ, and relevant standards development organizations come to consensus regarding standards for CDSMs, then we may consider pointing to such standards as a requirement for qualified CDSMs under this program. We believe standards would make it possible to achieve interoperability, allowing any CDSM to incorporate any standardized AUC and for sets of AUC to be easily interchangeable among various CDSMs. We will continue to work with the ONC and AHRQ to facilitate movement in this direction.

Recent work under the federally-sponsored Clinical Quality Framework (CQF) initiative has successfully developed an integrated approach that harmonizes standards for electronic clinical quality measurement with those that enable shareable clinical decision support artifacts (for example, AUC). The CQF initiative is working to support semantically interoperable data exchange for (1) sending patient data to a service for clinical decision support guidance and receiving clinical decision support guidance or quality measurement results in return, and (2) enabling a system to consume and internally execute decision support artifacts. As this standard is considered sufficiently mature for widespread adoption, the ONC may consider it for use in future editions of certification criteria for health IT. While the current regulation requires no specific standard, the CMS and ONC are supportive of this approach and additional information can be found at *http://hl7-fhir.github.io/cqif/cqif.html*.

Under § 414.94(g)(1), we propose to codify in regulations the seven requirements for qualified CDSMs set forth in section 1834(q)(3)(B)(ii) of the Act. The Act requires qualified CDSMs to make available to the ordering professional specified applicable AUC and the supporting documentation for the applicable imaging service ordered. We do not interpret this requirement to mean that every qualified CDSM must make available every specified applicable AUC. In the CY 2016 PFS final rule with comment period we allowed for the approval of massive libraries of AUC (resulting from approvals for qualified PLEs with comprehensive and extensive libraries), yet we expressed our intention to establish priority clinical areas. While there is a statutory requirement to consult AUC for each applicable imaging service, we recognize that ordering professionals may choose to thoroughly improve their understanding of, and focus their internal quality improvement (QI) programs on, those priority clinical areas; and these areas will in turn serve as the basis for future outlier calculations.

Consistent with that approach, we propose to add a requirement in § 414.94(g)(1)(iii) that qualified CDSMs must make available to ordering professionals, at a minimum, specified applicable AUC that reasonably encompass the entire clinical scope of all priority clinical areas. We encourage and expect some CDSMs, based on the needs of the professionals they serve, will choose to include a far more comprehensive set of AUC going above and beyond the minimum set as we understand many ordering professionals want such comprehensive access to AUC. When this Medicare AUC program is fully implemented, all ordering professionals must consult specified applicable AUC through a qualified

CDSM for every applicable imaging service that would be furnished in an applicable setting and paid for under an applicable payment system in order for payment to be made for the service. However, when identifying the outlier ordering professionals who will be subject to prior authorization beginning in 2020, we anticipate focusing on consultation with specified applicable AUC within priority clinical areas rather than the universe of specified applicable AUC. The concept of priority clinical areas will allow us to implement an AUC program that combines two approaches to implementation allowing clinicians flexibility to either engage with a rapid rollout of comprehensive specified applicable AUC or adopt a focused approach to consulting AUC. Thus, they can choose their approach and select a CDSM and AUC set(s) that fit their needs and preferences, while being sure that each qualified CDSM will include AUC that address all priority clinical areas.

We further propose to add a requirement in § 414.94(g)(1)(iv) of our regulations that qualified CDSMs must be able to incorporate specified applicable AUC from more than one qualified PLE. We believe this approach ensures that CDSMs can expand the AUC libraries they can provide access to in order to represent AUC across all priority clinical areas (consistent with the requirements under proposed § 414.94(g)(1)(iii)). We do not necessarily expect that a single qualified PLE will develop AUC addressing every priority clinical area domain, especially since we believe that over time and through future rulemaking, the list of priority clinical areas will expand and cross additional clinical domains. Ensuring that qualified CDSMs are not limited in their technology to incorporating AUC from only one qualified PLE will help to ensure that ordering professionals will not be in a position of consulting a CDSM that cannot offer them access to AUC that address all priority clinical areas. As stakeholders continue to advance CDSM technology, we look forward to standards being developed and widely accepted so that AUC are incorporated in a standardized format across CDSM platforms. Increasing standardization in this area will move the industry closer to the goal of interoperability across CDSMs and EHRs.

We also propose to add a requirement in § 414.94(g)(1)(i) that specified applicable AUC and related documentation supporting the appropriateness of the applicable imaging service ordered must be made available within the qualified CDSM. For example, the ordering professional would have immediate access to the full appropriate use criterion, citations supporting the criterion and a summary of key evidence supporting the criterion.

We propose to add a requirement in § 414.94(g)(1)(ii), consistent with section 1834(q)(3)(B)(ii)(II) of the Act, that the qualified CDSM must clearly identify the appropriate use criterion consulted if the tool makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario. We believe this is important since CDSMs that choose to incorporate a comprehensive AUC library may be offering the ordering professional access to AUC from multiple qualified PLEs. In such scenarios, it is important that the ordering professional knows which appropriate use criterion is being consulted and have the option to choose one over the other if more than one criterion applies to the scenario.

We propose to add a requirement in § 414.94(g)(1)(v), consistent with section 1834(q)(3)(B)(ii)(III) of the Act, that the qualified CDSM must provide to the ordering professional a determination, for each consultation, of the extent to which an applicable imaging service is consistent with specified applicable AUC or a determination of ''not applicable'' when the mechanism does not contain a criterion that would apply to the consultation. This determination would communicate the appropriateness of the applicable imaging service to the ordering professional. In addition to this determination, we also propose that the CDSM provide the ordering professional with a determination of ''not applicable'' when the mechanism does not contain an appropriate use criterion applicable to that patient's specific clinical scenario.

We propose to add a requirement in § 414.94(g)(1)(vi), consistent with section 1834(q)(3)(B)(ii)(IV) of the Act, that the qualified CDSM must generate and provide to the ordering professional certification or documentation that documents which qualified CDSM was consulted, the name and NPI of the ordering professional that consulted the CDSM and whether the service ordered would adhere to applicable AUC, whether the service ordered would not adhere to such criteria, or whether such criteria was not applicable for the service ordered. We propose to require under § 414.94(g)(1)(vi)(A) that this certification or documentation must be issued each time an ordering professional consults the qualified CDSM. Since Medicare claims will be filed only for services that are rendered to beneficiaries, we will not see CDSM consultation information on the claim form specific to imaging services that are not ordered. We believe that for the CDSM to be able to provide meaningful feedback to ordering professionals, information regarding consultations that do not result in imaging is just as important as information on consultations that do result in an order for advanced imaging.

Thus, we propose to require under § 414.94(g)(1)(vi)(B) that the documentation or certification provided by the qualified CDSM must include a unique consultation identifier. This would be a unique code issued by the CDSM that is specific to each consultation by an ordering professional. This type of unique code may serve as a platform for future collaboration and aggregation of consultation data across CDSMs. In addition, at some point in the future, this unique code may assist in more seamlessly bringing Medicare data together with CDSM clinical data to maximize quality improvement in clinical practices and to iteratively improve the AUC itself.

We propose in § 414.94(g)(1)(vii), consistent with section 1834(q)(3)(B)(ii)(V) of the Act, that the specified applicable AUC content within qualified CDSMs be updated at least every 12 months to reflect revisions or updates made by qualified PLEs to their AUC sets or to an individual appropriate use criterion. We propose 12 months as the maximum acceptable delay for updating content. We believe that in most cases it will be possible to update AUC content more frequently than every 12 months, particularly for cloud-based CDSMs. We further propose in § 414.94(g)(1)(vii)(A) that qualified CDSMs have a protocol in place to more expeditiously remove AUC that are determined by the qualified PLE to be potentially dangerous to patients and/or harmful if followed.

In addition, we propose in § 414.94(g)(1)(vii)(B) that qualified CDSMs must make available for consultation specified applicable AUC that address any new priority clinical areas within 12 months of the priority clinical area being finalized by CMS. We believe this would allow the CDSM sufficient time to incorporate the AUC into the CDSM. Thus, any new priority clinical areas finalized, for example, in the CY 2018 PFS final rule with comment period that would be effective January 1, 2018, would need to be incorporated into a qualified CDSM by January 1, 2019. To accommodate this time frame, we would accept a not applicable determination from a CDSM

for a consultation on a priority clinical area for dates of service through the 12-month period that ends, in this example, on January 1, 2019. We note that all qualified CDSMs that are approved by June 30, 2017 should be capable of supporting AUC for all priority clinical areas that are finalized in the CY 2017 PFS final rule with comment period.

We propose to add a requirement in § 414.94(g)(1)(viii), consistent with section 1834(q)(3)(B)(ii)(VI) of the Act, that the qualified mechanism must meet privacy and security standards under applicable provisions of law. Potentially applicable laws may include the HIPAA Privacy and Security rules.

We propose to add a requirement in § 414.94(g)(1)(ix), consistent with section 1834(q)(3)(B)(ii)(VII) of the Act, that qualified CDSMs must provide ordering professionals aggregate feedback in the form of an electronic report on an annual basis (at minimum) regarding their consultations with specified applicable AUC. Our intent is to require records to be retained in a manner consistent with the HIPAA Security Rule. To provide such feedback, and to make detailed consultation information available to ordering professionals, furnishing professionals (when they have authorized access to the CDSM), auditors and CMS, we propose in § 414.94(g)(1)(x) that a qualified CDSM must maintain electronic storage of clinical, administrative and demographic information of each unique consult for a minimum of 6 years. We believe CDSMs could fulfill this requirement in a number of ways, including involving a third party in the storage of information as well as for providing feedback to ordering professionals. We recognize that these requirements represent a minimum floor that clinicians may choose to expand upon in their local QI programs.

In the event requirements under § 414.94(g)(1) are modified through rulemaking during the course of a qualified CDSM's 5-year approval cycle, we propose in § 414.94(g)(1)(xi) that the CDSM would be required to comply with the modification(s) within 12 months of the effective date of the modification.

d. Process for CDSMs To Become Qualified and Determination of Non-Adherence

We propose that CDSMs must apply to CMS to be specified as a qualified CDSM. We propose that CDSM developers who believe their mechanisms meet the regulatory requirements must submit an application to us that documents adherence to each of the requirements to be a qualified CDSM.

We propose to require in § 414.94(g)(2) that CDSM developers must submit applications to CMS for review that document adherence to each of the CDSM requirements. Applications to be specified as a qualified CDSM must be submitted by January 1 of a year in order to be reviewed within that year's review cycle. For example, the first applications would be accepted from the date of publication of the PFS final rule until January 1, 2017. A determination on whether the applicants are qualified would be made by June 30, 2017. Applications must be submitted electronically to *ImagingAUC@cms.hhs.gov*. This process and timeline mirror the qualified PLE application and approval process and timeline. As we did for qualified PLEs, we will post a list of all applicants that we determine to be qualified CDSMs to our Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html* by June 30. We propose that all qualified CDSMs must reapply every 5 years and their applications must be received by January 1 during the 5th year that they are qualified CDSMs. It is important to note that, as with PLE applications, the application for qualified CDSMs is not a CMS form; rather it is created by the applicant. A CDSM that is specified as qualified for the first 5-year cycle beginning on July 1, 2017 would be required to submit an application for requalification by January 1, 2022. A determination would be made by June 30, 2022, and, if approved, the second 5-year cycle would begin on July 1, 2022.

An example of our proposed timeline for applications and the approval cycle is as follows:

- Year 1 = July 2017 to June 2018.
- Year 2 = July 2018 to June 2019.
- Year 3 = July 2019 to June 2020.
- Year 4 = July 2020 to June 2021.
- Year 5 = July 2021 to June 2022 (reapplication is due by January 1, 2022).

We believe it is important for us to have the ability to remove from the list of specified qualified CDSMs a CDSM that we determine fails to adhere to any of the qualification requirements, including removal outside of the proposed 5-year cycle. We propose to state under § 414.94(h) that, at any time, we may remove from the list of qualified CDSMs a CDSM that fails to meet the criteria to be a qualified CDSM or consider this information during the requalification process. Such determinations may be based on public comment or our own review and we may consult with the National Coordinator for Health Information Technology or her designee to assess whether a qualified CDSM continues to adhere to requirements.

We invite comments on how we could streamline and strengthen the approval process for CDSMs in future program years. For instance, CMS may consider a testing framework for CDSMs that would validate adherence to specific standards that enable seamless incorporation of AUC across CDSMs.

e. Consultation by Ordering Professional and Reporting by Furnishing Professional

Although we continue to aggressively move forward to implement this AUC program, ordering professionals will not be expected to consult qualified CDSMs by January 1, 2017. At the earliest, under this proposal, the first qualified CDSM(s) will be specified on June 30, 2017. We anticipate that some ordering professionals could be able to begin consulting AUC through qualified CDSMs very quickly as some may already be aligned with a qualified CDSM.

We anticipate that furnishing professionals may begin reporting as early as January 1, 2018. This reporting delay is necessary 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. While there will be further rulemaking next year, we are announcing this date because the agency expects physicians and other stakeholders/regulated parties to begin preparing themselves to begin reporting on that date. We will adopt procedures for capturing this information on claims forms and the timing of the reporting requirement through PFS rulemaking for CY 2018.

As we expect to implement the AUC consultation and reporting requirements under section 1834(q)(4)(A) and (B) of the Act on January 1, 2018, we are interested in receiving feedback from the public to include a discussion of specific operational considerations that we should take into account and include in such rulemaking. For example, commenters could consider alternatives for reporting data on claims and for seeking exceptions, as discussed below. We also seek information on the barriers to implementation along this timeline that allows ordering and furnishing professionals to be prepared to consult AUC and report consultation information on the claims and whether

separate rulemaking outside of the payment rule cycle would be preferred.

Under section 1834(q)(4)(B) of the Act, Medicare claims for applicable imaging services furnished in applicable settings can only be paid under the applicable payment systems if certain information is included on the claim including: Which qualified CDSM was consulted by the ordering professional for the service; whether the service, based on the CDSM consultation, adheres to specified applicable AUC, does not adhere to specified applicable AUC or whether no criteria in the CDSM were applicable to the patient's clinical scenario; and, the national provider identifier (NPI) of the ordering professional. This section further allows payment for these services only if the claim contains such information beginning January 1, 2017. To develop and operationalize a meaningful solution to collecting new AUC consultation-related information on the claims, we must diligently evaluate our options taking into account the vast number of claims impacted and the limitations of the legacy claims processing system. While we could have moved more quickly to establish some sort of AUC consultation indicator for Medicare claims, any such indicator would have been a relatively meaningless token. Additionally, in the case of advanced imaging services, related claims are already required to append certain HCPCS modifiers and G codes for purposes of proper payments. In the recent implementation of section 218(a) of the PAMA, we established a HCPCS modifier for CT services rendered on machines that do not meet an equipment standard. It is important that we understand and evaluate how the additional requirements for AUC reporting would impact the information that is already required for advanced imaging services. Moving too quickly to satisfy the reporting requirement could inadvertently result in technical and operational problems that could cause delays in payments.

Section 1834(q)(4)(C) of the Act includes exceptions that allow claims to be paid even though they do not include the information about AUC consultation by the ordering 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 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 are considering the mechanisms for appending the AUC consultation information to various types of Medicare claims and expect to develop requirements for appending such information in the CY 2018 PFS rulemaking process. Stakeholders interested in sharing feedback related to reporting and claims processing are welcome to do so as part of the comment period for this proposed rule. We are particularly interested in receiving feedback on, for example, whether the information should be collected using HCPCS level II G codes or HCPCS modifiers. We will use this feedback to inform CY 2018 rulemaking.

f. Exceptions To Consulting and Reporting Requirements

Section 1834(q)(4)(C) of the Act provides for certain exceptions to the AUC consultation and reporting requirements under section 1834(q)(4)(B) of the Act. First, the statute provides for an exception under section 1834(q)(4)(C)(i) of the Act where an applicable imaging service is ordered for an individual with an emergency medical condition as defined in section 1867(e)(1) of the Act. We believe this exception is warranted because there can be situations in which a delay in action would jeopardize the health or safety of individuals. Though we believe they occur primarily in the emergency department, these emergent situations could potentially arise in other settings. Furthermore, we recognize that most encounters in an emergency department are not for an emergency medical condition as defined in section 1867(e)(1) of the Act.

We propose to provide for an exception to the AUC consultation and reporting requirements under § 414.94(i)(1) for an applicable imaging service ordered for an individual with an emergency medical condition as defined in section 1867(e)(1) of the Act. For example, if a patient, originally determined by the clinician to have an emergency medical condition prior to ordering an applicable imaging service, is later determined not to have had an emergency medical condition at that time, the relevant claims for applicable imaging services would still qualify for an exception. To meet the exception for an emergency medical condition as defined in section 1867(e)(1) of the Act, the clinician only needs to determine that the medical condition manifests itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in: Placing the health of the individual (or a woman's unborn child) in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part. Orders for advanced imaging services for beneficiaries with an emergency medical condition as defined under section 1867(e)(1) of the Act are excepted from the requirement to consult AUC. We intend through the CY 2018 PFS proposed rule to propose more details around how this exception will be identified on the Medicare claim.

The second exception is under section 1834(q)(4)(ii) of the Act for applicable imaging services ordered for an inpatient and for which payment is made under Medicare Part A. We propose to codify this exception in new § 414.94(i)(2). While we are including this exception consistent with statute, we note that if payment is made under Medicare Part A, the service would not be paid under an applicable payment system, such that the AUC consultation and reporting requirements under § 414.94 would never apply.

The third exception is under section 1834(q)(4)(iii) of the Act for applicable imaging services ordered by an ordering professional who the Secretary determines, on a case-by-case basis and subject to annual renewal, that consultation with applicable AUC would result in a significant hardship, such as in the case of a professional practicing in a rural area without sufficient Internet access. We propose to codify this exception in new § 414.94(i)(3) by specifying that ordering professionals who are granted a significant hardship exception for purposes of the Medicare EHR Incentive Program payment adjustment under § 495.102(d)(4)(i), (ii), or (iii)(A)(B) of our regulations would also be granted a significant hardship exception for purposes of the AUC consultation requirement. We are proposing, to the extent technically feasible, that the year for which the eligible professional is excepted from the EHR Incentive Program payment adjustment is the same year that the ordering professional is excepted from the requirement to consult AUC through a qualified CDSM. We propose not to adopt the Meaningful Use significant hardship exception under § 495.102(d)(4)(iv)(C) as an exception for purposes of the AUC consultation requirement. Therefore, ordering professionals with a primary specialty of anesthesiology, radiology or

pathology will not be categorically excepted from AUC consultation requirements.

We believe there is substantial overlap between the eligible professionals that would seek a hardship exception under the EHR Incentive Program and those ordering professionals that would seek a hardship exception under the AUC program and, as such, this proposal would be administratively efficient. Using an existing program is the most efficient and expeditious manner to implement the significant hardship exception under the Medicare AUC program. We also believe it is the only administratively feasible option for a national significant hardship identification process that can be implemented by January 1, 2018, though we intend to revisit this option for years after 2018 as the current EHR Incentive Program payment adjustment is set to expire after the 2018 payment year as the Merit-Based Incentive Payment System takes effect. In addition, below we discuss considerations for a supplemental process to account for hardships for ordering professionals that are not eligible to apply for a significant hardship under the EHR Incentive Program (for example, non-physician practitioners) and ordering professionals that incur a significant hardship outside of the EHR Incentive Program application deadline.

The criteria for significant hardships under the EHR Incentive Program relate to insufficient internet connectivity, practicing for less than 2 years, practicing at multiple locations with the inability to control the availability of Certified EHR Technology, lack of face-to-face interaction with patients or a primary specialty designation of anesthesiology, radiology or pathology. We believe that most of these criteria would be relevant to demonstrate a significant hardship for ordering professionals to consult AUC. Regarding hardship exceptions for certain specialty designations, based on Medicare claims data for advanced imaging services from the first 6 months of 2014, approximately 1.2 percent of those claims were for advanced imaging services that had been ordered by a professional with one of the three primary specialty designations. While their combined ordering volume is small, we do not believe that categorical exclusion of certain specialties of which the practitioner selected as their primary specialty designation for Medicare enrollment would necessarily be appropriate under the AUC program. Since eligible professionals in these three specialties are categorically excepted from the EHR Incentive Program payment adjustment, few of them would have applied for an exception on the other grounds. Therefore, we must consider another mechanism to evaluate whether ordering practitioners with these medical specialties experience a significant hardship for purposes of the AUC program.

We understand that there are differences between the purpose and timing of significant hardship exceptions for the EHR Incentive Program and the Medicare AUC program. Foremost, a significant hardship under the EHR Incentive Program is generally based on a hardship that occurred in a prior period, impacting meaningful EHR use that would affect payments in a subsequent calendar year. For example, a professional that submits an application in March 2017 and qualifies for the hardship exception under the EHR Incentive Program would be exempt from the EHR payment adjustment for calendar year 2018. Although significant hardship exceptions for the EHR payment adjustment year generally are based on the existence of a hardship in a prior period, we believe it would be appropriate for these professionals to also qualify for a significant hardship exception for purposes of the AUC consultation requirement during calendar year 2018. It is also our best, most efficient, administratively feasible means of determining significant hardships for ordering professionals for CY 2018.

We also recognize the possibility that an ordering professional could suffer a significant hardship during the AUC program year, and therefore, is immediately unable to consult AUC. In addition, while again we believe there is significant overlap, there may be circumstances where an ordering professional is not considered to be an eligible professional under the EHR Incentive Program (for example, an ordering professional that is not a physician). We are seeking feedback from commenters regarding processes that could be put in place to accommodate ordering professionals with primary specialties that categorically receive significant hardship exceptions under the EHR Incentive Program, real-time hardships that arise during a year, and ordering professionals that are not eligible to apply using the EHR Incentive Program significant hardship exception process and need to seek a significant hardship exception for the purposes of the AUC program. We believe this would involve only a small number of ordering professionals. To the extent technically feasible, some possibilities for implementing such hardship exceptions may include Medicare Administrative Contractors granting hardships on a case-by-case basis or establishing another mechanism to allow for self-attestation of a significant hardship for a defined period of time (for example, a calendar quarter or a calendar year). We intend to propose a process in the CY 2018 PFS proposed rule.

We invite the public to comment on our proposal for ordering professionals granted a hardship exception for the EHR Incentive Program for payment year 2018 to also be granted a hardship exception to the Medicare AUC program for those years. We propose that the year the practitioner is excepted from the EHR Incentive Program payment adjustment is the same year that the practitioner would be excepted from consulting AUC.

6. Summary

Section 1834(q) of the Act includes rapid timelines for establishing a Medicare AUC program for advanced diagnostic imaging services. The number of clinicians impacted by the scope of this program is massive as it will apply to every physician or other practitioner who orders or furnishes applicable imaging services. 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.

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 are proposing to continue a stepwise approach, adopted through notice and comment rulemaking. We propose this second component to the program to specify qualified CDSMs, identify the initial list of priority clinical areas, and establish requirements related to CDSMs, as well as consulting and reporting exceptions. However, we also recognize the importance of moving expeditiously to accomplish a fully implemented program. Under this proposal, the first list of qualified CDSMs will be posted no later than June 30, 2017, allowing ordering professionals to begin aligning themselves with a qualified CDSM. We anticipate that furnishing professionals could begin reporting AUC information starting as early as January 1, 2018, but will provide details in CY 2018 PFS

rulemaking for how to report that information on claims.

In summary, we propose definitions of terms and processes necessary to implement the second component of the AUC program. We invite the public to submit comments on these proposals. We are particularly seeking comment on the proposed priority clinical areas and the requirements that must be met by CDSMs to become qualified. We believe the proposed requirements for qualified CDSMs will allow for flexibility so mechanisms can continue to reflect innovative concepts in decision support and develop customer-driven products to ultimately provide information to the ordering professional in such a manner that will maximize appropriate ordering of advanced diagnostic imaging while seamlessly integrating into workflow. As the stakeholders continue to move to a place of consensus-based standards deemed ready for deployment, we may become more prescriptive in future requirements for CDSMs. We also seek comment on the exceptions to the requirements to consult applicable AUC using CDSMs.

D. Reports of Payments or Other Transfers of Value to Covered Recipients: Solicitation of Public Comments

1. Background

In the February 8, 2013 **Federal Register** (78 FR 9458), we published the ''Transparency Reports and Reporting of Physician Ownership or Investment Interests'' final rule (Open Payments Final Rule) which implemented section 1128G of the Act, as added by section 6002 of the Affordable Care Act. Under section 1128G(a)(1) of the Act, manufacturers of covered drugs, devices, biologicals, and medical supplies (applicable manufacturers) are required to submit on an annual basis information about certain payments or other transfers of value made to physicians and teaching hospitals (collectively called covered recipients) during the course of the preceding calendar year. Section 1128G(a)(2) of the Act requires applicable manufacturers and applicable group purchasing organizations (GPOs) to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. The Open Payments program creates transparency around the nature and extent of relationships that exist between drug, device, biologicals and medical supply manufacturers, and physicians and teaching hospitals (covered recipients and physician owner or investors). The implementing regulations are at 42 CFR part 402, subpart A, and part 403, subpart I.

In addition to the Open Payments final rule, we issued final regulations in the CY 2015 PFS final rule with comment period (79 FR 67758) that revised the Open Payments regulations. Specifically, we: (1) Deleted of the definition of ''covered device''; (2) removed the continuous medical education (CME) exclusion; (3) expanded the marketed name reporting requirements to biologicals and medical supplies; and (4) required stock, stock options, and any other ownership interests to be reported as distinct forms of payment.

Since the publication and implementation of the Open Payments Final Rule and the CY 2015 PFS, various stakeholders have provided feedback to us regarding aspects of the Open Payment program. We have identified areas in the rule that might benefit from revision. In order to consider the views of all stakeholders, we are soliciting comments to inform future rulemaking. We do not intend to finalize any requirements related to Open Payments directly as a result of this proposed rule; rather, we expect to conduct future rulemaking. We are particularly interested in receiving comments on the following:

- We would like to know if the nature of payment categories as listed at § 403.904(e)(2) are inclusive enough to facilitate reporting of all payments or transfers of value to covered recipient physicians and teaching hospitals. We also seek feedback on further categorization of reported research payments.
- Although there is a 5-year record retention requirement at § 403.912(e), our regulations are currently silent on how long applicable manufacturers and applicable GPOs remain obligated to report on past years of payments or ownership or investment interests. We are soliciting feedback on how many years an applicable manufacturer or applicable GPO should continue to monitor and report on past program years for Open Payments reporting purposes.
- We are continuing to refresh all years of program data in addition to newly submitted payment records. We are interested in receiving feedback on how many years of Open Payments data is relevant to our stakeholders to help us determine how many years to continue to publish and refresh annually on our Web site. In addition, we are looking for feedback on how many years may be useful or relevant to Open Payments data users as archive files available for download on our Web site.
- We are seeking feedback on a requirement for all applicable manufacturers and applicable GPOs as defined in § 403.902 to register each year, regardless of whether the entity will be reporting payments or other transfers of value, or ownership or investment interests for the program year. We also seek comment on requiring applicable manufacturers and applicable GPOs to include the reason for not reporting any payments or other transfers of value, or ownership or investment interests.
- We are constantly striving to ensure that all published Open Payments data is valid and reliable. As part of this effort we are seeking comment on a requirement for applicable manufacturers and applicable GPOs to pre-vet payment information with covered recipients and physicians owners or investors before reporting to the Open Payments system, which we understand is an increasingly common practice. Specifically, we would like feedback on pre-vetting based on threshold payment values or random samplings of covered recipients. We are also interested in hearing how applicable manufacturers and applicable GPOs are successfully pre-vetting payment or transfer of value records.
- We continue to receive feedback that the current definition of a covered recipient teaching hospital, as defined at § 403.902, makes reporting payments or transfers of value difficult for applicable manufacturers. Section 1128G of the Act is silent on the definition of a covered recipient teaching hospital. We are soliciting feedback on the specific hurdles that the current definition presents. Additionally we would like to receive proposed alternative operationally feasible definitions or definitional elements of a covered recipient teaching hospital.
- We have heard from stakeholders that verifying receipt of payments or transfers of value to teaching hospitals is a difficult process on the recipient end for a various number of reasons (such as size of hospitals, number of departments, etc.). Without context around a payment record, teaching hospitals have reported difficulties verifying payments attributed to them. This leads to payment disputes. We are seeking feedback on adding a new non-public data element to assist in review and affirmation of payment records. Some examples might be hospital contact name or department etc. Would a free form text field be preferable?

Should this field be mandatory to facilitate review of any attributed payments to a teaching hospital?

• Some reporting entities have expressed interest to upload data into the Open Payments system before the end of the calendar year for which the data is collected. We believe this may increase data validity and minimize disputes. We solicit feedback on the benefit for applicable manufacturers and applicable GPOs to report data to CMS early or ongoing throughout the year.

• We recognize that some entities may experience mergers, acquisitions, corporate organizations and reorganizations, and other structural corporate changes. We seek feedback on how we might change our reporting requirements to ensure that industry can properly, and easily, represent these changes while still monitoring for compliance with reporting requirements.

• We have received feedback from industry that there is confusion surrounding requirements for reporting ownership and investment interests. Keeping in mind that these reporting requirements are statutorily mandated, we solicit feedback on operationally feasible definitions regarding ownership or investment interests. Specifically, we would like feedback on the terms ''value or interest'' and ''dollar amount invested.'' We also solicit comments on additional terms that may require further clarification to facilitate compliance with reporting requirements.

• We solicit ideas on how to define physician-owned distributors (PODs) for data reporting purposes, as well as what data elements PODs should be required to report. We also seek feedback on what portion of the reported data we should share on our Web site.

• From a data collection perspective, we welcome suggestions on ways to streamline or make the process more efficient, while facilitating our role in oversight, compliance, and enforcement.

• With respect to all solicitations, we are requesting an estimate of the time and cost burden associated with reporting for purposes of compliance with the Paperwork Reduction Act.

E. Release of Part C Medicare Advantage Bid Pricing Data and Part C and Part D Medical Loss Ratio (MLR) Data

1. Background

As part of the annual bidding process required under section 1854(a) of the Act, Medicare Advantage organizations (MAOs) submit bids for each plan they wish to offer in the upcoming contract year (calendar year). We refer to each of these bids as a Medicare Advantage (MA) plan bid. As required by sections 1857(e)(4) and 1860D–12(b)(3)(D) of the Act, data supporting medical loss ratios (MLR) are submitted annually to us by MAOs and Part D sponsors, respectively. Using this authority, we codified the MLR submission requirement in the MLR final rule for Part C and Part D published in the **Federal Register** (78 FR 31284) on May 23, 2013.

We are proposing to release to the public MA bid pricing data and Part C and Part D MLR data on a specific schedule and subject to specified exclusions. We propose to add contract terms and expand the basis and scope of our regulations on MA bidding and Part C and Part D MLR submission to incorporate section 1106(a) of the Act (42 U.S.C. 1306(a)), which authorizes disclosure of information filed with this agency in accordance with regulations adopted by the agency. (*See Parkridge Hospital, Inc.* v. *Califano,* 625 F.2d 719, 724–25 (6th Cir. 1980). A substantive regulation issued following rulemaking provides the legal authorization for government officials to disclose commercial information that would otherwise be required to be kept confidential in accordance with 18 U.S.C. 1905. *See Chrysler Corp.* v. *Brown,* 441 U.S. 281, 306–08 (1979). We note as well that under 45 CFR 401.105(a),[6] we have adopted a regulation that permits publication and release of data that would not be exempt from disclosure under FOIA or prohibited from disclosure under other law, even if a request has not been submitted. We further note that because we collect Part D MLR information under section 1860D–12(b)(3)(D) of the Act, we have the authority to use such information for purposes of improving public health through research on the utilization, safety, effectiveness, quality and efficiency of health care services. We propose to adopt a regulation that clearly identifies the categories of data from submitted bids and reports of medical loss ratios that will be released so as to avoid repeating FOIA analyses and reviews of each request, to standardize the disclosure and the procedures for disclosure, and in the interest of furthering goals related to the MA and Part D programs.

The purposes underlying these proposed data releases include allowing public evaluation of the MA and Part D programs encouraging research into these programs and better ways to provide health care, and reporting to the public regarding federal expenditures and other statistics involving these programs. In particular, we believe that facilitating public research using this bid pricing data could lead to better understanding of the costs and utilization trends in MA and support future policymaking for the MA program. For example, MA bid pricing data (which contains actual and projected cost figures) could be used to understand patterns of health care utilization such as how projected and actual costs may differ across geographic areas and different beneficiary populations. Release of MLR data from the MA and Part D programs could lead to research into how managed care in the Medicare population differs from and is similar to managed care in other populations (such as the individual and group markets) where MLR data is also released publicly; such research could inform future administration of these programs. Further, we believe that making certain MA bid pricing data and Part C and Part D MLR data available publicly aligns with Presidential initiatives to improve management and transparency of federal information. The President's January 21, 2009, *Memorandum on Transparency and Open Government* (74 FR 4685) instructed federal agencies to take specific actions to implement increased data transparency and access to federal datasets. Subsequent Presidential memoranda (including the May 23, 2012 memorandum *Building a 21st Century Digital Government* and May 9, 2013 memorandum *Making Open and Machine Readable the New Default for Government Information*) further stated the policy initiative to increase open access to and interoperability among such government data sets. These memoranda demonstrate a commitment to making information about government activities and government spending available to the public and using the internet as a means of public disclosure in order to eliminate as many barriers as possible to public access to such information. Our proposal would promote accountability in the MA and Part D programs, by making MLR information publicly available for use by beneficiaries who are making enrollment choices and by allowing the

[6] The regulation, which implements 42 U.S.C. 1306(a), provides that the Freedom of Information Act rules shall be applied to every proposed disclosure of information. If, considering the circumstances of the disclosure, the information would be made available in accordance with the Freedom of Information Act rules, then the information may be disclosed regardless of whether the requester or beneficiary of the information has a statutory right to request the information under the Freedom of Information Act, 5 U.S.C. 552, or whether a request has been made.

public to see whether and how privately-operated MA and Part D plans administer Medicare—and supplemental—benefits in an effective and efficient manner. Disclosing MA pricing data would provide the public with insight as to how public dollars are spent in this aspect of the Medicare program. Further, we have received requests under FOIA for data of the type of the pricing data we propose to release here and we anticipate that, as the MLR Reports from MA and Part D plans are submitted, we will receive requests for those reports and that data.

These interests, however, must also be balanced with the need to protect the privacy of individuals, the confidentiality of information about Medicare beneficiaries, and the proprietary interests of the MA and Part D plans that submit the information. While transparency in governmental activities and spending is important, we recognize that some of the information we collect in the form of MA bid pricing submissions and Part C and Part D MLR reports should not be publicly disclosed. We believe that our proposal balances these various interests and goals, both in carving out from the planned and authorized releases certain specific data, and (in the case of the MA bid pricing data) in delaying the release past the point of the commercial usefulness of the data.

We are seeking to balance protection of the proprietary interests of MAOs and Part D sponsors with the need to effectively and transparently administer federal health care programs and to encourage research into better ways to provide health care. Further, we believe that adopting a fixed schedule for release of this information and standardizing releases of this data through this rule, will reduce the burdens on the public, CMS, and the submitters of the data that are associated with individual requests for information. Proposing a rule for these releases provides the opportunity for a fulsome and public dialogue that is not always the case with individual requests for information. We encourage commenters to identify and explain additional uses of the information we propose here to release and to suggest additional protections from release if commenters disagree with how we have balanced the competing interests. We hope to receive comments from all viewpoints to ensure that the lines for releasing and protecting information are appropriately drawn.

2. MA Bid Submission and Pricing Data

We make monthly prospective payments to MAOs for providing Part C coverage to Medicare beneficiaries enrolled in their MA plans. As mandated in section 1854 of the Act, amended by Title II of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), our payments to MAOs for their MA plan enrollees are based on bids that MAOs must submit to us no later than the first Monday in June for the upcoming contract year. Each MA plan bid is an estimate of the plan's revenue requirement to cover plan benefits for a projected population. The monthly aggregate bid amount for an MA plan is composed of estimated benefit expenses (direct medical expenses), non-benefit expenses (administrative expenses), and a gain/loss margin (profit) for coverage of original Medicare benefits, Part C supplemental benefits (if any), and Part D benefits (if any). We are not proposing to release Part D bid pricing data in this rule. Also, cost plans operated under section 1876 and section 1833 of the Act, Program for All Inclusive Care for the Elderly (PACE) organizations, and Medicare-Medicaid demonstration plans operated under the Financial Alignment Initiative (*https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/FinancialModelstoSupportStatesEffortsinCareCoordination.html*) do not submit Part C bids to us so pricing data relating to those plans is not part of this proposed rule.

Section 1854(a) of the Act requires that MA bid submissions, including coverage, cost-sharing, and pricing, be in a form and manner specified by the Secretary. The statute, as specified in paragraphs (a)(1), (a)(3), and (a)(6), requires that bids include the plan type, the plan's geographic service area, projected enrollment under the plan, bid amounts for the provision of Part C benefits, bid amounts for Part D benefits (if offered by the MA plan), descriptions of beneficiary cost-sharing liability for each type of benefit, the plan's use of the beneficiary rebate (if any), and the actuarial basis for determining the bid pricing amounts. Part C benefits include basic benefits (that is, the benefits available under Original Medicare Parts A and B) and non-Medicare supplemental benefits (both mandatory and optional); supplemental benefits may include benefits not available under Original Medicare (for example, vision and dental benefits) or the reduction in cost-sharing obligations of enrollees compared to Original Medicare.

The regulation at § 422.254 addresses the content of the bid submission as well but does not specify the form or manner of the submission. We developed standardized templates for MAOs to populate and upload to our Health Plan Management System (HPMS) as the bid submission described in the statute and regulation. These standardized MA bid submission templates collect the information required under § 422.254, and organize the information as follows:

- Plan Benefit Package (PBP) information (describing the Part C benefits and cost-sharing for each MA plan);
- Service Area information (identifying geographic areas where an MA plan is to be offered by the MAO);
- Plan Crosswalk information (identifying plan consolidations, terminations, and/or service area changes from one year to the next); and
- The MA bid pricing data for each PBP (that is, each MA plan). MA bid pricing data is uploaded to HPMS in a template referred to as the MA Bid Pricing Tool (MA BPT).

Currently, we publicly release information on the Plan Benefit Package, service area, and plan crosswalks each year. These data sets can be found on our Web site at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html,* under the subpages Benefits-Data, MA-Contract-Service-Area-by-State-County, and Plan-Crosswalks, respectively.

In this rule, we propose to release MA bid pricing data, as defined at proposed § 422.272, which would be implemented as a release of data housed in the MA BPT for each MA plan subject to specified exclusions from release (noted in this section of the proposed rule). The MA BPT is a standardized Excel workbook with multiple worksheets and special functions built-in (for example, validation features). There are also separate BPTs used to price two types of MA plans: Medicare Medical Savings Account plans (the MSA BPT); and End-Stage Renal Disease-only special needs plans (the ESRD–SNP BPT). The MSA BPT was first released for calendar year (CY) 2009 bidding, and the ESRD–SNP BPT was first released for CY 2014 bidding. We maintain and update these three MA BPT formats under OMB #0938–0944, and release annual versions every April.

The MA BPT templates can be found on our Web site at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Bid-Forms-Instructions.html,* accompanied

by instructions on how to populate the tool and a data dictionary for all data elements. Information pertaining to the MSA BPT and the ESRD–SNP BPT can be found in the Appendices within the general MA BPT instructions, which can be found on the Bid-Forms Web site.

Below we describe the general categories of MA bid pricing data contained in the MA BPT templates, indicating the associated BPT worksheet. Worksheets 1 through 6 of the MA BPT template collect information for the development and identification of the revenue requirements for basic benefits and mandatory supplemental benefits. Optional supplemental benefits, which enrollees may opt to purchase separately, are addressed in a separate worksheet. The BPT as a whole collects the information described in § 422.254(b), (c) and (d) for coordinated care and private fee-for-service plans and in § 422.254(b) and (e) for MA–MSA plans. The regulation describes the required bid elements in general terms, which we implemented and operationalized at a detailed level in the BPT.

a. MA Base Period Experience and Projection Assumptions (MA BPT Worksheet 1)

MAOs must report base period experience data, which is defined as claims incurred in the calendar year 2 years prior to the contract year for which the bid is being submitted, for basic benefits and mandatory supplemental benefits. For example, for CY 2017 bids (which must be submitted June 6, 2016), the base period data is for CY 2015. For the historical period, MAOs report the plan's actual allowed per member per month (PMPM) cost, unit cost and utilization by service type (for example, inpatient, outpatient, etc.); cost sharing and net costs are also reported. MAOs must also report actual enrollment and revenue, as well as expenses for claims, administration, and gain/loss margin, for this base period. Finally, MAOs must report the assumptions they use to project (that is, trend) the base period claims experience to the contract year for which they are bidding.

b. MA Projected Allowed Costs (MA BPT Worksheet 2)

MAOs provide the projected allowed PMPM costs, unit costs, and utilization by service type for the contract year, using the claims experience and projection assumptions described previously; such information demonstrates the actuarial bases of the bid. Allowed costs are ''gross'' costs, that is, before the application of any beneficiary cost sharing. Total projected allowed costs are reported separately for dual eligible beneficiaries without full Medicare cost-sharing liability versus other beneficiaries. MAOs may also enter manual rates and the credibility assumptions used to blend together manual rates with projected experience.

c. MA Projected Cost Sharing (MA BPT Worksheet 3)

MAOs present the effective value of a plan's level of cost-sharing by service type, which must include both in-network and out-of-network cost sharing (copays and coinsurance) and other amounts such as plan deductibles and the plan's out-of-pocket maximum cost-sharing amount.

d. MA Projected Revenue Requirement (MA BPT Worksheet 4)

MAOs then combine their allowed cost data and cost sharing information (described in sections III.E.2.b. and c. of this proposed rule) to calculate the plan's projected revenue requirement, which consists of benefit costs (direct medical costs) net of cost-sharing, non-benefit expenses (administrative costs), and gain/loss margin. The plan's projected revenue requirement is allocated to the following: Medicare-covered A/B services, prescription drug coverage (if the plan is an MA–PD plan), and non-Medicare covered services (mandatory supplemental benefits under the plan).[7] MAOs report the revenue requirement separately for dual eligible beneficiaries without full Medicare cost-sharing liability versus other enrolled beneficiaries. They also report administrative expenses by category (for example, direct versus indirect administration) and information related to the plan's gain/loss (profit) margin.

MAOs have the option of reporting enrollment, revenue and expense information related to their plan enrollees with End Stage Renal Disease (ESRD) on worksheet 4; these costs are otherwise excluded from bid development. (We have the authority to determine whether and when it is appropriate to apply the bidding methodology to ESRD MA enrollees, as set forth at § 422.254(a)(2).) MAOs also have the option of reporting information related to Medicaid revenue and expenses for dual eligible beneficiaries.

The plan's expected risk profile (average risk score) is reflected in the projected revenue requirements (costs) for both A/B and supplemental bid amounts. That is, the projected costs will reflect the expected risk profile of that plan's population because the utilization projections built into the costs projected in the bid reflect the underlying risk and need for services of the expected enrollees for that plan. When these projected costs are divided by the plan's projected risk score for a projected enrollment, the costs become ''standardized.'' Standardized costs have a risk score equal to one, which means that they reflect the risk profile of the average Medicare beneficiary.

e. MA BPT Benchmark (Worksheet 5)

The MA BPT illustrates development of the plan-specific A/B benchmark, based on the service area of the plan and the county rates (or MA regional rates) applicable to the plan; the benchmark is identified and calculated using information provided by the plan and county rate information announced by CMS. See § 422.254 and § 422.258. The service-area level benchmark represents the upper limit that the federal government will pay PMPM for coverage of A/B benefits in the defined service area, given the plan's quality rating, prior to risk adjusting payments. The service-area level benchmark for (non-regional) plans that cover multiple counties is a weighted average of the projected plan enrollment and the applicable county ratebook amounts.

For benchmark development, the MAO reports the following: Projected enrollment in member months per county; projected average risk score for the projected enrollment in each county in the plan's service area; and a plan-level factor for the proportion of beneficiaries with Medicare as Secondary Payer. Plan-level projected member months and risk scores are reported separately for dual eligible beneficiaries without full Medicare cost-sharing liability versus other beneficiaries.

The MA BPT is programmed to compare the A/B bid amount from the MAO to the benchmark to determine whether the plan has a beneficiary rebate (defined at § 422.266) and must submit information required by § 422.254(d). If the plan A/B bid amount is lower than the plan benchmark, a percentage of the difference determines the beneficiary rebate amount (where the percentage is based on the plan's quality rating). If the bid is greater than benchmark, the plan must charge a

[7] We are not proposing to release any Part D bid pricing data as part of this proposed rule. Therefore, for any MA–PD bid, the Part D information underlying the pricing of Part D benefits would be redacted from any data release under this rule. However, the amount of beneficiary rebate applied to buy-down the Part D premiums if any, is included at § 422.264(b)(2) as a use of Part C dollars, so will be included in the MA bid pricing data release. See section III.E.3.a.1.

member premium for coverage of A/B benefits.

f. MA Bid Summary (MA BPT Worksheet 6)

The MA BPT presents a summary of key figures developed in the tool, including the bid, benchmark, projected risk score, and rebate amount, to support the final step of bid pricing—development of the beneficiary premium (if any) for the plan. To determine the premium, MAOs indicate how the rebate amount will be allocated. Under § 422.266(b), the rebate must be allocated to some combination of MA mandatory supplemental benefits (defined at § 422.2), which can include buy down of original Medicare A/B cost-sharing and offering additional benefits not covered by original Medicare; and buy down of the Part D basic premium, the Part D supplemental premium, and/or the Part B premium.

g. Optional Supplemental Benefits (MA BPT Worksheet 7)

MAOs may offer optional supplemental benefits, which plan enrollees may opt to purchase for a separate, additional premium. MAOs present the actuarial pricing elements for any optional supplemental benefit packages to be offered during the contract year, up to a maximum of 5 packages. Not all MA plans offer optional supplemental benefits. MAOs report projected member months, allowed costs PMPM, cost sharing, administrative costs and gain/loss margin for each optional supplemental benefit package. MAOs also report base period experience for optional supplemental benefits, including revenue, enrollment, claim expenses, administrative expenses, and gain/loss margin. The information is reported separately as enrollees must make a separate election to purchase these benefits, and for coordinated care plans and private fee-for-service plans they cannot be funded by beneficiary rebates.

h. MSA BPT and ESRD–SNP BPT

Regarding the MSA BPT and ESRD–SNP BPT, the same general requirements apply: Submission of base period experience data; projected allowed costs by service type; projected enrollee cost-sharing payments; projected revenue requirements (medical, administrative, and margin); and development of the plan benchmark against which the bid is compared. Unique to the MSA BPT is development of the beneficiary deposit amount for the high-deductible plan. Unique to the ESRD–SNP BPT are service categories such as dialysis and nephrologist.

i. Additional Documentation

In addition to the categories of data noted in this section of the proposed rule, MAOs must also submit supporting documentation to substantiate the actuarial basis of pricing and an actuarial certification of the bid for their MA BPTs, MSA BPTs, and ESRD–SNP BPTs, as required at §§ 422.254(b)(5) and 422.256(c)(5).

3. Proposed Regulatory Changes for Release of MA Bid Pricing Data

We are proposing to amend our MA regulations to provide for the release of certain MA bid pricing data. We propose to release to the public each year, after the first Monday in October, MA bid pricing data that we accepted or approved for a contract year at least 5 years prior to the upcoming calendar year, subject to specific exclusions described in proposed § 422.272(c). We believe this disclosure is consistent with Presidential directives to make information available to the public, and with our goals of allowing public evaluation of the MA program, encouraging research into better ways to provide health care, and reporting to the public regarding federal expenditures and other statistics involving this program. For example, MA bid pricing data (which contains actual and projected cost figures) could be used to understand patterns of health care utilization such as how projected and actual costs may differ across geographic areas and different beneficiary populations, which could inform future bidding and payment policies. Further, releasing pricing data, particularly in conjunction with information already released under § 422.504(n), will provide insight into the use of public funds for the MA program, providing appropriate transparency about the administration of the program.

We propose to codify the requirements for release of MA bid pricing data for MA plan bids accepted or approved by us by adding a new § 422.272 to subpart F of part 422. First, we discuss the definition of MA bid pricing data, then our proposal to release MA bid pricing data for MA plan bids accepted or approved by us, and the types of information we propose be excluded from these data releases. Next, we discuss the specific proposal for the timing of the public data release. Finally, we solicit public comment on approaches to releasing more recent MA bid pricing data. We also solicit comment on our goals and purposes stated above for the release of MA bid pricing data.

(a) Terminology

At § 422.272(a), we propose a definition of MA bid pricing data to mean the information that MAOs must submit for the annual bid submission for each MA plan, in a form and manner specified by us. Specifically, we propose that MA bid pricing data includes the information described at § 422.254(a)(1) and the information required for MSA plans at § 422.254(e). We use § 422.254(a)(1) in our proposed definition because it provides an overview of the submission requirements in our MA bidding regulations. Specifically, § 422.254(a)(1) references § 422.254(b), (c), and (d), which address, respectively, general bid requirements, information required for coordinated care plans and private fee-for-service plans, and information on beneficiary rebates. At § 422.272(a)(2), we propose to include in the definition the information required for bids for MSA plans, set forth at § 422.254(e), which includes the amount of plan deductible for the high-deductible plan.

By proposing to define MA bid pricing data at § 422.272(a) using cross-references to existing regulation at § 422.254(a)(1) and (e), we are proposing in operational terms that the term encompass all plan-specific data fields in the MA BPT, the MSA BPT, and the ESRD–SNP BPT, that is, the figures that MAOs input and those that are calculated within the BPT. The BPTs also include data that are not plan-specific, which consist of look-up tables built-in to facilitate calculations. We do not propose to include these look-up tables as part of the proposed definition of MA bid pricing data, as they are not submitted by the MAO. These look-up tables are hidden Excel worksheets (which can be ''unhidden'' within Excel), and are currently available to the public in the BPT templates on the CMS Web site at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Bid-Forms-Instructions.html.* Selected data from the look-up tables are reflected in each MA plan's BPT. For example, there is a look-up table in the BPTs with the county rates for the contract year and when the MAO enters a state-county code, the BPT extracts the appropriate rate amount for the county from the look-up table and populates the appropriate data field.

Our proposed definition of MA bid pricing data references elements required at § 422.254(b) and includes information described in section III.E.2. (MA Bid Pricing Data) of this proposed rule: The estimated revenue required by an MA plan for providing original

Medicare benefits and mandatory supplemental health care benefits, if any (composed of direct medical costs by service type, administrative costs and return on investment); and the plan pricing of enrollee cost-sharing for original Medicare benefits and mandatory supplemental benefits. In addition, the definition references the MA bid pricing data elements required at § 422.254(c), which include more detail about the Medicare-covered and supplemental bid amounts such as the actuarial bases for the bid amounts, projected enrollment, and data specific to regional MA plans.

Finally, we propose to define MA bid pricing data to include elements required at § 422.254(d), thus incorporating a reference to the forms of beneficiary rebate at § 422.266(b). That is, for plans that bid below the benchmark for their service areas, the term would include the beneficiary rebate amounts that are allocated in the BPTs to the uses allowed in law: Reduction of cost-sharing below original Medicare levels, offering additional benefits not covered by original Medicare, and reduction of the Part D basic premium, the Part D supplemental premium, and/or the Part B premium. Unlike the underlying components of the Part D pricing (that is, pricing information related to the Part D benefit analogous to the information included in the MA BPT), we consider beneficiary rebate amounts that are applied to reduce the Part D basic and supplemental premiums to be Part C amounts that are part of the MA bid pricing submission, not the Part D bid pricing submission.

(b) Release of Accepted or Approved MA Bid Pricing Data With a 5 Year Lag

In § 422.272(b), we propose to authorize the public release of MA bid pricing data for the MA plan bids that were accepted or approved by us for a contract year under § 422.256. We propose that the annual release will contain MA bid pricing data from the final list of MA plan bids accepted or approved by us for a contract year that is at least 5 years prior to the upcoming calendar year.

We use the phrase ''accepted or approved'' in the proposed regulation text because both terms are used in existing regulation when referring to MA bids. We consider these words to mean the same thing in the context of MA bid pricing submissions, and we use both words in proposed § 422.272(b) to mirror existing regulation. For example, existing § 422.256(b) states that CMS can only accept bids that meet the standards in that paragraph. However, § 422.256(b)(4)(i) and (ii) use the phrase ''CMS approves a bid. . . .'' The phrases ''decline to accept'' and ''decline to approve'' are used at § 422.254(a)(5) and § 422.256(a), respectively. In the remainder of this preamble, we will use the term ''accepted'' to represent the phrase ''accepted or approved.''

During our annual bid review process, we determine which MAOs must submit one or more updated versions of the initial MA BPT for one or more of their MA plans, in response to questions from our bid reviewers. In addition, as part of the bid pricing submission process, an MAO may have to adjust its allocation of beneficiary rebate dollars for some or all of its MA plans that offer Part D and for their regional PPOs, after we publicly release the Part D national average bid amount and the final MA regional plan benchmarks. Any reallocation of rebate dollars results in a revised MA bid, which must be submitted to us as an updated version of the original submission. Finally, on occasion an MAO will withdraw an MA plan after we have accepted the plan bid. For these reasons, we propose that the MA bid pricing data to be released will only be the data found in the final list of accepted bids; for operational purposes, this means the final accepted MA BPTs, MSA BPTs, and ESRD–SNP BPTs, subject to exclusions noted in proposed paragraph (c).

Finally, in § 422.272(b), we propose to authorize the annual release of MA bid pricing data for a contract year that is at least 5 years prior to the upcoming calendar year. We believe that 5 years is an appropriate length of time for the MA bid pricing data to no longer be competitively sensitive. (The base period data on actual expenses in the MA BPT, MSA BPT, and ESRD–SNP BPT is 2 years older than the data for the bidding year—see the description of the MA BPT category MA Base Period Experience and Projection Assumptions in section III.E.2. of this proposed rule.) Since this will be an annual release, over time the public would have the ability to trend bid cost projections across years, to compare actual costs from the MA BPT with projections from prior years, and to observe bidding patterns over ever-longer periods of time.

We are seeking to balance the protection of commercially sensitive information with our goals to effectively administer federal health care programs, increase data transparency regarding federal expenditures, and encourage research into better ways to provide health care. We propose that a 5-year delay renders multi-year comparisons of pricing trends less relevant to the current year of MA plan pricing. The time lag represents a buffer between the development and implementation of pricing strategies that can be distilled from data multiple years for and the observed relationship and trend from one year to the next, thus mitigating possible competitive disadvantage from the proposed data disclosure. For example, an MAO looking to enter a new MA market is significantly less likely to gain an unfair commercial advantage from being able to examine and trend 5-year-old bid pricing data than if the MAO were able to examine and trend more recent bid pricing data.

We solicit comment on the proposed 5 year delay for reducing competitive disadvantages to MAOs. We solicit comments explaining whether a shorter period would suffice to protect MAOs from competitive harm associated from the disclosure of confidential commercial information or if a longer period is necessary to adequately protect the information and assure the continued submission of accurate data.

(c) Exclusions From Release

In § 422.272(c), we propose that several types of MA bid pricing information be excluded from the data releases under paragraph (b). First, we note that we are not proposing to release Part D bid pricing data in this rule. For this reason, the exclusion from release at proposed § 422.272(c)(1) is information pertaining to the Part D prescription drug bid amount for an MA plan offering Part D benefits, specifically the information required for Part D bid submission at § 422.254(b)(1)(ii), (c)(3)(ii), and (c)(7). We consider this exclusion at proposed § 422.272(c)(1) to include the following amounts in the MA BPT that pertain to the Part D premiums: The Part D basic premium before and after application of beneficiary rebate amounts; the Part D supplemental premium before and after application of beneficiary rebate amounts; the combined MA plus Part D total plan premium; and the target Part D basic premium.

Regarding Part D bid pricing data, section 1860D–15(f) of the Act contains protections for data submitted by Part D Sponsors in accordance with section 1860D–15; these protections would generally prohibit public release of such data. We propose that the Part D bid pricing elements listed in this section of the proposed rule, which appear in the MA bid pricing tools, would be excluded from release. However, we note that the Part C statute does not establish similar protections for MA bid pricing data, and we believe that MA

bid pricing data is not subject to the protections imposed by section 1860D–15 of the Act.

Second, at § 422.272(c)(2), we propose to exclude from release two categories of additional information that we require to verify the actuarial bases of the MA plan bids. At paragraph (c)(2)(i), we propose to exclude from release any narrative information in the MA BPT, MSA BPT, and ESRD SNP BPT regarding base period factors, manual rates, cost-sharing methodology, optional supplemental benefits, or other topics for which narratives are required by us under § 422.254. These narrative fields provide additional information to allow us to verify the actuarial bases of the bid, as described at § 422.256(c)(5). For the base period narratives, MAOs are asked to describe the source of the base period experience data, and any other utilization adjustment factors, unit cost adjustment factors, and additive adjustment factors that the MAO applied. For projected allowed costs, the narrative field captures descriptions of manual rates including trending assumptions in the manual rates. For projected cost sharing, the narrative fields contains a description of the methodology for reflecting the impact of maximum cost-sharing. Finally, for optional supplemental benefits, there is a general comments field. The proposed regulation text would also exclude from release any other narrative fields in the BPT that we may require as the bid submission process changes over time. We propose to exclude these text fields in the BPTs. MAOs may populate them with information pertinent to more than the individual MA plan bid in which the narrative is included, such as regional or national-level information on an MAO's approach to cost-sharing methodology or projection factors. For example, MAOs may provide information on provider contracting, such as the fee schedules. Further, these explanations and additional information provide insight into the exercise of actuarial judgment in developing the bids. We believe that it is reasonable to treat such summary statements of MAO methodology or strategy as information proprietary to the MAO that should remain protected from public disclosure. The release of such information (for example, fee schedules or national pricing strategy) may provide an unfair commercial advantage to certain entities, such as new market entrants, and likely would impair the government's ability to obtain such information in the future, since MAOs have greater discretion in deciding what written information to share with us and would likely attempt to avoid sharing fee schedule and pricing strategy information.

Another category of information that we propose to exclude from release, at § 422.272(c)(2)(ii), is the supporting documentation that MAOs submit to us to support the actuarial bases of each MA plan bid; these materials are collected outside of the BPT templates so this proposed exclusion would be operationalized by withholding from release any materials submitted as part of an MA bid that were not part of the BPT worksheet submission. Supporting documentation for each MA plan bid can consist of multiple text, spreadsheet, and email files. MAOs submit the first round of supporting documentation with the initial bid submission. Subsequently, during the bid review process, our reviewers may communicate requests for additional supporting documentation, and in response, MAOs may submit multiple updated versions of an MA plan's BPT and additional supporting documentation. There are no standard formats for supporting documentation. A range of files (Word, Adobe, Excel, and email formats) may be uploaded for each of the MA plan bids, and there is no way to identify clearly which data elements in any of the supporting documentation for an MA plan bid applies to the final accepted version of the bid. Supporting documentation often links a particular plan bid to an MAO's broader pricing approaches, such as financial arrangements with providers, and we believe that such analytical information at a regional or national level could be commercially sensitive information in a way that the cost and enrollment estimates in the BPT are not, since such strategic pricing and contracting information could provide an unfair commercial advantage to certain entities, such as new market entrants, who would not need to release such strategic information. We also are concerned whether release of supporting documentation could have a chilling effect on the scope of information provided by MAOs for future bidding and our ability to accurately evaluate bids. We rely on MAOs to provide detailed explanations of the bids in order for CMS to fully understand the judgment calls underlying the assumptions reflected in the bids. If MAOs believe that the explanations and additional information are not protected from disclosure, they may provide less information and less explanation. In order to preserve the access we have, we are proposing to protect this information.

Third, at § 422.272(c)(3), we propose to exclude from release any information identifying Medicare beneficiaries and other individuals. We believe that this identifying information should be excluded from a public data release to protect the privacy of individuals, including but not limited to protecting the confidentiality of information about Medicare beneficiaries. Regarding Medicare beneficiaries, we propose to exclude from release any MA bid pricing data element that is based on fewer than 11 Medicare beneficiaries as we believe that this threshold establishes the point at which individual-level data can be discerned. Following our longstanding data release policy for protecting individually identifiable information, in the event that data fields in an MA BPT, MSA BPT, or ESRD SNP BPT are populated with fewer than 11 MA plan members (or 132 member months, assuming each individual is counted for 12 months), we would suppress all of those data fields in the public release file for that MA plan bid under our proposed rule. We are not proposing to build this threshold into the regulation text, however, as we believe that technology and the ability to reverse-engineer data to identify beneficiaries may change over time. We may revisit this threshold as we administer the data releases proposed here (and in other Medicare contexts) and will make adjustments as necessary to ensure that we do not disclose data that could be used to identify beneficiaries. For example, data fields with member months, utilizers, and utilization per 1,000 could be populated based on fewer than 11 MA plan members and would be suppressed from the release under this proposed rule. Protection of information that could identify Medicare beneficiaries, particularly in the context of their receipt of health care services, is a long-standing principle of ours in the context of the Medicare program. Incorporating this principle and the necessary protection of this data into this proposal to disclose information is appropriate.

Regarding other individuals, we require the names and contact information of certifying actuaries and MA plan contacts in the MA bid submission, that is, in certain fields in the MA BPT, MSA BPT, and ESRD–SNP BPT, and we also require the names and contact information in the actuarial certifications submitted by actuaries who prepared the bids. We propose to exclude this information from the release that we propose to implement. The actuarial certification consists of standardized language that we

developed for the purpose of bidding; for example, the language notes that the actuary is a member of the American Academy of Actuaries, federal law and CMS guidance regarding MA bids were followed, the data and assumptions used in the development of the bid are reasonable, and Actuarial Standards of Practice were applied. (Certifying actuaries may choose whether to append additional language.) We do not believe that these bid certification paragraphs represent information that serves the goals for this proposed release of MA bid pricing data (for example, to inform research and public evaluation of the MA program and to be transparent about spending). In addition, identifying specific individuals who have worked on a bid for an MAO appears an unnecessary intrusion into the personal privacy of these individuals. In sum, we propose to not release any information identifying individual actuaries or their associated certification paragraphs, to protect individual names and to not expend resources separating names from each of the hundreds of identical or similar paragraphs of attestation language.

Finally, at § 422.272(c)(4), we propose to exclude from release bid review correspondence between us (including our contractors) and the MAO, and internal bid review reports (for example, bid desk review documentation housed in the HPMS Bid Desk Review module, which supports the automated aspects of bid review). First, bid review correspondence (emails) often involves follow-up questions requesting clarification of supporting documentation, so our concerns described above regarding the release of supporting documentation apply to bid review correspondence. Second, it would not be operationally feasible to determine which set of bid review emails between our reviewers and MAOs and which internal bid review reports pertain to the final accepted/approved bid for an MA plan, which is the data we propose to release.

(d) Timing of MA Bid Pricing Data Release

At § 422.272(d), we propose the timing of the release of MA bid pricing data as provided in paragraph (b) and limited by the exclusions in paragraph (c). We propose that the annual release would occur after the first Monday in October. We selected the first Monday in October as the date after which the release could occur each year because the annual bidding cycle has come to a close at this point and we have completed the approval of MA plan bids for the upcoming contract year (calendar year). For example, after the first Monday in October 2016, the bids for contract year 2017 have been accepted; thus, a public release in December 2016 or January 2017 would be a release of the final accepted MA bid pricing data for a contract year not more recent than 2012.

Under this example, our December 2016 release of MA bid pricing data under this proposed rule may include the following: (1) The accepted MA BPT worksheets for 2012 in their entirety, subject to the exceptions § 422.272(c); (2) the accepted MSA BPT worksheets for 2012 in their entirety, subject to the same exceptions; (3) accepted MA BPTs for 2006 through 2011, subject to the same exceptions; and (4) MSA BPTs for 2009 through 2011 (as 2009 was the first year this BPT was used), subject to the same exceptions, because these years are more than 5 years prior to 2017. However, under the example of a December 2016 release, we would not release any Part C pricing data for ESRD–SNPs because the ESRD–SNP BPT was used for the first time for contract year 2014; the first time that data from accepted ESRD–SNP BPTs could be released under this proposal is after the first Monday in October 2018.

While we propose to authorize release of this data after the first Monday in October each year, we are not committing to a specific date for each annual release. We will provide details on each year's release schedule through sub-regulatory communications. We anticipate that as the release process becomes more standardized over the years, we will be able to release these files closer to the proposed regulatory timeline. In addition, we intend that the first time we implement a public release MA bid submission data, we may release data for multiple contract years that meet the criterion of at least 5 years prior to the upcoming calendar year.

As mentioned in the Background (section III.E.1), in crafting this proposal to release MA bid pricing data, we are seeking to balance proprietary interests with our mission to effectively administer federal health care programs and increase data transparency. We are soliciting comments on the approach we are proposing for the public release of MA bid pricing data based on a 5-year lag in the data, and whether that is the appropriate timeframe to apply to this data release. We also seek comment on the scope of the proposed release of BPT worksheets and data elements. We are particularly interested in whether of the MA bid pricing data we are proposing to release contains proprietary information, and if so, are requesting detailed explanations of good cause for its redaction from public availability and suggestions for what safeguards might be implemented to appropriately protect those portions of the data. Detailed explanations should contain specific examples which show how this information disclosure could cause substantial competitive harm to MAOs. Specific examples should (1) cite the particular information proposed to be released and explain how that information differs from publicly available data; (2) point to the particular entity or entity type that could gain an unfair competitive advantage from the information release; and (3) fully explain the mechanism by which the release of that particular information would create an unfair competitive advantage for that particular entity. Similarly, we are interested in comments that our proposed scope for release is too narrow and unnecessarily protects data that is not confidential and should not be protected. We are soliciting comments and explanations that show how the data is not confidential, could not be used to create unfair competitive disadvantage, and that its release would not have a chilling effect on the nature and scope of the data that we currently receive from MAOs in the bid submissions. As noted above, we view this rulemaking as the opportunity to solicit wide ranging comments on this issue in order to chart the wisest course for release of pricing data in support of our goals.

4. Proposed Technical Change

We propose to amend § 422.250 on the basis and scope of the MA program to add a reference to section 1106 of the Act. As discussed in the Background (section E.1.), section 1106(a) of the Act (42 U.S.C. 1306(a)) provides us the authority to enact regulations that would enable the agency to release information filed with this agency.

5. Other Approaches To Release of MA Bid Pricing Data

We are also considering whether to release MA bid pricing data for years more recent than the 5-year data lag proposal. In 2011, an academic researcher submitted a request to CMS for certain data elements regarding the 2009 MA Base Period Experience in the 2011 MA bid pricing submissions. We rejected the request under Exemption 4 to the FOIA, 5 U.S.C. 552(b)(4), which exempts from disclosure trade secrets and confidential or privileged commercial or financial information that is obtained from a person. In a 2013 opinion, *Biles* v. *Dep't of Health and Human Services,* 931 F. Supp. 2d 211 (D.D.C. 2013), the U.S. District Court for

the District of Columbia ordered the release of the requested bid information, rejecting HHS's argument that release would cause substantial competitive harm to the private companies that submit bid data to CMS. The court remarked that the HHS statements about substantial competitive harm were conclusory. As a result of this ruling, we released the requested data to the academic researcher (and the public) at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/DataRequests.html*. In light of this litigation, as well as anticipated additional requests for more recent MA bid pricing data, we are soliciting public comments on a range of approaches we could implement to release data more recent than the proposal we are currently setting forth for consideration.

For example, we are considering whether to release MA bid pricing data on a shorter timeframe than the proposed 5-year lagged timeframe, which could be as recent as MA bid pricing data from the previously-concluded MA contract year. We are also seeking comment as to whether the relationship between the passage of time and commercial sensitivity of the bid data changes more rapidly for some MA bid pricing data elements than others. If commenters believe this to be the case, we are seeking the submission of detailed analysis that sets forth which data elements meet this standard and why.

If unfair competitive harm is included as a rationale for us to consider in withholding some or all elements of more recent MA bid pricing data from release, either to external researchers subject to some limitations in redisclosure of the data or the public at large, we seek evidence of this competitive harm linked to particular bid data elements, and a fulsome discussion as to how each of the elements identified could be used by a competitor to directly harm a competing MAO. See section III.E.3.d above for detail on what a fulsome discussion would include, in our explanation of ''specific examples.'' If there are commercially sensitive data elements in the MA bids, we also seek comment as to whether there are safeguards that might be appropriately implemented to protect those identified data elements, while still allowing releases of more recent data.

Finally, we are seeking comment regarding to whom we should release more recent MA bid pricing data. Specifically, should such a release be made fully available to the public at large, or only to researchers who have studies approved through an application process and who are subject to our long-standing data sharing procedures. If we were to release MA bid pricing data for years more recent than the 5 year lagged data we propose here, we also seek comment on whether to use the existing policies for the release of Part D prescription drug event (PDE) data at § 423.505(m) and Part C encounter data at § 422.310(f)(2). We also seek comment on whether research results from the analysis of MA bid pricing data should be subject to additional restrictions, such as a prohibition of publication of MA bid pricing data at the plan level or prohibitions on the identification of the applicable MAO that submitted the data. We seek comment on whether external researchers should be able to use MA bid pricing data for commercial purposes rather than to produce research that could be useful to us in our administration of the Medicare program generally. We are considering limiting conditions of this type as means to release as much data while protecting what should be protected.

As discussed in section III.E.3.d above, we are seeking comment on our proposal that 5 years is an appropriate length of time for the MA bid pricing data we are proposing to release to no longer be competitively sensitive. In addition, in setting forth this section III.E.5 discussion, we are also soliciting comments on how we can best serve the needs of the public through the sharing of MA bid pricing data that is less than 5 years old while at the same time addressing the concerns of MAOs that we appropriately guard against the potential misuse of data in ways that would undermine protections put in place to ensure nondisclosure of proprietary data. The purpose of this solicitation is to both inform our decision-making process about the 5-year threshold proposed above, as well as to inform future policy development.

6. Background on Part C and Part D Medical Loss Ratio Data

Section 1103 of Title I, Subpart B of the Health Care and Education Reconciliation Act (Pub. L. 111–152) amends section 1857(e) of the Act to add medical loss ratio (MLR) requirements to Medicare Part C. An MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care rather than for such other items as administrative expenses or profit. Because section 1860D–12(b)(3)(D) of the Act incorporates by reference the requirements of section 1857(e) of the Act, these MLR requirements also apply to the Part D program. In the May 23, 2013 final rule (78 FR 31284), we codified the MLR requirements for MAOs and Part D sponsors in the regulations at part 422, subpart X, and part 423, subpart X.

For contracts beginning in 2014 or later, MAOs, cost plans, and Part D sponsors are required to report their MLRs and are subject to financial and other penalties for a failure to meet the statutory requirement that they have an MLR of at least 85 percent (see § 422.2410 and § 423.2410). The statute imposes several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds to CMS, a prohibition on enrolling new members, and ultimately contract termination. The minimum MLR requirement in section 1857(e)(4) of the Act creates incentives for MAOs and Part D sponsors to reduce administrative costs, such as marketing costs, profits, and other uses of the funds earned by plan sponsors, and helps to ensure that taxpayers and enrolled beneficiaries receive value from Medicare health plans.

Under the regulations at § 422.2410 and § 422.2460, with respect to MAOs, and § 423.2410 and § 423.2460, with respect to Part D sponsors, for each contract year, each MAO and Part D sponsor is required to submit a report to us, in a timeframe and manner that we specify, which includes the data needed to calculate and verify the MLR and remittance amount, if any, for each contract. The information that MAOs and Part D sponsors report to us includes incurred claims for medical services and prescription drug costs, expenditures on activities that improve health care quality, taxes, licensing and regulatory fees, non-claims costs, and revenue.

We have developed a standardized MLR Report template, called the MLR Report, for MAOs and Part D sponsors to populate with the data used to calculate the MLR and remittance amount owed to us under § 422.2410 and § 423.2410, if any. The MLR Report is a standardized Excel workbook with three worksheets and special functions built in (for example, validation features). We maintain and update the MLR Report data collection format under OMB #0938–1232.

For each contract year beginning in 2014 or later, MAOs and Part D sponsors are required to enter their MLR data and upload their MLR Reports to our Health Plan Management System (HPMS). Based on the data entered by the MAO or Part D sponsor, the Report calculates the MLR for the contract. An MA or Part D contract's MLR is increased by a credibility factor if the contract's experience for the contract

year is partially credible in actuarial terms, as provided at § 422.2440 and § 423.2440. Finally, we also require MAOs and Part D sponsors to include in their MLR Reports a detailed description of the methods used to allocate expenses, including how each specific expense meets the criteria for the expense category to which it was assigned. The MLR Report is on our Web site at *https://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/medicallossratio.html*, accompanied by instructions on how to populate the Report.

Below we describe the categories of Part C and Part D MLR data submitted in the MLR Reports:

- *Revenue.* MAOs and Part D sponsors must report revenue received under the contract. The MLR Report includes separate lines for MAOs and Part D sponsors to report the amounts of revenue received, such as beneficiary premiums; MA plan payments (based on A/B bids); MA rebates; Part D direct subsidies; federal reinsurance subsidies; Low Income Premium Subsidy Amounts; risk corridor payments; and MSA enrollee deposits (see § 422.2420(c)(1) and § 423.2420(c)(1)).
- *Claims.* MAOs and Part D sponsors must report incurred claims for clinical services and prescription drug costs, including categories such as the following: Direct claims paid to providers (including under capitation contracts with physicians) for covered services; for an MA contract that includes MA–PD plans, or a Part D contract, the MLR Report must include drug costs provided to all enrollees under the contract; liability and reserves for claims incurred during the contract year; paid and accrued medical incentive pools and bonuses; reserves for contingent benefits and the medical or Part D claim portion of lawsuits; MA rebate amounts that are used to reduce enrollees' Part B premiums; total fraud reduction expenses and total claim payment recoveries as a result of fraud reduction efforts; MSA enrollee deposits; and direct and indirect remuneration (see § 422.2420(b) and § 423.2420(b)).
- *Federal and State Taxes and Licensing or Regulatory Fees.* The MLR Report includes MAOs and Part D sponsors' outlays for taxes and fees, such as federal income taxes and other federal taxes; state income, excise, business, and other taxes; state premium taxes; allowable community benefit expenditures; and licensing and regulatory fees (see § 422.2420(c)(2) and § 423.2420(c)(2)).
- *Health Care Quality Improvement Expenses Incurred.* MAOs and Part D sponsors must enter their expenditures for health care quality improvement. Expenditures are categorized separately depending on the primary purpose of the activity. Quality improvement expenses are reported in categories such as: (1) Expenses for improving health outcomes through the implementation of activities such as quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance initiatives; (2) expenses for implementing activities to prevent hospital readmissions; (3) expenses for activities primarily designed to improve patient safety, reduce medical errors, and lower infection and mortality rates; (4) expenses for activities primarily designed to implement, promote, and increase wellness and health activities; (5) expenditures to enhance the use of health care data to improve quality, transparency, and outcomes and support meaningful use of health information technology; or (6) allowable ICD–10 implementation costs (see § 422.2430(a)(1) and § 423.2430(a)(1)).
- *Non-Claims Costs.* MAOs and Part D sponsors must report expenditures for non-claims costs, such as administrative fees, direct sales salaries and benefits, brokerage fees and commissions, regulatory fines and penalties, cost containment expenses not included as quality improvement expenses, all other claims adjustment expenses, non-allowable community benefit expenditures, and non-allowable ICD–10 implementation costs (see § 422.2430(b) and § 423.2430(b)).
- *Employer Group Waiver Plan (EGWP) Reporting Methodology.* We only apply the MLR requirement to the Medicare-funded portion of EGWPs. MLR Reports submitted for MA or Part D contracts that include EGWPs must specify the percentage of the contract's total revenue that was funded by Medicare. The MLR Report must also identify the methodology that the MAO or Part D sponsor used to determine the Medicare-funded portion of the EGWP (see § 422.2420 and § 423.2420).
- *Total Member Months.* MAOs and Part D sponsors must report all member months across all plans under the contract (see § 422.2440 and § 423.2440).
- *Plan-Specific Data.* MAOs and Part D sponsors enter a list of all of the plans offered under the contract, and the member months associated with each plan entered. They must provide additional details about each plan that is listed, including whether the plan is a Special Needs Plan for beneficiaries who are dually eligible for both Medicare and Medicaid (D–SNP); whether the plan's defined service area includes counties in one of the territories; and plan-level cost and revenue information for D–SNPs in territories (see § 422.2420(a) and § 423.2420(a)).
- *Medical Loss Ratio Numerator.* This is a calculated field that is the sum of all amounts reported as claims or as health care quality improvement expenses in the MLR Report (see § 422.2420(b) and § 423.2420(b)).
- *Medical Loss Ratio Denominator.* This field is calculated by taking the contract's total revenue and deducting the sum of the reported licensing or regulatory fees, federal and state taxes, and allowable community benefit expenditures (see § 422.2420(c) and § 423.2420(c)).
- *Credibility Adjustment.* An MAO or Part D sponsor may add a credibility adjustment to a contract's MLR if the contract's experience is partially credible, as determined by us (see § 422.2440(d) and § 423.2440(d)). If a contract receives a credibility adjustment (determined by the number of total member months under the contract), this field is populated by a percentage that represents the credibility adjustment factor (see § 422.2440(a) and § 423.2440(a)).
- *Unadjusted MLR.* This is a calculated field that reflects the MLR for an MA or Part D contract before application of the credibility adjustment (see § 422.2440 and § 423.2440).
- *Adjusted MLR.* This is a calculated field that represents the MLR after the application of the credibility adjustment factor (see § 422.2440(a) and § 423.2440(a)).
- *Remittance Amount Due to CMS for the Contract Year.* The MLR Report includes any amounts that the MAO or Part D sponsor must remit to us. The MLR Report identifies the amount of the remittance that is allocated to Parts A and B, and the amount allocated to Part D (see § 422.2410(c) and § 423.2410(c)).

7. Proposed Regulatory Changes for Release of MLR Data

a. Proposed Addition of § 422.2490 and § 423.2490 Authorizing Release of Part C and Part D Medical Loss Ratio Data

We are proposing to add new contract requirements, codified in new regulations at §§ 422.504 and 422.2490 of part 422, with respect to Part C MLR data, and §§ 423.505 and 423.2490 of part 423, with respect to Part D MLR data, to authorize release to the public by CMS of certain MLR data submitted by MAOs and Part D sponsors. We propose to define Part C MLR data at § 422.2490(a), and Part D MLR data at

§ 423.2490(a), as the data the MAOs and Part D sponsors submit to us in their annual MLR Reports, as required under existing § 422.2460 and § 423.2460. At § 422.2490(b) and § 423.2490(b), we propose certain exclusions to the definitions of Part C MLR data and Part D MLR data, respectively. Finally, we propose at § 422.2490(c) and § 423.2490(c) to release the Part C MLR data and Part D MLR data, respectively, for each contract for each contract year, no earlier than 18 months after the end of the applicable contract year.

Generally, the MLR for each MA and Part D contract reflects the ratio of costs (numerator) to revenues (denominator) for all enrollees under the contract. For an MA contract, the MLR reflects the percentage of revenue received under the contract spent on incurred claims for all enrollees, prescription drug costs for those enrollees in MA plans under the contract offering the Part D benefit, quality initiatives that meet the requirements at § 422.2430, and amounts spent to reduce Part B premiums. The MLR for a Part D contract reflects the percentage of revenue received under the contract spent on incurred claims for all enrollees for Part D prescription drugs, and on quality initiatives that meet the requirements at § 423.2430. The percentage of revenue that is used for other items such as administration, marketing, and profit is excluded from the numerator of the MLR (see § 422.2401 and § 423.2401; § 422.2420(b)(4) and § 423.2420(b)(4); § 422.2430(b) and § 423.2430(b)).

As discussed in section III.F.1. of this proposed rule, our proposed release of Part C and Part D MLR data is in keeping with Presidential initiatives to improve federal management of information resources by increasing data transparency and access to federal datasets. In proposing this release, we are also seeking to align with current disclosures of MLR data that issuers of commercial health plans submit each year as required by section 2718 of the Public Health Service Act. We have published similar commercial MLR data on our Web site at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html*.

The MLR data that we propose to release will enable enrollees, consumers, regulators, and others to see how much of plan sponsors' revenue is used to pay for services, quality improving activities, and Part B premium rebates versus how much is used to pay for ''non-claims,'' or administrative expenses, incurred by the plan sponsor. We believe that the release of this data will facilitate public evaluation of the MA and Part D programs by providing insight into the efficiency of health insurers' operations. In addition, we believe that our proposed policy for the release of certain MLR data will provide beneficiaries with information that can be used to assess the relative value of Medicare health and drug plans.

b. Exclusions From the Release of Part C and Part D MLR Data

For the purpose of this data release under proposed § 422.2490 and § 423.2490, we would exclude four categories of information from the release of Part C and Part D MLR data, as described at proposed § 422.2490(b) and § 423.2490(b), respectively. First, at § 422.2490(b)(1) and § 423.2490(b)(1), we propose to exclude from release any narrative information that MAOs and Part D sponsors submit to support the amounts that they include in their MLR Reports, such as descriptions of the methods used to allocate expenses. MAOs and Part D sponsors are required to describe the methods they used to allocate expenses, including incurred claims, quality improvement expenses, federal and state taxes and licensing or regulatory fees, and other non-claims costs. A detailed description of each expense element should be provided, including how each specific expense meets the criteria for the type of expense in which it is categorized. We believe that descriptions of expense allocation methods should be excluded because MAOs and Part D sponsors may be required to provide information that is pertinent to more than the individual MA or Part D contract for which the MLR Report is being submitted (see, for example, § 422.2420(d)(1)(ii) and § 423.2420(d)(1)(ii), which requires that expenditures that benefit multiple contracts, or contracts other than those being reported, be reported on a pro rata share), such as an MAO's or Part D sponsor's proprietary approach to setting payment rates in contracts with providers, or its strategies for investing in activities that improve health quality. We are concerned that MAOs and Part D sponsors would be reluctant to submit narrative descriptions that include information that they regard as proprietary if they know that it will be disclosed to the public, which could impair our ability to assess the accuracy of their allocation methods.

Second, at § 422.2490(b)(2) and § 423.2490(b)(2), we propose to exclude from release any plan-level information that MAOs and Part D sponsors submit in their MLR Reports. Some of the plan-level data in MAO's and Part D sponsors' MLR Reports is also included in their plan bids as base period experience data, such as plan IDs, plan member months, and Medicaid per member per month gain/loss. As discussed in our proposal to release certain MA bid pricing data, we believe bid data would no longer be competitively sensitive after 5 years; however, we do not believe that bid data becomes no longer competitively sensitive within the 18-month timeframe for our proposed release of MLR data. Therefore, we will exclude from our proposed release plan-level data that is included as base period experience data in plan bids. We also propose to exclude the plan-level information submitted in MLR Reports because we do not regard it as relevant to the purposes of our proposed release of Part C and Part D MLR data, which include giving the public access to data that can be used to evaluate the efficiency of MAOs and Part D sponsors and providing enrollees with information that can be used to compare the relative value of health plans. For example, our proposed release would exclude MAOs' and Part D sponsors' responses to questions in the MLR Report that ask whether each plan under a contract is a Special Needs Plan for beneficiaries who are dually eligible for both Medicare and Medicaid (D–SNP), or whether the plan's defined service area includes counties in one of the territories.

Third, at § 422.2490(b)(3) and § 423.2490(b)(3), we propose to exclude from release any information identifying Medicare beneficiaries or other individuals. This exclusion is proposed for the same reason we propose to exclude similar information from MA bid submission data that will be released; we believe that it is important to protect the privacy of individuals identified in these submissions, particularly Medicare beneficiaries. Protection of information that could identify Medicare beneficiaries, particularly in the context of their receipt of health care services, is a long-standing principle of ours in the context of the Medicare program. Incorporating this principle and the necessary protection of this data into this proposal to disclose information is appropriate. With respect to Medicare beneficiaries, we propose to exclude from release any information (that is, data elements) in an MLR Report for a contract if the total number of beneficiaries under the contract is fewer than 11, as we believe that this threshold establishes the point at which individual-level data can be discerned. Following our longstanding data release policy for protecting

individually identifiable information, if a data field in the MLR Report for an MA or Part D contract is calculated based on figures associated with fewer than 11 enrollees (or 132 member months, assuming each individual is counted for 12 months), we would suppress all the data from such fields in the public release file for that contract. We are not proposing to build this threshold into the regulation text, however, as we believe that as technology changes and the ability to reverse-engineer data to identify beneficiaries may change over time. We may revisit this threshold as we administer the data releases proposed here (and in other Medicare contexts) and will make adjustments as necessary to ensure that we do not disclose data that could be used to identify beneficiaries.

Regarding other individuals, we require that MAOs and Part D sponsors provide in their MLR Reports the names and contact information of individuals who can answer questions about the data submitted in an MLR Report. We propose to exclude this information from release. We do not believe that the release of this information serves the purposes of our proposed release of certain MLR data, which are to provide the public with data that can be used to evaluate MA and Part D contracts' efficiency, and to provide beneficiaries with information that can be used to compare the relative value of Medicare plans. Further, release of this identifying and contact information appears to be an unnecessary intrusion into information about private individuals.

Fourth, at § 422.2490(b)(4) and § 423.2490(b)(4), we propose to exclude from release any MLR review correspondence. In the course of the MLR review process, our reviewers may engage in correspondence with MAOs and Part D sponsors in order to validate amounts included in their MLR Reports. Such correspondence may include requests for evidence of amounts reported to us. Responses to these requests could include competitively-sensitive information, such as MAOs' and Part D sponsors' negotiated rates of reimbursement. Release of this correspondence could cause MAOs to be less forthcoming in the information provided to CMS, which would impede the ability of the agency to verify the information submitted by MAOs and Part D sponsors.

c. Timing of Release of Part C and Part D MLR Data

We are proposing to release the MLR data specified in this rule for each MA and Part D contract on an annual basis no earlier than 18 months after the end of the contract year to which the MLR data applies. We are proposing to follow the commercial MLR approach in making the data we receive in MLR Reports available to the public. For Part C and Part D MLR reporting, the data is due about 12 months after the end of the contract year. After we receive MAOs' and Part D sponsors' MLR Reports, we anticipate that it will take up to six months for us to review and finalize the data submitted by MAOs and Part D sponsors.

We believe that our proposed release of contract-level MLR data strikes the appropriate balance between safeguarding information that could be commercially sensitive or proprietary and providing enrollees of health plans, consumers, regulators, and others with a measure that can be used to evaluate health insurers' efficiency. The Part C MLR data and Part D MLR data that we propose to release is aggregated at the contract level. Costs in the MLR numerator are aggregated across providers, beneficiaries, and sites of service. Costs and revenues are further aggregated across all plans under the contract. We do not believe that there is a realistic possibility that the MLR data that we propose to release could be disaggregated or reverse engineered to reveal commercially sensitive or proprietary information. We seek comment on this point and on our analysis of the commercial sensitivity of this information.

We believe the availability of the Part C MLR data and Part D MLR data we are proposing to release will provide beneficiaries a measure by which they can compare the relative value of Medicare products. Our proposed release of MLR data will permit enrollees of health plans, consumers, regulators, and others to take into consideration MLRs when evaluating health insurers' efficiency.

We also believe the availability of MLR data will enhance the competitive nature of the MA and Part D programs. The proposed access to data will support potential plan sponsors in evaluating their participation in the Part C and D programs and will facilitate the entry into new markets of existing plan sponsors. In knowing historical MLR data, new business partners might emerge, and better business decisions might be made by existing partners. As a result, we believe that releasing Part C and Part D MLR data as proposed is both necessary and appropriate for the effective operation of these programs.

We seek comment on the release of Part C MLR data and Part D MLR data as outlined above. We solicit comment on whether the Part C MLR data and Part D MLR data we propose to release contain proprietary information, and if so, what safeguards might be appropriate to protect those data, such as recommended fields to be redacted, the minimum length of time that such data remains commercially sensitive, and any suggestions for publishing aggregations of Part C MLR data and Part D MLR data in lieu of publishing the MLR data as submitted by MAOs and Part D sponsors. We invite commenters to provide analysis and explanations to support comments that information should be protected for a longer—or shorter—period of time so that we may properly evaluate our proposal in adopting a final rule. Analysis and explanations should (1) cite the particular information proposed to be released and explain how that information differs from publicly available data; (2) point to the particular entity or entity type that could gain an unfair competitive advantage from the information release; and (3) fully explain the mechanism by which the release of that particular information would create an unfair competitive advantage for that particular entity.

We also solicit comment on whether MLR data that is associated single-plan contracts is more commercially sensitive than MLR data that is associated with contracts that include multiple plans, and if so, whether we should take any protective measures when releasing the MLR data for single-plan contracts, such as redacting data fields that could be used to identify the contract, withholding the MLR data for all single-plan contracts and instead publishing a data set consisting of figures that have been averaged across all single-plan contracts, or by releasing a more limited data set for single-plan contracts.

8. Proposed Technical Changes

We are proposing to amend § 422.2400, which identifies the basis and scope of the MLR regulations for MAOs, and § 423.2400, which identifies the basis and scope of the MLR regulations for Part D sponsors, to add a reference to section 1106 of the Act, which governs the release of information gathered in the course of administering our programs under the Act.

F. Prohibition on Billing Qualified Medicare Beneficiary Individuals for Medicare Cost-Sharing

We remind all Medicare providers (including providers of services defined in section 1861 of the Act and

physicians) that federal law prohibits them from collecting Medicare Part A and Medicare Part B deductibles, coinsurance, or copayments, from beneficiaries enrolled in the Qualified Medicare Beneficiaries (QMB) program (a Medicaid program which helps certain low-income individuals with Medicare cost-sharing liability). In July 2015, we released a study finding that confusion and inappropriate balance billing persist notwithstanding laws prohibiting Medicare cost-sharing charges for QMB individuals, Access to Care Issues Among Qualified Medicare Beneficiaries (QMB) (''Access to Care'') *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Access_to_Care_Issues_Among_Qualified_Medicare_Beneficiaries.pdf*.

These findings underscore the need to re-educate providers about proper billing practices for QMB enrollees.

In 2013, approximately 7 million Medicare beneficiaries were enrolled in the QMB program. State Medicaid programs are liable to pay Medicare providers who serve QMB individuals for the Medicare cost-sharing. However, as permitted by federal law, states can limit provider payment for Medicare cost-sharing to the lesser of the Medicare cost-sharing amount, or the difference between the Medicare payment and the Medicaid rate for the service. Regardless, Medicare providers must accept the Medicare payment and Medicaid payment (if any, and including any permissible Medicaid cost sharing from the beneficiary) as payment in full for services rendered to a QMB individual. Medicare providers who violate these billing prohibitions are violating their Medicare Provider Agreement and may be subject to sanctions. (See sections 1902(n)(3); 1905(p); 1866(a)(1)(A); 1848(g)(3) of the Act.)

Providers should take steps to educate themselves and their staff about QMB billing prohibitions and to exempt QMB individuals from impermissible Medicare cost-sharing billing and related collection efforts. For more information about these requirements, steps to identify QMB patients and ways to promote compliance, see *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/se1128.pdf*.

Given that original Medicare providers may also serve Medicare Advantage enrollees, we note that the CY 2017 Medicare Advantage Call Letter reiterates the billing prohibitions applicable to dual eligible beneficiaries (including QMBs) enrolled in Medicare Advantage plans and the responsibility of plans to adopt certain measures to protect dual eligible beneficiaries from unauthorized charges under § 422.504(g). (See pages 181–183 at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf*).

G. Recoupment or Offset of Payments to Providers Sharing the Same Taxpayer Identification Number

1. Overview and Background

Medicare payments to providers and suppliers may be offset or recouped, in whole or in part, by a Medicare contractor if the Medicare contractor or CMS has determined that a provider or supplier has been overpaid. Historically, we have used the Medicare provider billing number or National Provider Identifier (NPI) to recoup overpayments from Medicare providers and suppliers until these debts were paid in full or eligible for referral to the Department of Treasury (Treasury) for further collection action under the Debt Collection Improvement Act of 1996 and the Digital Accountability and Transparency Act of 2014. Once an overpayment is referred to Treasury, the Treasury's Debt Management Services uses various tools to collect the debt, including offset of federal payments against entities that share the same provider Taxpayer Identification Number (TIN). Hence, Treasury has the ability to collect our overpayments using the provider TIN and we pay a fee for every collection made.

On March 23, 2010, the Affordable Care Act (ACA) was enacted. Section 6401(a)(6) of the Affordable Care Act established a new section 1866(j)(6) of the Act. Section 1866j(6) of the Act allows the Secretary to make any necessary adjustments to the payments to an applicable provider of services or supplier to satisfy any amount due from an obligated provider of services or supplier. The statute defines an applicable provider of services or supplier (applicable provider) as a provider of services or supplier that has the same taxpayer identification number as the one assigned to the obligated provider of services or supplier. The statute defines the obligated provider of services or supplier (obligated provider) as a provider of services or supplier that owes a past-due overpayment to the Medicare program. For purposes of this provision, the applicable and obligated providers must share a TIN, but may possess a different billing number or National Provider Identifier (NPI) number than one another.

For example, a health care system may own a number of hospital providers and these providers may share the same TIN while having different NPI or Medicare billing numbers. If one of the hospitals in this system receives a demand letter for a Medicare overpayment, then that hospital (Hospital A) will be considered the obligated provider while its sister hospitals (Hospitals B and C) will be considered the applicable providers. This authority allows us to recoup the overpayment of the obligated provider, Hospital A, against any or all of the applicable providers, Hospitals B and C, with which it, Hospital A, shares a TIN.

2. Provisions of the Proposed Regulations

If CMS or a Medicare contractor has decided to put into effect an offset or recoupment, then § 405.373(a) requires the Medicare contractor to notify the provider or supplier in writing of its intention to fully or partially offset or recoup payment and the reasons for the offset or recoupment. Currently, the written demand letter sent by the Medicare contractor to a provider or supplier serves as notification of the overpayment and intention to recoup or offset if the obligated provider, Hospital A, fails to repay the overpayment in a timely manner.

With the passage of section 1866(j)(6) of the Act, the requirements in § 405.373(a) could be interpreted to require the Medicare contractor to provide notification to both the obligated provider, Hospital A, and the applicable provider, Hospital B, of its intention to recoup or offset payment. Because we don't think it is necessary to provide separate notice to both the obligated provider and the applicable provider, we propose to amend the notice requirement in § 405.373. Specifically, we propose to create a new paragraph (f) in § 405.373 to state that § 405.373(a) does not apply in instances where the Medicare Administrative Contractor intends to offset or recoup payments to the applicable provider of services or supplier to satisfy an amount due from an obligated provider of services or supplier when the applicable and obligated provider of services or supplier share the same Taxpayer Identification Number.

Before the effective date of this rule, we intend to notify all potentially affected Medicare providers of the implementation of section 1866j(6) of the Act through Medicare Learning Network (MLN) or MLN Connects Provider eNews article(s), an update to

the current Internet Only Manual instructions including, the Medicare Financial Management Manual, and the addition of clarifying language in the demand letters issued to obligated providers. We believe these actions would provide adequate notice to providers and suppliers sharing a TIN, if they choose, provide the opportunity to implement a tracking system of Medicare overpayments on the corporate level for the affected providers. We also believe these actions are sufficient because of Treasury's analogous practice of offsetting using a TIN without furnishing notice to all potentially affected providers and suppliers. It has been a long standing practice for Treasury to offset federal payments using the TIN and Treasury currently does not issue a notice of intent to recoup or offset to applicable providers and suppliers when Treasury recoups CMS overpayments.

Additionally, in our review of § 405.373(a) and (b), we propose to replace the terms intermediary and carrier with the term Medicare Administrative Contractor as intermediaries and carriers no longer exist.

H. Accountable Care Organization (ACO) Participants Who Report Physician Quality Reporting System (PQRS) Quality Measures Separately

The Affordable Care Act gives the Secretary authority to incorporate reporting requirements and incentive payments from certain Medicare programs into the Shared Savings Program, and to use alternative criteria to determine if payments are warranted. Specifically, section 1899(b)(3)(D) of the Act affords the Secretary discretion to incorporate reporting requirements and incentive payments related to the physician quality reporting initiative (PQRI), under section 1848 of the Act, including such requirements and such payments related to electronic prescribing, electronic health records, and other similar initiatives under section 1848, and permits the Secretary to use alternative criteria than would otherwise apply (under section 1848 of the Act) for determining whether to make such payments.

Current Shared Savings Program regulations at § 425.504(c) do not allow eligible professionals (EPs) billing through the Taxpayer Identification Number (TIN) of an Accountable Care Organization (ACO) participant to participate in PQRS outside of the Shared Savings Program, and these EPs and the ACO participants through which they bill may not independently report for purposes of the PQRS apart from the ACO. This policy was designed to ease reporting burden for individual EPs and group practices and promote integration of providers and suppliers within the ACO in order to help achieve the Shared Savings Program goals of improving quality and coordination of care. While over 98 percent of ACOs satisfactorily report their quality data annually, if an ACO fails to satisfy the PQRS reporting requirements, the individual EPs and group practices participating in that ACO will receive the PQRS payment adjustment along with the automatic VM downward payment adjustment.

We are proposing to amend the regulation at § 425.504 to permit EPs that bill under the TIN of an ACO participant to report separately for purposes of the 2018 PQRS payment adjustment when the ACO fails to report on behalf of the EPs who bill under the TIN of an ACO participant. Specifically, we are proposing to remove the requirement at § 425.504(c)(2) so that, for purposes of the reporting period for the 2018 PQRS payment adjustment (that is, January 1, 2016, through December 31, 2016), EPs who bill under the TIN of an ACO participant have the option of reporting separately as individual EPs or group practices. If the ACO fails to satisfactorily report on behalf of such EPs or group practices, we are proposing to consider this separately reported data for purposes of determining whether the EPs or group practices are subject to the 2018 PQRS payment adjustment. We are also proposing to amend § 425.504(c)(2) to apply only for purposes of the 2016 payment adjustment. We propose at § 425.504(d) the revised requirements for the 2017 and 2018 PQRS payment adjustment under the Shared Savings Program. We discuss the proposed changes for the 2017 PQRS payment adjustment under the Shared Savings Program in more detail later in this section.

We note that the registration deadline for participating in the PQRS Group Practice Reporting Option (GPRO) is June 30 of the applicable reporting period. Since affected EPs are not able to register for the PQRS GPRO by the applicable deadline for the 2018 PQRS payment adjustment, we propose that such EPs would not need to register for the PQRS GPRO for the 2018 PQRS payment adjustment, but rather mark the data as group data in their submission. Thus, we are proposing to eliminate a registration process for groups submitting data using third party entities. When groups submit data utilizing third party entities, such as a qualified registry, QCDR, direct EHR product, or EHR data submission vendor, we are able to obtain group information from the third party entity and discern whether the data submitted represents group submission or individual submission once the data is submitted. In addition, we propose that an affected EP may utilize the secondary reporting period either as an individual EP using one of the registry, qualified clinical data registry (QCDR), direct Electronic Health Record (EHR) product, or EHR data submission vendor reporting options or as a group practice using one of the registry, QCDR, direct EHR product, or EHR data submission vendor reporting options. We note that this would exclude, for individual EPs, the claims reporting option and, for group practices, the Web Interface and certified survey vendor reporting options.

Furthermore, we recognize that certain EPs are similarly situated with regard to the 2017 PQRS payment adjustment, which will be applied beginning on January 1, 2017. We believe it is appropriate and consistent with our stated policy goals to afford these EPs the benefit of this proposed policy change. Accordingly, as noted above,we are proposing to permit EPs that bill through the TIN of an ACO participant to report separately for purposes of the 2017 PQRS payment adjustment if the ACO failed to report on behalf of the EPs who bill under the TIN of an ACO participant. Specifically, we are proposing to remove the requirements at § 425.504(c)(2) so that, for purposes of the reporting period for the 2017 PQRS payment adjustment, EPs who bill under the TIN of an ACO participant have the option of reporting separately as individual EPs or group practices. As noted above, we are proposing to amend § 425.504(c)(2) to apply only for purposes of the 2016 payment adjustment. We propose at § 425.504(d) the revised requirements for the 2017 and 2018 PQRS payment adjustment under the Shared Savings Program.

The previously established reporting period for the 2017 PQRS payment adjustment is January 1, 2015, through December 31, 2015. To allow affected EPs that participate in an ACO to report separately for purposes of the 2017 PQRS payment adjustment, we are proposing at § 414.90(j)(1)(ii) to establish a secondary PQRS reporting period for the 2017 PQRS payment adjustment for individual EPs or group practices who bill under the TIN of an ACO participant if the ACO failed to report on behalf of such individual EPs or group practices during the previously established reporting period for the

2017 PQRS payment adjustment. This option is limited to EPs that bill through the TIN of an ACO participant in an ACO that failed to satisfactorily report on behalf of its EPs and would not be available to EPs that failed to report for purposes of PQRS outside the Shared Savings Program.

In addition, we propose that these affected EPs may utilize the secondary reporting period either as an individual EP using the registry, QCDR, direct EHR product, or EHR data submission vendor reporting options or as a group practice using one of the registry, QCDR, direct EHR product, or EHR data submission vendor reporting options. We note that this would exclude, for individual EPs, the claims reporting option and, for group practices, the Web Interface and certified survey vendor reporting options.

We note that the registration deadline for the participating in the PQRS GPRO is June 30 of the applicable reporting period. Since the applicable deadline for the 2017 PQRS payment adjustment has passed, we propose that such EPs would not need to register for the PQRS GPRO for the 2017 PQRS payment adjustment, but rather would be able to report as a group practice via the registry, QCDR, direct EHR product, or EHR data submission vendor reporting options. Therefore, we propose at § 414.90(j)(4)(v) that sections § 414.90(j)(8)(ii), (iii), and (iv) would apply to affected EPs reporting as individuals using this secondary reporting period for the 2017 PQRS payment adjustment. In addition, we propose at § 414.90(j)(7)(viii) that sections § 414.90(j)(9)(ii), (iii), and (iv) would apply to affected EPs reporting as group practices using this secondary reporting period for the 2017 PQRS payment adjustment. Further, we propose at § 414.90(k)(4)(ii) that § 414.90(k)(5) would apply to affected EPs reporting as individuals or group practices using this secondary reporting period for the 2017 PQRS payment adjustment.

We are also proposing that the secondary reporting period for the 2017 PQRS payment adjustment would coincide with the reporting period for the 2018 PQRS payment adjustment (that is, January 1, 2016 through December 31, 2016). In addition, for operational reasons and to minimize any additional burden on affected EPs (who are already required to report for CY 2016 for purposes of the 2018 PQRS payment adjustment), we propose to assess the individual EP or group practice's 2016 data using the applicable satisfactory reporting requirements for the 2018 PQRS payment adjustment (including, but not limited to, the applicable PQRS measure set). We invite comment on any 2018 requirements that may need to be modified when applied for purposes of the 2017 PQRS payment adjustment,

As a result, individual EP or group practice 2016 data could be used with respect to the secondary reporting period for the 2017 payment adjustment or for the 2018 payment adjustment or for both payment adjustments if the ACO in which the affected EPs participate failed to report for purposes of the applicable payment adjustment. We believe this change to our program rules is necessary for affected individual EPs and group practices to be able to take advantage of the additional flexibility proposed at section III.K.1.e. for the Shared Savings Program. If an affected individual EP or group practice decides to use the secondary reporting period for the 2017 payment adjustment, it is important to note that this EP or group practice should expect to receive a PQRS payment adjustment for services furnished in 2017 until CMS is able to determine that the EP or group practice satisfactorily reported for purposes of the 2017 PQRS payment adjustment. First, we would need to process the data submitted for 2016. Second, we would need to determine whether or not the individual EP or group practice met the applicable satisfactory reporting requirements for the 2018 PQRS payment adjustment. Third, we would need to update the individual EP or group practice's status so that the EP or group practice stops receiving a negative payment adjustment on claims for services furnished in 2017 and reprocess all claims that were previously paid. In addition, as discussed further in section III.L. of this proposed rule, the EP or group practice would also avoid the automatic downward VM adjustment, but would not qualify for an upward adjustment since the ACO failed to report.

Since EPs and group practices taking advantage of this secondary reporting period for the 2017 PQRS payment adjustment will have missed the deadline for submitting an informal review request for the 2017 PQRS payment adjustment, we propose the informal review submission periods for these EPs or group practices would occur during the 60 days following the release of the PQRS feedback reports for the 2018 PQRS payment adjustment.

We request comments on these proposals.

I. Medicare Advantage Provider Enrollment

1. Background

a. General Overview

The Medicare program is the primary payer of health care for approximately 54 million beneficiaries and enrollees. Section 1802(a) of the Act permits beneficiaries to obtain health services from any individual or organization qualified to participate in the Medicare program. Providers and suppliers furnishing items or services must comply with all applicable Medicare requirements stipulated in the Act and codified in the regulations. These requirements are meant to promote quality care while protecting the integrity of the program. As a major component of our fraud prevention activities, we have increased our efforts to prevent unqualified individuals or organizations from enrolling in Medicare.

The term ''provider of services'' is defined in section 1861 of the Act as a hospital, a critical access hospital (CAH), a skilled nursing facility (SNF), a comprehensive outpatient rehabilitation facility (CORF), a home health agency (HHA), or a hospice. The term ''supplier'' is defined in section 1861(d) of the Act as, unless context otherwise requires, a physician or other practitioner, facility or other entity (other than a provider of services) that furnishes items or services under title XVIII of the Act. Other supplier categories may include, for example, physicians, nurse practitioners, and physical therapists.

Providers and suppliers that fit into these statutorily defined categories may enroll in Medicare if they meet the proper screening and enrollment requirements. This proposed rule would require MA organization providers and suppliers to be enrolled in Medicare in an approved status. We generally refer to an ''approved status'' as a status whereby a provider or supplier is enrolled in, and is not revoked from, the Medicare program. For example, a provider or supplier that has submitted an application, but has not completed the enrollment process with their respective Medicare Administrative Contractor (MAC), is not enrolled in an approved status. The submission of an enrollment application does not deem a provider or supplier enrolled in an approved status. A provider or supplier that is currently revoked from Medicare is not in an approved status. Out-of network or non-contract providers and suppliers are not required to enroll in

Medicare to meet the requirements of this proposed rule.

b. Background

To receive payment for a furnished Medicare Part A or Part B service or item, or to order, certify, or prescribe certain Medicare services, items, and drugs, a provider or supplier must enroll in Medicare. The enrollment process requires the provider or supplier to complete, sign, and submit to its assigned Medicare contractor the appropriate Form CMS–855 enrollment application. The CMS–855 application form captures information about the provider or supplier that is needed for CMS or its contractors to screen the provider or supplier and determine whether the provider or supplier meets all Medicare requirements. This screening prior to enrollment helps to ensure that unqualified individuals and entities do not bill Medicare and that the Medicare Trust Funds are accordingly protected. Data collected and verified during the enrollment process generally includes, but is not limited to: (1) Basic identifying information (for example, legal business name, tax identification number); (2) state licensure information; (3) practice locations; and (4) information regarding ownership and management control.

We strive to further strengthen its provider and supplier enrollment process to prevent and deter problematic providers and suppliers from entering the Medicare program. This includes, but is not limited to, enhancing its program integrity monitoring systems and revising its provider and supplier enrollment regulations in 42 CFR 424, subpart P, and elsewhere as needed. With authority granted by the Act, including provisions in the Affordable Care Act and Medicare Access and CHIP Reauthorization Act, we have revised our provider and supplier enrollment regulations by issuing the following:

• In the February 2, 2011 **Federal Register** (76 FR 5861), we published a final rule with comment period titled, ''Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers.'' This final rule with comment period implemented major Affordable Care Act provisions, including the following:

++ A requirement that institutional providers and suppliers must submit application fees as part of the Medicare, Medicaid, and CHIP provider and supplier enrollment processes.

++ Establishment of Medicare, Medicaid, and CHIP provider and supplier risk-based enrollment screening categories and corresponding screening requirements.

++ Authority that enabled imposition of temporary moratoria on the enrollment of new Medicare, Medicaid, and CHIP providers and suppliers of a particular type (or the establishment of new practice locations of a particular type) in a geographic area.

• In the April 27, 2012 **Federal Register** (77 FR 25284), we published a final rule titled, ''Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements and Changes in Provider Agreements.'' The rule implemented another major Affordable Care Act provision and required, among other things, that providers and suppliers that order or certify certain items or services be enrolled in or validly opted-out of the Medicare program.

++ This requirement was expanded to include prescribers of Medicare Part D drugs in the final rule published in the May 23, 2014 **Federal Register** (79 FR 29844) titled, ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs.''

Through improved processes and systems, since March 2011 we have:

• Saved over $927 million by revoking Medicare Part A and B providers and suppliers that did not comply with Medicare requirements;

• Avoided over $2.4 billion in costs by preventing further billing from revoked and deactivated Medicare Part A and B providers and suppliers;

• Deactivated more than 543,163 Medicare Part A and B providers and suppliers that did not meet Medicare enrollment standards;

• Revoked enrollment and billing privileges under § 424.535 for more than 34,888 Medicare Parts A and B providers and suppliers that did not meet Medicare enrollment standards, and

• Denied 4,949 applications for providers and suppliers in Medicare Parts A and B that did not meet Medicare enrollment standards within a recent 12-month period.[8]

The public may review CMS' Reports to Congress each year for more information on program integrity efforts, including how we calculate savings to the Medicare and Medicaid programs. The Department of Health and Human Services Office of Inspector General (OIG), Government Accountability Office (GAO), and other federal agencies routinely review Medicare's provider and supplier enrollment processes and systems, including a recent study stating that ''as part of an overall effort to enhance program integrity and reduce fraud risk, effective enrollment-screening procedures are essential to ensure that ineligible or potentially fraudulent providers or suppliers do not enroll in the Medicare program.'' (GAO–15–448) The enrollment screening authorities granted in the Affordable Care Act and used to prevent and detect ineligible or potentially fraudulent providers and suppliers from enrolling in the Medicare program are working to protect beneficiaries and the Medicare Trust Funds.

Under applicable provisions of the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982, Medicare began to pay health plans on a prospective risk basis for the first time. The Balanced Budget Act of 1997 (BBA) modified these provisions and established a new Part C of the Medicare program, known as Medicare+Choice (M+C), effective January 1999. As part of the M+C program, the BBA authorized us to contract with public or private organizations to offer a variety of health plan options for enrollees, including both traditional managed care plans (such as those offered by HMOs, as defined in section 1876 of the Act) and new options not previously authorized.

The M+C program was renamed the Medicare Advantage (MA) program under Title II of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), which was enacted on December 8, 2003. The MMA updated and improved the choice of plans for enrollees under MA and changed how benefits are established and payments are made. Under the MMA, enrollees may choose from additional plan options. In addition, Title I of the MMA established the Medicare prescription drug benefit (Part D) program and amended the MA program to allow most MA plans to offer prescription drug coverage.

All Medicare health plans, with the exception of PACE organizations, operating in geographic areas that we determine to have enough qualified providers and suppliers with which to contract in order for enrollees to have access to all Medicare Part A and Part B services, must develop a network of qualified providers and suppliers that

[8] Taken from Shantanu Agrawal, M.D. testimony to Congress on July 22, 2015 *http://www.aging.senate.gov/imo/media/doc/CMS%20_Agrawal_7_22_15.pdf.*

meet our network adequacy standards. As a condition of contracting with us, the health plans' contracted network of providers and suppliers must be approved by us as part of application approval (§ 417.406). PACE organizations must furnish comprehensive medical, health, and social services that integrate acute and long-term care in at least the PACE center, the participant's home, or inpatient facilities, and must ensure accessible and adequate services to meet the needs of its participants. Under current guidance, Medicare health plans may include in their networks providers and suppliers that are not enrolled in Medicare.

2. Provisions of the Proposed Regulation

a. Need for Regulatory Action

This proposed rule would require providers or suppliers that furnish health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization to be enrolled in Medicare and be in an approved status. The term ''MA organization'' refers to Medicare Advantage plans and also MA plans that provide drug coverage, otherwise known as an MA–PD plan. This proposal would create consistency with the provider and supplier enrollment requirements for all other Medicare (Part A, Part B, and Part D) programs. We believe that this proposed rule is necessary to help ensure that Medicare enrollees receive items or services from providers and suppliers that are fully compliant with the requirements for Medicare enrollment and that are in an approved enrollment status in Medicare. This proposed rule would assist our efforts to prevent fraud, waste, and abuse and to protect Medicare enrollees by carefully screening all providers and suppliers, especially those that potentially pose an elevated risk to Medicare, to ensure that they are qualified to furnish Medicare items and services. Out-of network or non-contract providers and suppliers are not required to enroll in Medicare to meet the requirements of this proposed rule.

We consider provider and supplier enrollment to be the gateway to the Medicare program and to beneficiaries. Requiring enrollment of those that wish to furnish Medicare items or services gives us improved oversight of the providers and suppliers treating beneficiaries and the Medicare Trust Funds dollars spent on their care. However, Medicare does not have direct oversight over all providers and suppliers in MA organizations. We note that § 422.204 requires MA organizations to conduct screening of their providers. We believe that we, through our enrollment processes, can further ensure that only qualified providers and suppliers treat Medicare beneficiaries by conducting rigorous screening and rescreening of providers and suppliers that include, for example, risk-based site visits and, in some cases, fingerprint-based background checks. We also has access to information not available to MA organizations, making oversight to ensure compliance with all federal and state requirements more robust. We also continually review provider and supplier enrollment information from multiple sources, such as judicial, law enforcement, state licensure, professional credentialing, and other databases. In short, we collect and carefully review and verify information prior to the provider's or supplier's enrollment and, of great importance, continue this monitoring throughout the period of enrollment. Section 422.204, on the other hand, neither requires MA organizations to, for instance, review a provider or supplier's final adverse action history (as defined in § 424.502), nor to verify a provider or supplier's practice location, ownership, or general identifying information.

We believe that MA organization enrollees should have the same protections against potentially unqualified or fraudulent providers and suppliers as those afforded to beneficiaries under the fee-for-service and Part D programs. Indeed, Medicare beneficiaries and enrollees, the Medicare Trust Funds, and the program at large, are at risk when providers and suppliers that have not been adequately screened and reviewed furnish, order, certify, or prescribe Medicare services and items and receive Medicare payments. For instance, a network provider with a history of performing medically unnecessary tests, treatments, or procedures could threaten enrollees' welfare, as could a physician who routinely overprescribes dangerous drugs. This could also result in improper Medicare payments, harming the Medicare Trust Funds and taxpayers. Requiring enrollment allows us to have proper oversight of providers and suppliers. Under the provisions of this proposed rule, if a provider or supplier fails to meet our requirements or violates federal rules and regulations, we may revoke their enrollment, thereby removing them from consideration as an MA organization provider or supplier.

Information regarding a provider or supplier's enrollment status is housed in our enrollment repository called the Provider Enrollment, Chain and Ownership System (PECOS). A link to that information is located on the CMS Web site. Initial data show a large percent of Medicare Advantage providers and suppliers are already enrolled in Medicare. We do not believe that this proposed rule would have a significant impact on MA organizations' ability to establish networks of contracted providers that meet CMS' MA network requirements. However, we are soliciting industry comment on the potential impact of this proposed rule on MA organizations ability to establish or maintain an adequate networks of providers.

We believe that preventing questionable providers or suppliers from participating in the MA program and removing existing unqualified providers and suppliers would help ensure that fewer enrollees are exposed to risks and potential harm, and that taxpayer monies are spent appropriately. Such a policy would also help comply with the GAO's recommendation that we improve its provider and supplier enrollment processes and systems to increase the protection of all beneficiaries and the Medicare Trust Funds. (GAO–15–448). The additional resources and oversight that we provide in its processes for enrolling providers and suppliers will enhance and complement the screening processes that MA organizations already are required to perform.

b. Statutory Authority

The following are the principal legal authorities for our proposed provisions:

- Section 1856(b) of the Act provides that the Secretary shall establish by regulation other standards for Medicare+Choice organizations and plans ''consistent with, and to carry out, this part.'' In addition, § 1856(b) states that these standards supersede any state law or regulation (other than those related to licensing or plan solvency) for all MA organizations.
- Sections 1102 and 1871 of the Act, which provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.
- Section 1866(j) of the Act, which provides specific authority with respect to the enrollment process for providers and suppliers in the Medicare program.

3. Major Provisions

Given the foregoing and the need to safeguard the Medicare program and its enrollees, we propose several provisions in this proposed rule.

Although existing regulations at § 422.204 address basic requirements for MA provider credentialing, we propose

in § 422.204(b)(5) to require plans to verify that they are compliant with the provider and supplier enrollment requirements. We believe this addition would help facilitate MA organizations' compliance.

In §§ 422.222, 417.478, 460.68, and 460.32, we propose to add a requirement that providers and suppliers enroll in Medicare in an approved status in order to provide health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization. This requirement would apply to network providers and suppliers; first-tier, downstream, and related entities (FDR); providers and suppliers participating in the Program of All-inclusive Care for the Elderly (PACE); suppliers in Cost HMOs or CMPs; providers and suppliers participating in demonstration programs; providers and suppliers in pilot programs; locum tenens suppliers; and incident-to suppliers. MA organizations that do not ensure that providers and suppliers comply with the provider and supplier enrollment requirements may be subject to sanctions and termination. Considering the serious risks to the Medicare program and enrollees from fraudulent or unqualified providers and suppliers, we believe that these are appropriate sanctions.

Current rules allow MA organizations to contract with different entities to provide services to beneficiaries. These contracted entities are referred to as first-tier, downstream, and related entities or FDRs, as defined in § 422.500.

PACE is a Medicare and Medicaid program that helps people meet their health care needs in the community instead of going to a nursing home or other care facility, wherein a team of health care professionals works with participants and their families to make sure participants get the coordinated care they need. A participant enrolled in PACE must receive Medicare and Medicaid benefits solely through the PACE organization. To ensure consistency within our programs, we believe that our proposed provider and supplier enrollment requirements should extend to this program.

Medicare Cost HMOs or CMPs are a type of Medicare health plan available in certain areas of the country. Some Cost HMOs or CMPs only provide coverage for Part B services. Cost HMOs or CMPs do not include Part D. These plans are either sponsored by employer or union group health plans or offered by companies that do not provide Part A services.

Demonstrations and pilot programs, also called research studies, are special projects that test improvements in Medicare coverage, payment, and quality of care. They usually operate only for a limited time for a specific group of people and/or are offered only in specific areas. Providers and suppliers in these programs would not be exempt from the requirements of this proposed rule.

In § 422.224, we also propose to prohibit MA organizations from paying individuals or entities that are excluded by the OIG or revoked from the Medicare program. In this proposal, there would be a first time allowance for payment; as part of this, the MA organization would be required to notify the provider or supplier and the enrollee that no future payment shall be made to, or on behalf of, the revoked or excluded provider or supplier. We believe such notification is necessary because enrollees and beneficiaries often do not know when their provider or supplier is excluded by the OIG or revoked from Medicare. We understand that MA organizations have little or no notice when enrollees seek out-of-network providers and suppliers and only obtain this information once an item or service has been provided. It is probable that some out-of-network providers or suppliers cannot meet Medicare enrollment requirements and therefore may be unable to enroll. We believe the proposals included in this proposed rule will allow for notification to be given to the enrollee and the provider or supplier that no further payments shall be made. We believe such excluded or revoked individuals and entities pose a significant risk to enrollees and should not receive federal dollars, even if payment is made through an intermediary such as an MA organization.

In § 422.501(c)(2), we propose to add to language to the MA organization application requirements requiring MA organizations to provide documentation that all applicable providers and suppliers are enrolled in Medicare in an approved status. We believe that this would assist CMS in the MA organization application process by requiring MA organizations to provide assurance that the designated providers and suppliers are properly screened and enrolled in Medicare.

In § 422.504(a)(6), we propose to add language to the conditions to which an MA organization must agree in its contract with us. MA organizations must agree to comply with all applicable provider requirements in subpart E of this part, including provider certification requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, and limits on physician incentive plans. In § 422.504(a)(6), we propose to extend this requirement to suppliers, not just limit it to providers. In this same section, we also propose to add a requirement at for MA organizations to comply with the provider and supplier enrollment requirements referenced in § 422.222. We believe these revisions would help facilitate the MA plan's compliance with § 422.222.

In §§ 422.504(i)(2)(v), 417.484, and 460.70, we propose to add provisions that requires MA organizations, Cost plans, and PACE organizations to require all FDRs and contracted entities to agree to comply with the provider and supplier enrollment provision.

In §§ 422.510(a)(4)(xiii) and 460.50, we propose provisions that would give us the authority to terminate a contract if an MA organization or PACE organization fails to meet provider and supplier enrollment requirements in accordance with § 422.222 and payment prohibitions in § 422.224. This section is necessary to ensure plan compliance with §§ 422.222 and 422.224 and to provide an appropriate remedy with respect to plans that fail to comply.

We also propose to add provisions to §§ 422.752(a) and 460.40 that would give us the authority to impose sanctions if an MA organization or PACE organizations fails to meet provider and supplier enrollment requirements in accordance with §§ 422.222 and 422.224. As with proposed § 422.510(a)(13), we believe this section is necessary to ensure plan compliance with §§ 422.222 and 422.224 and to furnish an appropriate remedy regarding plans that do not comply.

Finally, we propose to make these provisions effective the first day of the next plan year that begins 2 years from the date of publication of the CY 2017 PFS final rule with comment period.

We believe this would give all stakeholders sufficient time to prepare for these requirements. We are unable to impose new requirements on MA organizations mid-year and therefore must wait to make these rules effective. We seek public comment on our proposed effective date.

J. Proposed Expansion of the Diabetes Prevention Program (DPP) Model

1. Background

In January 2015, the Administration announced the vision of ''Better Care, Smarter Spending, Healthier People'' with emphases on improving the way providers are paid, improving and innovating in care delivery, and sharing information to support better decisions.

Diabetes is at epidemic levels in the Medicare population, affecting more than 25 percent of Americans aged 65 or older.[9] Care for Americans aged 65 and older with diabetes accounts for roughly $104 billion annually, and these costs are growing; by 2050, diabetes prevalence is projected to increase 2 to 3 fold if current trends continue.[10] Fortunately, Type 2 diabetes is typically preventable with appropriate lifestyle changes.

A diabetes prevention program is an evidence-based intervention targeted to individuals with prediabetes, meaning those who have blood sugar that is higher than normal but not yet in the diabetes range. The risk of progression to Type 2 diabetes in an individual with prediabetes is around 5–10 percent per year, or about 5–20 times higher than in individuals with normal blood glucose.[11] The National Diabetes Prevention Program (DPP) administered by the Centers for Disease Control and Prevention (CDC), is a structured health behavior change program delivered in community and health care settings by trained community health workers or health professionals. The National DPP consists of 16 intensive ''core'' sessions of a CDC-approved curriculum in a group-based setting that provides practical training in long-term dietary change, increased physical activity, and problem-solving strategies for overcoming challenges to sustaining weight loss and a healthy lifestyle. After the 16 core sessions, monthly maintenance sessions help to ensure that the participants maintain healthy behaviors. The primary goal of the intervention is to reduce incidence of Type 2 diabetes by achieving at least 5 percent average weight loss among participants. To learn more about the National DPP please visit *http://www.cdc.gov/diabetes/prevention/lifestyle-program/index.html*.

In 2012, the Center for Medicare & Medicaid Innovation (the Innovation Center) awarded a Health Care Innovation Award (HCIA) to The Young Men's Christian Association (YMCA) of the USA (Y–USA) to test whether DPP services could be successfully furnished by non-physician, community-based organizations to Medicare beneficiaries diagnosed with prediabetes and therefore at high risk for development of Type 2 diabetes. The HCIA model tests are being conducted under the authority of section 1115A of the Act (added by section 3021 of the Affordable Care Act) (42 U.S.C. 1315a). The statute authorizes the Innovation Center to test innovative health care payment and service delivery models that have the potential to reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of patient care.

Between February 2013 and June 2015, the Y–USA, in partnership with 17 local YMCAs, the Diabetes Prevention and Control Alliance, and seven other non-profit organizations, enrolled a total of 7,804 Medicare beneficiaries into the model. Enrolled beneficiaries represented a diverse geography across the eight states of Arizona, Delaware, Florida, Indiana, Minnesota, New York, Ohio, and Texas. According to the second year independent evaluation report of the Y–USA Diabetes Prevention Program model, Medicare beneficiaries demonstrated high rates of participation and sustained engagement in the Diabetes Prevention Program. Approximately 83 percent of recruited Medicare beneficiaries attended at least 4 core sessions and approximately 63 percent completed 9 or more core sessions. The first and second independent evaluation reports are available on the Innovation Center's Web site at *https://innovation.cms.gov/initiatives/Health-Care-Innovation-Awards/*.

2. Certification of the Medicare Diabetes Prevention Program (MDPP)

CMS' Office of the Actuary has determined that DPP is likely to reduce Medicare expenditures if made available to eligible Medicare beneficiaries based on historical evidence from evaluations of the Y–USA DPP and other DPPs in the CDC Diabetes Prevention Recognition Program. In addition, to evaluate the longer-term impact of the program, the CMS Actuary developed a model to estimate lifetime per participant savings of a Medicare beneficiary receiving DPP services.

The full CMS Actuary Report is available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf*.

3. Requirements for Expansion

Section 1115A(c) of the Act provides the Secretary with the authority to expand (including implementation on a nationwide basis) through rulemaking the duration and scope of a model that is being tested under section 1115A(b) of the Act if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act: (1) The Secretary determines that the expansion is expected to either reduce spending without reducing quality of care or improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that the expansion would reduce (or would not result in any increase in) net program spending; and (3) the Secretary determines that the expansion would not deny or limit the coverage or provision of benefits.

- *Improved Quality of Care without Increased Spending:* Weight loss is a key indicator of success among persons enrolled in a DPP. According to the second year independent evaluation of the Y–USA DPP HCIA project, those beneficiaries who attended at least one core session lost an average of 7.6 pounds while beneficiaries who attended at least four core sessions lost an average of 9 pounds. BMI was reduced from 32.9 to 31.5 among Medicare beneficiaries that attended at least four core sessions. Based on these findings and results from other DPP evaluations demonstrating the effectiveness of the program in preventing diabetes onset, the Secretary determined that expansion of the DPP will reduce spending and improve the quality of care.
- *Impact on Medicare Spending:* The CMS Chief Actuary has certified that expansion of the DPP would not result in an increase of Medicare spending.
- *No Alteration in Coverage or Provision of Benefits:* The DPP, if implemented in Medicare, would provide services in addition to existing Medicare services, and beneficiaries receiving DPP services would retain all benefits covered in traditional Medicare. Therefore, the Secretary has determined that expansion of DPP would not deny or limit the coverage or provision of Medicare benefits for Medicare beneficiaries.

[9] Centers for Medicare and Medicaid Services. Chronic Conditions among Medicare Beneficiaries, Chartbook, 2012 Edition. Baltimore, MD. 2012.

[10] Boyle, J.P., Thompson, T.J., Gregg, E.W., Barker, L.E., & Williamson, D.F. (2010). Projection of the year 2050 burden of diabetes in the US adult population: Dynamic modeling of incidence, mortality, and prediabetes prevalence. Popul Health Metr, 8(1), 29.

[11] Zhang, X., Gregg, E.W., Williamson, D.F., Barker, L.E., Thomas, W., Bullard, K.M., & Albright, A.L. (2010). A1C level and future risk of diabetes: a systematic review. Diabetes Care, 33(7), 1665–1673.

4. Proposed Expansion of Medicare Diabetes Prevention Program

We propose to expand the duration and scope of the DPP model test by expanding DPP under section 1115A(c) of the Act, and we propose to refer to this expanded model as the Medicare Diabetes Prevention Program (MDPP). In this section of this proposed rule, we propose a basic framework for the MDPP. If finalized, we will engage in additional rulemaking, likely within the next year, to establish specific requirements of the MDPP. We seek comment on all of the proposals below and on any other policy or operational issues that need to be considered in implementing this expansion. The MDPP will become effective January 1, 2018.

• *MDPP as an ''Additional Preventive Service'' under section 1861(ddd) of the Act: CMS Authority to to Designate MDPP as an ''Additional Preventive Service'':* We propose to designate MDPP services as ''additional preventive services'' available under Medicare Part B. Section 1861(ddd) defines ''additional preventive services'' as services that are not preventive services or personalized prevention plan services (as those terms defined in section 1861(ddd)(3)(A) and (C)) that identify medical conditions or risk factors and that the Secretary determines are (A) reasonable and necessary for the prevention or early detection of an illness or disability; (B) recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF); and (C) appropriate for individuals entitled to benefits under Part A or enrolled in Part B.

We believe that MDPP services are generally consistent with the types of additional preventive services that are appropriate for Medicare beneficiaries. In particular, we believe that MDPP services we are proposing under the expanded MDPP model meet the requirements of section 1861(ddd)(1)(A) of the Act because they are specifically designed to prevent prediabetes from advancing into diabetes. MDPP services do not meet the requirement in section 1861(ddd)(1)(B) of the Act that they have received a recommendation with a grade of A or B by the USPSTF. However, under section 1115A(d)(1) of the Act, the Secretary has authority to waive certain requirements. We propose to use this waiver authority to waive section 1861(ddd)(1)(B) of the Act with respect to MDPP services because they have been recommended by the Community Preventive Services Task Force, which is similar to the USPSTF, and therefore a USPSTF recommendation is not necessary. We believe that MDPP services are appropriate for individuals entitled to benefits under part A or enrolled in Part B, and thus meet the requirements of section 1861(ddd)(1)(C) of the Act, because findings from the second year independent evaluation of the Y–USA DPP HCIA project and results from other DPP evaluations demonstrate effectiveness of the program in preventing diabetes onset and thus improve quality of care for Medicare beneficiaries.

Section 1861(ddd)(2) of the Act requires the Secretary to make the determinations required under section 1861(ddd)(1) of the Act using the process for making national coverage determinations (NCDs). However, we propose to waive this requirement because using the NCD process to implement the MDPP would create implementation problems, especially as this rule proposes to create a supplier class and this is an issue that the NCD process does not address.

We seek comment on these proposals.

MDPP Benefit Description: We propose MDPP to be a 12 month program using the CDC-approved DPP curriculum, consisting of 16 core sessions over 16–26 weeks and the option for monthly core maintenance sessions over 6 months thereafter if the beneficiary achieves and maintains a minimum weight loss in accordance with the CDC Diabetes Prevention Recognition Program Standards and Operating Procedures. CDC-approved DPP session curriculum requirements are detailed below.

CDC-Approved DPP Session Curriculum Requirements

During the first 6 months (weeks 1–26) of the DPP intervention, each of the 16 core sessions must address one of these curriculum topics, and all topics must be addressed by the end of the 16 sessions.

1. Welcome to the National Diabetes Prevention Program
2. Self-Monitoring Weight and Food Intake
3. Eating Less
4. Healthy Eating
5. Introduction to Physical Activity (Move Those Muscles)
6. Overcoming Barriers to Physical Activity (Being Active—A Way of Life)
7. Balancing Calorie Intake and Output
8. Environmental Cues to Eating and Physical Activity
9. Problem Solving
10. Strategies for Healthy Eating Out
11. Reversing Negative Thoughts
12. Dealing with Slips in Lifestyle Change
13. Mixing Up Your Physical Activity: Aerobic Fitness
14. Social Cues
15. Managing Stress
16. Staying Motivated, Program Wrap Up

The last 6 months (weeks 27–52) of the DPP 12-month intervention must include at least one core maintenance session delivered in each of the 6 months (for a minimum of six sessions), and all core maintenance sessions must address different topics.

1. Welcome to the Second Phase of the Program
2. Healthy Eating: Taking It One Meal at a Time
3. Making Active Choices
4. Balance Your Thoughts for Long-Term Maintenance
5. Healthy Eating With Variety and Balance
6. Handling Holidays, Vacations, and Special Events
7. More Volume, Fewer Calories (Adding Water Vegetables and Fiber)
8. Dietary Fats
9. Stress and Time Management
10. Healthy Cooking: Tips for Food Preparation and Recipe Modification
11. Physical Activity Barriers
12. Preventing Relapse
13. Heart Health
14. Life With Type 2 Diabetes
15. Looking Back and Looking Forward

CDC-approved curriculum can be found at *http://www.cdc.gov/diabetes/prevention/pdf/curriculum_toc.pdf.*

We propose that the MDPP expanded model will use the CDC-approved curriculum. We also propose that beneficiaries who meet the coverage criteria that we propose below would be able to enroll in the MDPP only once; however, we propose that those beneficiaries who complete the 12 month program and achieve and maintain a required minimum level of weight loss would be eligible for additional monthly maintenance sessions for as long as the weight loss is maintained. We propose that these ongoing maintenance sessions adhere to the same curriculum requirements as the core maintenance sessions. We propose to require that each MDPP session be at least an hour in duration.

We propose to describe the services that would be covered under the Medicare Diabetes Prevention Program expanded model at § 410.79. Consistent with our statutory authority, we will continue to test and evaluate the nationwide MDPP as finalized. In the

future, we will assess whether the nationwide implementation of the MDPP is continuing to reduce Medicare spending without reducing quality of care or improve the quality of patient care without increasing spending, and could modify the nationwide MDPP as appropriate. We seek comment on this proposal.

• *Enrollment of New Medicare Suppliers:*

MDPP Supplier Enrollment Requirements: As of 2015, more than 800 organizations have preliminary or full recognition from the CDC Diabetes Prevention Recognition Program (DPRP) to provide DPP services. These organizations have served more than 40,000 participants. More than 60 health plans provide some coverage of DPP services.

We propose that any organization recognized by the CDC (that is, those with preliminary or full recognition) to provide DPP services would be eligible to apply for enrollment in Medicare as a supplier beginning on or after January 1, 2017. This proposal would promote timely enrollment of CDC-recognized organizations before billing begins, and would permit full implementation of the MDPP expansion by January 1, 2018. We propose that MDPP suppliers would be subject to the enrollment regulations set forth in 42 CFR part 424, subpart P. Organizations seeking to enroll in Medicare specifically to become MDPP Suppliers would be subject to screening under § 424.518. We are considering what level of application screening is most appropriate, and we are currently proposing that potential MDPP Suppliers be screened according to the high categorical risk category defined in § 424.518(c) because we acknowledge that MDPP may bring organization types that are entirely new to Medicare. We also believe that MDPP suppliers have some similarities to home health agencies because non-medical personnel may deliver MDPP services in a non-clinical setting, such as at Y–USA. We seek comments on this approach.

As suppliers, enrolled MDPP organizations would be obligated to comply with all statutes and regulations that establish generally applicable requirements for Medicare suppliers. For example, there are regulations that specify time limits for filing claims (§ 424.44), requirements to report and return overpayments (§ 401.305), and procedures for suspending, offsetting or recouping Medicare payments in certain situations (§ 405.371).

We propose that before enrolling in Medicare, DPP organizations must have either preliminary or full CDC recognition status. Organizations that apply for CDC recognition can attain preliminary CDC recognition within 1 year of applying, and full upon demonstrating program effectiveness within 24–36 months of applying. We propose that if an organization loses its CDC recognition status at any point, or withdraws from the CDC recognition program at any point, or fails to move from preliminary to full recognition within 36 months of applying for CDC recognition, the organization would be subject to revocation of its Medicare billing privileges for MDPP services as provided by 42 CFR part 424, subpart P. Under the CDC standards for recognition, an organization that loses its CDC recognition (and thus, under our proposal, would no longer be able to bill Medicare for MDPP services) must wait 12 months before reapplying for recognition. We propose that DPP organizations would be eligible to re-enroll in Medicare as an MDPP supplier if, after reapplying for CDC recognition, the organization again achieves preliminary recognition. CDC's standards for recognition as a DPP organization can be found at *http://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf*.

We propose to permit CDC-recognized organizations who are not already enrolled in Medicare (on the basis of being an existing Medicare provider or supplier) to apply to enroll any time on or after January 1, 2017. Existing Medicare providers and suppliers that wish to bill for MDPP services would have to inform us of that intention and satisfy all other requirements, but would not need to enroll a second time. These existing Medicare providers and suppliers would be eligible to bill for MDPP services furnished on or after January 1, 2018. We also considered an alternative approach where existing Medicare providers and suppliers would have to submit a separate enrollment application (including any applicable enrollment application fee) and be separately screened to be eligible to bill for MDPP services. We seek comments on our approach.

Requirements for MDPP Coaches: We propose to require personnel who would deliver MDPP services, referred to hereafter as ''coaches'', to obtain a National Provider Identifier (NPI) to help ensure the coaches meet CMS program integrity standards. We are also considering requiring that coaches enroll in the Medicare program in addition to obtaining an NPI, and we seek comment on this approach. An alternative policy we considered was to require DPP organizations to collect and submit to Medicare information on the coaches who would deliver MDPP services, which could include identifying information such as first and last name and social security number. However, we determined that doing so would require CMS implement a new process, rather than leveraging an existing process, and increase CMS use of social security numbers as a primary identifier. In addition, by requiring coaches to obtain NPIs, we align with current process for provider enrollment and program integrity efforts. We propose to require MDPP suppliers to submit the active and valid NPIs of all coaches who would furnish MDPP services on behalf of the MDPP supplier as an employee or contractor. If MDPP suppliers fail to provide active and valid NPIs of their coaches, or if the coaches fail to obtain or lose their active and valid NPIs, the MDPP supplier may be subject to compliance action or revocation of MDPP supplier status.

Revocation of MDPP billing privileges: We propose that all MDPP suppliers would be required to comply with the requirements of 42 CFR part 424. If an MDPP supplier has its Medicare enrollment revoked or deactivated for reasons independent of DPRP recognition, that supplier would lose its ability to bill Medicare for MDPP services but would not automatically lose its DPRP recognition from the CDC. We propose that existing Medicare providers and suppliers who lose CDC recognition would lose their Medicare billing privileges with respect to MDPP services, but may continue to bill for other non-MDPP Medicare services for which they are eligible to bill. We propose that MDPP Suppliers that have their Medicare billing privileges revoked or that lose billing privileges for MDPP may appeal these decisions in accordance with the procedures specified in 42 CFR part 405, subpart H, 42 CFR part 424, and 42 CFR part 498. We propose to add a new § 424.59 to our regulations to specify the suppliers who would be eligible for Medicare enrollment and billing for MDPP services. We seek comment on this proposal.

• *Expected MDPP Reimbursement:*

Expected MDPP Reimbursement Structure: We plan to reimburse for MDPP services at the times and in the amounts set forth in the Table 35, with payment tied to number of sessions attended and achievement of a minimum weight loss of 5 percent of baseline weight (body weight recorded during the beneficiary's first core session). MDPP suppliers would be required to attest to beneficiary session attendance and weight loss at the time claims are submitted to Medicare for payment. Each beneficiary's attendance

must be documented through paper or electronic means and that each beneficiary's weight must be measured and recorded every MDPP session the beneficiary attends. MDPP suppliers would be required to securely maintain beneficiary attendance records and measured weights and make them available to CMS or its designee for audit at any time.

TABLE 35—DPP PAYMENT MODEL

	Payment per beneficiary (non-cumulative)
Core Sessions	
1 session attended	$25
4 sessions attended	50
9 sessions attended	100
Achievement of minimum weight loss of 5% from baseline weight	160
Achievement of advanced weight loss of 9% from baseline weight	*25
Maximum Total for Core sessions	360
Maintenance Sessions (Maximum of 6 monthly sessions over 6 months in Year 1)	
3 Maintenance sessions attended (with maintenance of minimum requiredweight loss from baseline)	45
6 Maintenance sessions attended (with maintenance of minimum required weight loss from baseline)	45
Maximum Total for Maintenance sessions	90
Maximum Total for first year	450
Maintenance Sessions After Year 1 (Minimum of 3 sessions attended per quarter/no maximum)	
3 Maintenance sessions attended plus maintenance of minimum required weight loss from baseline	45
6 Maintenance sessions attended plus maintenance of minimum required weight loss from baseline	45
9 Maintenance sessions attended plus maintenance of minimum required weight loss from baseline	45
12 Maintenance sessions attended plus maintenance of minimum required weight loss from baseline	45
Maximum Total After First Year	180

*In addition to $160 above.

Submission of Claims for MDPP Services: As Table 35 illustrates, proposed payments would be heavily weighted toward achievement of weight loss over the first 6 months, and no payments would be available after the first 6 months without achievement of the minimum weight loss. In the proposed payment structure, claims for payment would be submitted following the achievement of core session attendance, minimum weight loss, maintenance session attendance, and maintenance of minimum weight loss. For example, MDPP suppliers would not be able to submit another claim after session one until the beneficiary has completed four sessions, and maintenance sessions would not qualify for payment unless minimum weight loss is achieved and maintained. Similar value-based payments are being offered by commercial insurers and accepted by DPP organizations. We seek comment on this payment structure. We seek comment on whether to update payment rates annually through an existing fee schedule, such as the PFS, or establish a new fee schedule for MDPP suppliers.

• *IT infrastructure and capabilities:* We propose that in order to receive payment, MDPP suppliers would be required to submit claims to Medicare using standard claims forms and procedures. Claims would be submitted in batches that contain beneficiary Protected Health Information (PHI) and Personally Identifiable Information (PII), including the Health Insurance Claim Number (HICN). Most Medicare claims are submitted electronically except in limited situations. We provide a free software package called PC–ACE Pro32 that creates a patient database and allows organizations to electronically submit claims to Medicare Part A and B. We understand there are several other electronic claims submissions software packages available in the market for purchase. We encourage current and prospective DPP organizations to investigate adopting these systems to enhance the efficiency of claims submission, and we seek comment on the capacity of DPP organizations to integrate these systems into their workflows. If this provision is finalized, we would provide technical assistance to MDPP suppliers to comply with the Medicare claims submission standards. We seek comment from current and prospective DPP organizations on their ability to transmit claims to Medicare in a timely and secure manner.

We propose to require MDPP suppliers to maintain a crosswalk between the beneficiary identifiers they submit to CMS for billing purposes and the beneficiary identifiers they provide CDC for the beneficiary level-clinical data. We propose that MDPP suppliers provide this crosswalk to the CMS evaluator on a regular basis. We seek comment on this approach.

We plan to propose to require MDPP suppliers to maintain records that document the MDPP services provided to beneficiaries. We propose that these records must contain detailed documentation of the services provided, including but not limited to the beneficiary's eligibility status, sessions attended, the coach furnishing the session attended, the date and place of service of sessions attended, and weight. MDPP suppliers would be required to maintain these records within a larger medical record, or within a medical record that an MDPP supplier

establishes for the purposes of administering MDPP. Consistent with the requirement in § 424.516(f) we propose that these records be retained for 7 years from the date of service and that MDPP suppliers would provide CMS or a Medicare contractor access to these records upon request. We propose to require MDPP suppliers to accurately track payments and resolve any discrepancies between claims and the beneficiary record within their medical record. We also propose that MDPP suppliers would be required to maintain and handle any beneficiary PII and PHI in compliance with HIPAA, other applicable privacy laws and CMS standards. If this provision is finalized, we intend to provide education and technical assistance to DPP organizations to mitigate the risk of data discrepancies and audits. We seek comment on our approach. We would address specific recordkeeping requirements and standards in future rulemaking.

• *MDPP Eligible beneficiaries:* We propose that coverage of MDPP services would be available for beneficiaries who meet the following criteria: (1) Are enrolled in Medicare Part B; (2) 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 and a BMI of at least 23 if self-identified as Asian. The CDC standards have defined a lower BMI for Asian individuals based on data that show Asians develop abnormal glucose levels at a lower BMI; (3) 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, or a fasting plasma glucose of 110–125 mg/dL, or a 2-hour post-glucose challenge of of 140–199 mg/dL (oral glucose tolerance test). We use this definition of prediabetes instead of the definition in § 410.18 because the 2016 American Diabetes Association Standards of Care includes the use of a hemoglobin A1c test to diagnose prediabetes and the CMS actuarial certification uses the World Health Organization definition of prediabetes as a fasting plasma glucose of 110–125 mg/dL; (4) have no previous diagnosis of Type 1 or Type 2 diabetes. A beneficiary with previous diagnosis of gestational diabetes is eligible for MDPP; and (5) does not have end-stage renal disease (ESRD).

The National DPP currently allows community-referral such as by Y–USA and self-referral of patients, in addition to referral by physicians and other health care practitioners, if the patient presents DPP-qualifying blood test results that the DPP organization keeps on record. We propose to similarly permit beneficiaries who meet the proposed criteria above to obtain MDPP services by self-referral, community-referral, or health care practitioner-referral.

We propose to establish the beneficiary eligibility criteria at § 410.79. We seek comment on this proposal.

• *Program integrity:* We propose all DPP organizations that are eligible and wish to bill Medicare would enroll as MDPP suppliers, and thus would be required to comply with applicable Medicare supplier enrollment, program integrity, and payment rules. We recognize the potential for fraud and abuse by filing inaccurate claims and/or duplicative claims on beneficiaries' sessions attended or weight loss achieved. We also recognize beneficiaries may move between MDPP suppliers, and we intend to address in future rulemaking requirements to prevent duplication of a beneficiary's claims for the same services by more than one MDPP supplier. We are also concerned about the potential for beneficiary inducement or coercion and the potential program risks posed by permitting a new type of organization to receive payment from CMS for providing MDPP services. We intend to develop policies, and will propose them in future rulemaking, to mitigate these risks, and monitor the MDPP expansion to ensure MDPP suppliers meet all applicable CMS program integrity and supplier enrollment standards. We intend to develop system checks to identify where CMS may need to audit an MDPP supplier's medical records. We are considering ways CMS could cross reference the data DPP organizations are currently required to report to the CDC to identify potential discrepancies with data submitted to us. We seek comment on such approaches. Finally, MDPP suppliers would be subject to audits and reviews performed by CMS program integrity and/or review or audit contractors in addition to program-specific audits. We seek comment on these approaches and others to mitigate these risks and strategies to ensure program integrity.

• *Site of service:* Currently, CDC-recognized DPP organizations deliver DPP services in-person or virtually via a telecommunications system or other remote technology. The majority of current DPP organizations provide DPP services in-person, but an emerging body of literature supports the effectiveness of virtual sessions delivered remotely. We propose to allow MDPP suppliers to provide MDPP services via remote technologies. As part of our evaluation of the MDPP expansion, to the extent feasible, we will evaluate the effectiveness of MDPP services, particularly in relation to virtual versus in-person services, and, using the evaluation data, may modify or terminate this component of the expansion as appropriate. To permit such evaluation, we are considering specifying the nature of the virtual service and the site of the service in codes included on claims submitted for payment, as well as collecting information on the nature of the virtual service and the site of service at the beneficiary level from MDPP suppliers. We seek comment on this approach. Under this last example, MDPP suppliers would be expected to maintain this information as part of the beneficiary level cross walk discussed under the IT Infrastructure and Capabilities section of this proposed rule.

We plan to monitor administrative claims for virtual services to identify any unusual and/or adverse utilization of the DPP benefit. We seek comment on specific monitoring activities or program integrity safeguards with respect to virtual services, in addition to the time period in which such enhanced monitoring activities should occur.

We note that MDPP services provided via a telecommunications system or other remote technology will not be part of the current Medicare telehealth benefits and have no impact on how telehealth services are defined by Medicare. We recognize that the provision of MDPP services by such virtual methods may introduce additional risks for fraud and abuse, and if this proposal is finalized, we would propose specific policies in future rulemaking to mitigate these risks. We thus seek comment on whether there are quality or program integrity concerns regarding the use of virtual sessions, or whether they offer comparable or higher quality MDPP services when compared to in-person services. We seek comment on strategies to strengthen program integrity and minimize the potential for fraud and abuse in virtual sessions.

• *Learning activities:* The CDC provides technical assistance to DPP organizations recognized by the DPRP to improve performance. We intend to coordinate with CDC to supplement this technical assistance with education, training and technical assistance on data security, claims submission and medical record keeping. We seek comment on what additional technical assistance would be needed by providers and other organizations in order to expand the MDPP model.

• *Quality monitoring and reporting:* We seek comment on the quality metrics

that should be reported by MDPP suppliers in addition to the reporting elements required on Medicare claims submissions outlined above (attendance and weight loss) or by the CDC recognition program. We seek comment specifically on what quality metrics should be considered for public reporting (not for payment) to guide beneficiary choice of MDPP suppliers.

• *Timing of the MDPP expansion:* Expanding the MDPP model will be a technically and logistically complex undertaking. One option may be to expand the MDPP nationally in its first year of implementation. Another option is a ''phase-in'' approach, where the MDPP is expanded initially for a period of time in certain geographic markets or regions, or is furnished by a subpopulation of MDPP suppliers, with the goal of addressing technical issues prior to broader expansion. We seek comment on expanding DPP nationally, and specifically on what factors we should consider in the selection of initial MDPP suppliers.

K. 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 providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce the rate of growth in health care costs. 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 Shared Savings Program: Accountable Care Organizations Final Rule (76 FR 67802) (November 2011 final rule)). A subsequent major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Shared Savings Program; Accountable Care Organizations Final Rule (80 FR 32692) (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) (June 2016 final rule)). As noted below, we have also made use of the annual PFS rules to address quality reporting and certain other issues.

Additionally, on April 27, 2016, the Department of Health and Human Services (HHS) issued a proposed rule to implement key provisions of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and establish a new Quality Payment Program (QPP) (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 (81 FR 28162) (QPP proposed rule)). The QPP proposed rule would establish a new program under which Medicare would reward physicians for providing high-quality care, instead of paying them only for the number of tests or procedures provided. The QPP proposed rule addresses issues related to APMs, such as the Medicare Shared Savings Program, and issues related to reporting for purposes of MIPS by eligible clinicians (ECs) that are participating in APMs.

Our intent in this proposed rule is to propose further refinements to the Shared Savings Program rules, and we have identified several policies that we propose to update or revise. First, we discuss and propose policies related to ACO quality reporting including proposing changes to the quality measures used to assess ACO quality performance, changes in the methodology used in our quality validation audits and the way in which the results of these audits may affect an ACO's sharing rate, various issues related to alignment with policies proposed in the QPP proposed rule, and revisions related to the terminology used in quality assessment such as ''quality performance standard'' and ''minimum attainment level.'' We are also proposing conforming changes to our regulatory text. Next, we address several issues unrelated to quality reporting and assessment. Specifically, we propose to implement a process by which beneficiaries may voluntarily align with an ACO by designating an ACO professional as responsible for their overall care. We also propose to introduce beneficiary protections related to use of the SNF 3-Day Waiver. Finally, we are proposing to make technical changes to certain rules related to merged and acquired TINs and the minimum savings rate (MSR) and minimum loss rate (MLR) that would be used during financial reconciliation for ACOs that fall below 5,000 assigned beneficiaries.

1. ACO Quality Reporting

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 requires the Secretary to establish quality performance standards to assess the quality of care furnished by ACOs, and to seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for the purposes of assessing the quality of care. Additionally, section 1899(b)(3)(D) of the Act gives the Secretary authority to incorporate reporting requirements and incentive payments related to the PQRS, EHR Incentive Program and other similar initiatives under section 1848 of the Act. Finally, section 1899(d)(1)(A) of the Act states that an ACO is eligible to receive payment for shared savings, if they are generated, only after meeting the quality performance standards established by the Secretary.

In the November 2011 final rule and recent CY PFS final rules with comment period (77 FR 69301 through 69304; 78 FR 74757 through 74764; 79 FR 67907 through 67931; and 80 FR 71263 through 712710), we have established the quality performance standard that ACOs must meet to be eligible to share in savings that are generated. For example, in the CY 2015 PFS final rule with comment period, we made a number of updates to the quality requirements within the program, such as updates to the quality measure set, the addition of a quality improvement reward, and the establishment of benchmarks for 2 years. We made further updates to the quality measure set, established policies to address outdated measures, and made conforming changes to align with PQRS in the CY 2016 PFS final rule with comment period. Through these previous rulemakings, we have worked to improve the alignment of quality performance measures, submission methods, and incentives under the Shared Savings Program and PQRS. Currently, eligible professionals billing through the TIN of an ACO participant may avoid the downward PQRS

payment adjustment when the ACO satisfactorily reports the ACO GPRO measures on their behalf using the CMS web interface.

We are proposing several changes and other revisions to our policies related to the quality measures and quality performance standard in this rule, including the following:

- Changes to the measure set used in establishing the quality performance standard;
- Changes to the methodology used to validate quality data submitted by the ACO along with penalties that may apply if the audit match rate is less than 90 percent;
- Revisions to the use of the terms ''quality performance standard'' and ''minimum attainment level'' in the regulation text;
- Revisions related to use of flat percentages to establish quality benchmarks; and
- Alignment with policies proposed in the QPP proposed rule.

a. Changes to the Quality Measure Set Used in Establishing the Quality Performance Standard

(1) Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both. In the November 2011 final rule, we established a quality performance standard consisting of 33 measures across four domains, including patient experience of care, care coordination/patient safety, preventive health, and at-risk population. In subsequent PFS final rules with comment period, we made a number of updates to the set of measures that make up the quality performance standard. For example, in the CY 2015 PFS final rule with comment period, we added new measures that ACOs must report, retired measures that no longer aligned with updated clinical guidelines, reduced the sample size for measures reported through the CMS web interface, established a schedule for the phase in of new quality measures, and established an additional reward for quality improvement. The revisions to the measures set made in the CY 2016 PFS final rule with comment period, resulted in a net increase in the quality measure set from 33 measure to 34 measures.

Quality measures are submitted by the ACO through the CMS web interface, calculated by CMS from administrative and claims data, and collected via a patient experience of care survey based on the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG–CAHPS) survey. The CAHPS for ACOs patient experience of care survey used for the Shared Savings Program includes the core CG–CAHPS modules, as well as some additional modules. The measures collected through the CMS web interface are also used to determine whether eligible professionals participating in an ACO avoid the PQRS and automatic Physician Value Modifier (VM) payment adjustments for 2015 and subsequent years. Currently, eligible professionals billing through the TIN of an ACO participant may avoid the downward PQRS payment adjustment when the ACO satisfactorily reports all of the ACO GPRO measures on their behalf using the CMS web interface. Beginning with the 2017 VM, ACO performance on the CMS web interface measures and all cause readmission measure will be used in calculating the quality component of the VM for groups and solo practitioners participating within an ACO (79 FR 67941 through 67947).

As we previously stated (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality health care at the individual and population levels with a focus on outcomes. We believe endorsed measures have been tested, validated, and clinically accepted, and therefore, when selecting the original 33 measures, we had a preference for NQF-endorsed measures. However, the statute does not limit us to using endorsed measures in the Shared Savings Program. As a result, we have also exercised our discretion to include certain measures that we believe to be high impact but that are not currently endorsed, including for example, ACO#11, which is currently titled Percent of PCPs Who Successfully Meet Meaningful Use Requirements.

In selecting the original measure set, we balanced a wide variety of important considerations. Our measure selection emphasized prevention and management of chronic diseases that have a high impact on Medicare FFS beneficiaries, such as heart disease, diabetes mellitus, and chronic obstructive pulmonary disease. We believed that the quality measures used in the Shared Savings Program should be tested, evidence-based, target conditions of high cost and high prevalence in the Medicare FFS population, reflect priorities of the National Quality Strategy, address the continuum of care to reflect the requirement that ACOs accept accountability for their patient populations, and align with existing quality programs and value-based purchasing initiatives.

In the CY 2015 PFS final rule with comment period we finalized a number of changes to the quality measures used in establishing the quality performance standard to better align with PQRS, retire measures that no longer align with updated clinical practice, and add new outcome measures that support the CMS Quality Strategy and National Quality Strategy goals. In the CY 2016 PFS final rule with comment period, in modifying the measures set we sought to include both process and outcome measures, including patient experience of care (80 FR 71263 through 71268). We believe it is important to retain a combination of both process and outcomes measures because ACOs are charged with improving and coordinating care and delivering high quality care, but also need time to form, acquire infrastructure and develop clinical care processes. However, as other CMS quality reporting programs, such as PQRS, move to more outcomes-based measures and fewer process measures over time, we have indicated that we might also revise the quality performance standard for the Shared Savings Program to incorporate more outcomes-based measures and fewer process measures over time.

We are also continuing to work with the measures community to ensure that the specifications for the measures used under the Shared Savings Program are up-to-date and reduce reporting burden. We believe that it is important to balance the timing of the release of specifications so they are as up-to-date as possible, while also giving ACOs sufficient time to review specifications. Our intention is to issue the specifications annually, prior to the start of the reporting period for which they will apply.

The Core Quality Measures Collaborative was formed in 2014, as a collaboration between CMS, providers, and other stakeholders, with the goal of aligning quality measures for reporting across public and private stakeholders in order to reduce provider reporting burden. On February 16, 2016, the Core Quality Measures Collaborative recommended a core quality measure set that aligns and simplifies quality reporting across multiple payers (*https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-02-16.html*) and made specific recommendations for ACOs (*https://*

www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/ACO-and-PCMH-Primary-Care-Measures.pdf). We proposed to integrate several recommendations made by the Core Quality Measures Collaborative into the CMS web interface as part of the QPP proposed rule (81 FR 28399). Groups that are eligible to report using the CMS web interface for purposes of reporting quality measures to CMS for various quality reporting initiatives such as PQRS, the Shared Savings Program are required to report on all measures included in the CMS web interface. In addition, in the QPP proposed rule, we proposed that groups would also be required to report on all CMS web interface measures.

(2) Proposals

In efforts to continue to align with other CMS initiatives and reduce provider confusion and the burden of reporting, we propose modifications to the quality measure set that an ACO is required to report. Specifically, to align the Shared Savings Program quality measure set with the measures recommended by the Core Quality Measures Collaborative and proposed for reporting through the CMS web interface under the QPP proposed rule, we propose to add, and in some cases to replace, existing quality measures with the following:

• *ACO–12 Medication Reconciliation Post-Discharge (NQF #0097).* This measure addresses adverse drug events (ADEs) through medication reconciliation, which is an important aspect of care coordination. According to HHS' Agency for Healthcare Research and Quality (AHRQ), ADEs account for nearly 700,000 emergency department visits and 100,000 hospitalizations each year.[12] The ACO–12 Medication Reconciliation measure was previously in the Shared Savings Program measure set, however, it was replaced with ACO–39, Documentation of Current Medications in the Medical Record (79 FR 67912 through 67914). The Core Quality Measures Collaborative, in coordination with providers and stakeholders, determined the original Medication Reconciliation measure would be more appropriate for alignment across quality reporting initiatives. Based on this recommendation, we have proposed to require reporting of the measure through the CMS web interface in the QPP proposed rule (81 FR 28403). In an effort to align with the QPP proposals, we therefore propose to replace the Documentation of Current Medications in the Medical Record measure (ACO–39) by reintroducing Medication Reconciliation (ACO–12) in the Care Coordination/Patient Safety domain. We note that in accordance with our policy for newly introduced measures, this measure would phase into pay for performance after two years as pay for reporting, unless the measure has been finalized only as pay for reporting. We propose to phase the measure into pay for performance in accordance with the schedule outlined in Table 36 which is consistent with the original phase in schedule for the measure under the 2011 final rule.

• *ACO–44 Use of Imaging Studies for Low Back Pain (NQF #0052).* Imaging utilization is an important area for quality measurement, because of the wide use of imaging services. This measure reports the percentage of patients with a primary diagnosis of low back pain that did not have an imaging study (for example, MRI, CT scan) within 28 days of the diagnosis. (A higher score indicates higher performance). The Use of Imaging Studies for Low Back Pain quality measure is specified for patients 18–50 years of age. This age range could result in smaller case sizes for some ACOs; however, it addresses the appropriate use of imaging for low back pain, which is a condition that affects a high volume of adults in the United States. We propose adding this measure in the Care Coordination/Patient Safety domain to address a gap in measures related to resource utilization and align with the ACO measures recommended by the Core Quality Measures Collaborative core measure set (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/ACO-and-PCMH-Primary-Care-Measures.pdf*). We note the measure is also proposed in the QPP proposed rule for measuring the quality of care furnished by individual and specialty ECs (81 FR 28399 and 28460 Tables A and E). If finalized, the measure would not be reported through the CMS web interface. Instead, it would be calculated using Medicare claims data without any additional provider reporting requirement. We note that in accordance with our policy for newly introduced measures, this measure would be designated as pay for reporting in 2017 and 2018, and then phase into pay for performance. We propose to phase the measure into pay for performance in accordance with the schedule outlined in Table 36. Specifically, following the initial 2 years of pay for reporting, we propose to phase in the measure to pay for performance starting with PY2 of an ACO's first agreement period. We believe this is reasonable because there is no reporting burden on the part of the ACO and because many stakeholders have some familiarity with similar claims-based outcomes measures. However, given the possible small case sizes due to the measure specifications, we seek comment on if this measure should be phased in to pay for performance or whether it should remain pay for reporting for all three performance years.

By aligning the Shared Savings Program measures with the Core Quality Measures Collaborative recommendations and proposals under the QPP proposed rule, we hope to reduce the burden of provider data collection and reporting of measures that do not align across public and private quality reporting initiatives. Therefore, we propose to retire or replace the following measures in order to reduce provider reporting burden by reducing the number of measures that must be reported and because these measures do not align with the core measure set recommendations from the Core Quality Measures Collaborative and the measures that we proposed for reporting through the CMS web interface in the QPP proposed rule:

• ACO–39 Documentation of Current Medications in the Medical Record.

• ACO–21 Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented.

• ACO–31 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).

• ACO–33 Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy—for patients with CAD and Diabetes or Left Ventricular Systolic Dysfunction (LVEF <40%).

In addition to our proposals above to modify the quality measure set to align with the Core Quality Measures Collaborative and the proposed modifications to the measures reported through the CMS web interface under the QPP proposed rule, we propose a few additional modifications as follows:

First, we propose to retire the two AHRQ Ambulatory Sensitive Conditions Admission measures (ACO–9 and ACO–10). Although ACO–9 and ACO–10 address admissions for patients with heart failure, chronic obstructive pulmonary disease (COPD), and asthma, we introduced two all-cause, unplanned admission measures for heart failure

[12] ''Medication Errors.'' AHRQ. *https://psnet.ahrq.gov/primers/primer/23/medication-errors.*

and multiple chronic conditions (ACO–37 and ACO–38, respectively) in the 2015 PFS final rule (79 FR 67911–67912). We believe ACO–37 and ACO–38 report on a similar population with similar conditions as ACO–9 and ACO–10. Therefore, in order to continue our efforts to reduce redundancies within the Shared Savings Program measure set, we propose to remove ACO–9 and ACO–10 from the measure set.

Second, while we are proposing above to remove ACO–9 and ACO–10, we continue to believe AHRQ's Prevention Quality Indicator (PQI) measures are important because they report on inpatient hospital admissions of patients with clinical conditions that could potentially be prevented with high-quality outpatient care. Coordination of patient care and patient access to primary care services can often prevent complications or hospital admissions. AHRQ's PQI #91 *Ambulatory Sensitive Condition Acute Composite* is a composite measure, currently used in the Physician Value-Based Payment Modifier, which includes PQIs reporting on admissions related to dehydration, bacterial pneumonia, and urinary tract infections (PQIs #10, 11, and 12). Dehydration, bacterial pneumonia, and urinary tract infection admissions may occur as a result of inadequate access to ambulatory care or poorly coordinated ambulatory care. As a result, we propose adding *ACO–43 Ambulatory Sensitive Condition Acute Composite (AHRQ PQI #91)* to the Care Coordination/Patient Safety domain. The measure will be risk-adjusted for demographic variables and comorbidities. In accordance with our policy for newly introduced measures, we propose that this measure be pay for reporting for two years, and then phase into pay for performance in accordance with the schedule outlined in Table 36.

Table 36 lists the Shared Savings Program quality measure set and summarizes our proposed measure changes, which will be used to assess quality performance starting with the 2017 performance year. We note that, consistent with our rules at § 425.502(a)(4), all newly introduced measures are set at the level of complete and accurate reporting for the first two reporting periods for which reporting of the measures is required. Therefore, the proposed new measures discussed above, including the Medication Reconciliation measure, would be pay for reporting for the 2017 and 2018 performance years. Beginning in the 2019 performance year, these quality measures will be assessed according to the phase-in schedule noted in Table 36.

As a result of these proposed measure changes, each of the four domains will include the following number of quality measures (See Table 37 for details.):

- Patient/Caregiver Experience of Care—8 measures
- Care Coordination/Patient Safety—10 measures
- Preventive Health—8 measures
- At Risk Population—5 measures (3 individual measures and a 2-component diabetes composite measure)

Table 37 provides a summary of the number of measures by domain and the total points and domain weights that would be used for scoring purposes with the proposed changes to the quality measures.

TABLE 36—MEASURES FOR USE IN THE ESTABLISHING QUALITY PERFORMANCE STANDARD THAT ACOS MUST MEET FOR SHARED SAVINGS

Domain	ACO measure #	Measure title	New measure	NQF #/measure steward	Method of data submission	Pay for performance phase in R—reporting P—performance		
						PY1	PY2	PY3
AIM: Better Care for Individuals								
Patient/Caregiver Experience ..	ACO–1	CAHPS: Getting Timely Care, Appointments, and Information.	.....	N#0005 AHRQ	Survey	R	P	P
	ACO–2	CAHPS: How Well Your Providers Communicate.[13]	.....	NQF #0005 AHRQ.	Survey	R	P	P
	ACO–3	CAHPS: Patients' Rating of Provider.[2]	.....	NQF #0005 AHRQ.	Survey	R	P	P
	ACO–4	CAHPS: Access to Specialists	.....	NQF #N/A CMS/AHRQ.	Survey	R	P	P
	ACO–5	CAHPS: Health Promotion and Education.	.....	NQF #N/A CMS/AHRQ.	Survey	R	P	P
	ACO–6	CAHPS: Shared Decision Making.	.....	NQF #N/A CMS/AHRQ.	Survey	R	P	P
	ACO–7	CAHPS: Health Status/Functional Status.	.....	NQF #N/A CMS/AHRQ.	Survey	R	R	R
	ACO–34	CAHPS: Stewardship of Patient Resources.	.....	NQF #N/A CMS/AHRQ.	Survey	R	P	P
Care Coordination/Patient Safety.	ACO–8	Risk-Standardized, All Condition Readmission.	.....	Adapted NQF #1789 CMS.	Claims	R	R	P
	ACO–35	Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM).	.....	Adapted NQF #2510 CMS.	Claims	R	R	P
	ACO–36	All-Cause Unplanned Admissions for Patients with Diabetes.	.....	NQF #TBD CMS.	Claims	R	R	P
	ACO–37	All-Cause Unplanned Admissions for Patients with Heart Failure.	.....	NQF #TBD CMS.	Claims	R	R	P
	ACO–38	All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions.	.....	NQF #TBD CMS.	Claims	R	R	P

TABLE 36—MEASURES FOR USE IN THE ESTABLISHING QUALITY PERFORMANCE STANDARD THAT ACOS MUST MEET FOR SHARED SAVINGS—Continued

Domain	ACO measure #	Measure title	New measure	NQF #/measure steward	Method of data submission	Pay for performance phase in R—reporting P—performance		
						PY1	PY2	PY3
	ACO–43	Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91).	X	AHRQ	Claims	R	P	P
	ACO–11	Use of certified EHR technology.	X	NQF #N/A CMS.	As proposed in the QPP proposed rule.	R	P	P
	ACO–12	Medication Reconciliation Post-Discharge.	X	NQF #0097 CMS.	CMS Web Interface.	R	P	P
	ACO–13	Falls: Screening for Future Fall Risk.		NQF #0101 NCQA.	CMS Web Interface.	R	P	P
	ACO–44	Use of Imaging Studies for Low Back Pain.	X	NQF #0052 NCQA.	Claims	R	P	P
AIM: Better Health for Populations								
Preventive Health	ACO–14	Preventive Care and Screening: Influenza Immunization.		NQF #0041 AMA–PCPI.	CMS Web Interface.	R	P	P
	ACO–15	Pneumonia Vaccination Status for Older Adults.		NQF #0043 NCQA.	CMS Web Interface.	R	P	P
	ACO–16	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow Up.		NQF #0421 CMS.	CMS Web Interface.	R	P	P
	ACO–17	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.		NQF #0028 AMA–PCPI.	CMS Web Interface.	R	P	P
	ACO–18	Preventive Care and Screening: Screening for Clinical Depression and Follow-up Plan.		NQF #0418 CMS.	CMS Web Interface.	R	P	P
	ACO–19	Colorectal Cancer Screening		NQF #0034 NCQA.	CMS Web Interface.	R	R	P
	ACO–20	Breast Cancer Screening		NQF #2372 NCQA.	CMS Web Interface.	R	R	P
	ACO–42	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease.		NQF #N/A CMS.	CMS Web Interface.	R	R	R
Clinical Care for At Risk Population—Depression.	ACO–40	Depression Remission at Twelve Months.		NQF #0710 MNCM.	CMS Web Interface.	R	R	R
Clinical Care for At Risk Population—Diabetes.	ACO–27	Diabetes Composite (All or Nothing Scoring): ACO–27: Diabetes Mellitus: Hemoglobin A1c Poor Control.		NQF #0059 NCQA (individual component).	CMS Web Interface.	R	P	P
	ACO–41	ACO–41: Diabetes: Eye Exam		NQF #0055 NCQA (individual component).	CMS Web Interface.	R	P	P
Clinical Care for At Risk Population—Hypertension.	ACO–28	Hypertension (HTN): Controlling High Blood Pressure.		NQF #0018 NCQA.	CMS Web Interface.	R	P	P
Clinical Care for At Risk Population—Ischemic Vascular Disease.	ACO–30	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.		NQF #0068 NCQA.	CMS Web Interface.	R	P	P

TABLE 37—NUMBER OF MEASURES AND TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD

Domain	Number of individual measures	Total measures for scoring purposes	Total possible points	Domain weight (percent)
Patient/Caregiver Experience	8	8 individual survey module measures	16	25
Care Coordination/Patient Safety	10	10 measures, including double-scored EHR measure.	22	25
Preventive Health	8	8 measures	16	25

[13] The quality measure title has been updated to ''Providers'' and is not only referencing ''Doctors.''

TABLE 37—NUMBER OF MEASURES AND TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD—Continued

Domain	Number of individual measures	Total measures for scoring purposes	Total possible points	Domain weight (percent)
At-Risk Population	5	3 individual measures, plus a 2-component diabetes composite measure that is scored as one measure.	8	25
Total in all Domains	31	30	62	100

b. Improving the Process Used To Validate ACO Quality Data Reporting

(1) Background

In the November 2011 final rule, we finalized a proposal to retain the right to validate the data ACOs enter into the Web Interface (76 FR 67893 through 67894). This validation process, referred to as the Quality Measures Validation audit, was based on the process used in Phase I of the Physician Group Practice (PGP) demonstration. The policy was finalized at § 425.500(e). In this audit process, CMS selects a subset of Web Interface measures, and selects a random sample of 30 confirmed and completely reported beneficiaries for each measure in the subset. The ACO provides medical records to support the data reported in the Web Interface for those beneficiaries. A measure-specific audit performance rate is then calculated using a multi-phased audit process:

- *Phase 1:* Eight randomly selected medical records for each audited measure are reviewed to determine if the medical record documentation supports what was reported (that is, a match). If all records reviewed support what was reported, the audit ends. If any records do not support what was reported (that is, a mismatch), the audit process continues in a second phase for any measure with a mismatch identified.
- *Phase 2:* The remaining 22 medical records are reviewed for any measure that had a mismatch identified in Phase 1. If less than 90 percent of the medical records provided for a measure support what was reported, the audit process continues to Phase 3.
- *Phase 3:* For each measure with a match rate less than 90 percent, CMS provides education to the ACO about how to correct reporting and the ACO is given an opportunity to resubmit the measure(s) in question.

If at the conclusion of the third phase there is a discrepancy greater than 10 percent between the quality data reported and the medical records provided during the audit, the ACO will not be given credit for meeting the quality target for any measure(s) for which the mismatch rate exists.

Since publication of the initial program rules in 2011, we have gained experience in conducting audits and believe that certain modifications to our rules should be made in order to increase the statistical rigor of the audit methodology, streamline audit operations, and more closely align the Quality Measures Validation audit used in Shared Savings Program audits with other CMS quality program audits including those performed in the Physician Quality Reporting Program and the Hospital Inpatient and Outpatient Quality Reporting programs. Below, we propose four improvements to the previously described process. The proposed changes address 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.

(2) Proposals

First, we propose to increase the number of records audited per measure to achieve a high level of confidence that the true audit match rate is within 5 percentage points of the calculated result. The November 2011 final rule indicated that CMS would review as few as 8 records (Phase 1 only) or as many as 30 records (Phase 1 and 2) per audited measure. With this phased methodology, the total number of records reviewed for each ACO varies (range of 40 to 150 records per audited ACO during the Performance Year 2014 audit). A sample size analysis found that the number of reviewed records needs to increase in order to provide the desired high level of confidence that the audited sample is representative of the ACO's quality reporting performance. We note that the precise number of records requested for review would vary, depending on the desired confidence level, the number of measures audited, and the expected match rate. Therefore, we are not proposing a specific number of records that would be requested for purposes of ACO quality validation audits in the future. However, based on an analysis using the poorest expected match rate, the highest degree of confidence and an estimated number of measures to be audited, we do not anticipate more than 50 records will be requested per audited measure.

Second, we propose to modify our regulations in order to conduct the quality validation audit in a single step rather than the current multi-phased process described at § 425.500(e)(2). We propose to use a more streamlined approach in which all records selected for audit are reviewed in a single step and some activities currently conducted in phase 3 would be removed from the audit process entirely while others would instead be addressed at the conclusion of the audit. During the proposed single step, we would review all submitted medical records and calculate the match rate. The education we currently provide to ACOs and the opportunity for ACOs to explain the mismatches that occur in Phase 3 of the current process would continue, but would occur at the conclusion of the audit. Under this proposal, there would not be an the opportunity for ACOs to correct and resubmit data for any measure with a >10 percent mismatch because we have learned through our experience with program operations that resubmission of CMS Web Interface measure data after the close of the CMS Web Interface is not feasible. Instead, we propose that an ACO's quality score would be affected by an audit failure as described below, without requiring re-opening of the CMS Web Interface. This single step process would allow us to maintain the desired level of confidence that the true audit match rate is within 5 percentage points of the calculated result and to complete the audit in a more timely manner. Therefore, we propose to remove the provision at § 425.500(e)(2) that requires 3 phases of medical record review. In so doing, we propose to redesignate § 425.500(e)(3) as § 425.500(e)(2).

Third, we propose to revise § 425.500(e)(3) in order to provide for an

assessment of the ACO's overall audit match rate across all measures, instead of assessing the ACO's audit mismatch rate at the measure level. Specifically, we propose to calculate an overall audit match rate which would be derived by dividing the total number of audited records that match the information reported in the Web Interface by the total number of records audited. This is a change from the current audit performance calculation methodology, which calculates a measure specific mismatch rate. We believe that making this change is necessary to minimize the number of records that must be requested in order to achieve the desired level of statistical certainty as described in our first proposal in this section. Our analysis suggests that we would have to request a much larger number of records (approximately 200 per measure) from the ACO during a quality validation audit of individual measures to achieve a 90 percent confidence interval for each measure. In addition, combining all records to calculate an overall audit match rate is less subject to variability based on the specific subset of measures chosen for audit each year and better aligns with the methodology used by other CMS quality program audits.

Fourth, we propose to revise the redesignated provision at § 425.500(e)(2), to indicate that if an ACO fails the audit (that is, has an overall audit match rate of less than 90 percent), the ACO's overall quality score would be adjusted proportional to its audit performance. Currently, our regulation at § 425.500(e)(3) states that if, at the conclusion of the audit process there is a discrepancy greater than 10 percent between the quality data reported and the medical records provided, the ACO will not be given credit for meeting the quality target for any measures for which this mismatch rate exists. In light of our proposed modifications to the quality validation audit process above in which we propose to assess and validate the ACO's performance overall rather than the ACO's performance on each measure, we believe a modification to this requirement is necessary to reflect an overall adjustment. Therefore, we propose to modify the provision at newly redesignated § 425.500(e)(2) to state that if an ACO fails the audit (that is, has an audit match rate of less than 90 percent), the ACO's overall quality score will be adjusted proportional to the ACO's audit performance. The audit-adjusted quality score will be calculated by multiplying the ACO's overall quality score by the ACO's 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 is 60 percent. The audit-adjusted quality score would be the quality score that is 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.

Finally, we propose to add a new requirement at § 425.500(e)(3) that in addition to the adjustment in the ACO's overall quality score, any 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 CMS approval. In the CAP, the ACO may be required to explain the cause of its audit performance and how it plans to improve the accuracy of its quality reporting in the future. In addition, CMS maintains 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.

We invite comment on the proposed improvements to the process used to validate ACO quality data reporting.

c. Technical Changes Related to Quality Reporting Requirements

The Shared Savings Program quality reporting rules were originally established through rulemaking in the November 2011 final rule. In this section, we make several proposals regarding the quality performance standard that an ACO must meet to be eligible to share in savings. Part of the determination of whether an ACO has met the quality reporting standard in each year is dependent on the ACO meeting the minimum attainment level for certain measures. We discuss how the ''minimum attainment'' requirement has been implemented to date and propose a modification that we believe is more consistent with our policies for assessing an ACO's performance over time. Finally, we propose to move references to compliance actions from § 425.502(d)(2)(ii) to a more appropriate provision at § 425.316(c).

First, we propose to make technical revisions to ensure stakeholder understanding of the definition of the quality performance standard. The quality performance standard is established under Subpart F for each performance year (§ 425.502(a)). For the first performance year of an ACO's first agreement period, the quality performance standard is defined as complete and accurate reporting of all quality measures. For each subsequent performance year, quality measures phase in to pay for performance, and although the ACO must continue to report all measures completely and accurately, the ACO will also be assessed on performance based on the quality performance benchmark and minimum attainment level of certain measures that are designated as pay for performance. The quality performance standard that applies to an ACO's final year in its first agreement period also applies to each year of an ACO's subsequent agreement period (§ 425.502(a)(3)) (79 FR 67925 through 67926). ACOs must meet or exceed the minimum quality performance standard in a given performance year to be eligible to receive payments for shared savings (§ 425.100(b)). Conversely, failure to meet the quality performance standard in a given performance year makes ACOs ineligible to share in savings, even if generated, and such ACOs may be subject to compliance actions.

Our intent in the November 2011 final rule was to establish a single quality performance standard that would apply for each performance year in which an ACO participates in the program. Because the quality performance standard changes, depending on the performance year, the ACO may be subject to multiple quality performance standards over the course of its 3-year agreement period. We recognize that some of the language used in subsequent revisions to our regulations may have generated some confusion related to this issue. For example, as explained above, the quality performance standard refers to the overall standard the ACO must meet, however, in § 425.502(a)(4), we state that the quality performance standard for a newly introduced measure is set at the level of complete and accurate reporting for the first two reporting periods for which reporting of the measure is required. We wish to clarify that while there are certain standards that must be met for each measure or in each domain, there is one overall quality performance standard that must be met in each performance year by an ACO. We propose to make conforming changes to the regulations text to remove references to the quality performance standard in contexts where it does not appear to apply to the overall quality performance standard (see § 425.316(c)(2), § 425.502(a)(4), and § 425.502(d)(1)). We do not believe that modifications necessarily must be made to the regulations text in all instances where there is a reference to multiple quality performance standards, however, because we recognize that the quality performance standard varies

depending on the performance year in question as indicated at § 425.502(a)(1)–(3) or, for example, where we refer to ACOs having to meet quality performance standards to be eligible to share in savings (§ 425.100(b)). Therefore, we propose to retain certain references to multiple quality performance standards, such as the one found in § 425.100(b), because we believe the use of the plural is appropriate in certain contexts.

Second, we wish to address the concept of the minimum attainment level and its use in determining whether an ACO has met the quality performance standard. As noted above, beginning in the second year of an ACO's first agreement period, the quality performance standard is met by complete and accurate reporting on all measures, but also includes meeting the minimum attainment level on ''certain'' measures. As provided at § 425.502(b)(1), we designate a performance benchmark and minimum attainment level for each measure. Pursuant to § 425.502(b)(3), the minimum attainment level is set at 30 percent or the 30th percentile of the performance benchmark. In § 425.502(c)(1) through (c)(2), we state that performance below the minimum attainment level for a measure will receive zero points for that measure and performance equal to or greater than the minimum attainment level for a measure will receive points on a sliding scale based on the level of performance. Finally, § 425.502(d) outlines quality performance requirements for the four domains, stating that the ACO must report all measures in a domain and must score above the minimum attainment level determined by CMS on 70 percent of the measures in each domain. If the ACO fails to achieve the minimum attainment level on at least 70 percent of the measures in a domain, CMS will take compliance action. Additionally, the ACO must achieve the minimum attainment level for at least one measure in each of the four domains to be eligible to share in savings. In guidance, we have interpreted the quality performance requirements for domains to apply only to pay for performance measures because minimum attainment applies only to ''certain'' measures according to the definition of the quality performance standard in § 425.502(a)(3), and we have interpreted the reference to ''certain'' measures in § 425.502(a)(2) to mean pay for performance measures. As a result of this interpretation, we believe an inconsistency in the application of the policy goals outlined in our November 2011 final rule has arisen. In particular, we believe certain current policies are inconsistent with our goal of holding ACOs to higher quality reporting standards over time. Specifically, because measures are phased-in from pay for reporting to pay for performance over the course of an ACO's first 3-year agreement period, there are no pay for performance measures during PY1 and fewer pay for performance measures in each domain in PY2 compared to PY3. Thus, under our current interpretation of the rules, it is not possible to take compliance actions against an ACO in its first performance year for failure to achieve the minimum attainment level on at least 70 percent of the measures in a domain because there are no pay for performance measures on which to assess performance on a domain. Additionally, because there are fewer pay for performance measures in PY2 than in PY3, it is more likely that a compliance action would be taken against an ACO due to failure to meet the minimum attainment level on 70 percent of the pay for performance measures in a domain in PY2 than in PY3. Since publication of the November 2011 final rule, we have used the annual PFS rule to update the measures that ACOs are required to report. Each time a new measure is added, the measure is designated as pay for reporting for the first 2 years it is in use so that we can establish a performance benchmark prior to using it as a pay for performance measure. This, in turn, diminishes even further the number of pay for performance measures available in a domain in PY2 and PY3 or in an ACO's second or subsequent agreement period, making it more likely that ACOs would be subject to compliance action. Based on this experience, we believe it would be more consistent with our policy goals to take all measures into account when determining whether a compliance action should be taken against an ACO based on its quality performance in one or more domains.

Therefore, we propose to take all measures into account when determining ACO performance at the domain level for purposes of compliance actions. Additionally, we believe that compliance actions should be addressed at § 425.316 rather than in the quality reporting section, and therefore, we propose to move the provisions governing the specific performance levels at which a compliance action would be triggered from § 425.502 to § 425.316. Specifically, we propose the following modifications to our regulations:

- Revise introductory text at § 425.502(a) to make it clear that the quality performance standard is the overall standard the ACO must meet to qualify to share in savings.
- Replace the word ''certain'' in § 425.502(a)(2) and (3) with ''all,'' so that the term ''minimum attainment level'' clearly applies to both pay for reporting and pay for performance measures.
- At § 425.502(a)(4), make modifications to remove the reference to the quality performance standard each time it appears to avoid causing confusion between the standards for individual measures and the overall quality performance standard.
- At § 425.502(b)(3), define ''minimum attainment level'' for both pay for reporting and pay for performance measures. We propose to set the minimum attainment level for pay for performance measures at the 30th percent or 30th percentile of the quality benchmark. We propose to set the minimum attainment level for pay for reporting measures at the level of complete and accurate reporting.
- At § 425.502(c)(2), we propose to revise the regulation text to specify that only pay for performance measures are assessed on a sliding scale.
- At § 425.502(c)(5), we propose to add a provision to specify that pay for reporting measures earn the maximum number of points for a measure when the minimum attainment level is met.
- Finally, we propose to modify § 425.502(d) to refer generally to compliance actions that may be taken for low quality performance. We propose to address specific levels of quality domain performance at which compliance action would be triggered by modifying § 425.316(c)(1).

d. Technical Change to Application of Flat Percentages for Quality Benchmarks

In the CY 2014 PFS final rule with comment period (78 FR 74761–74763), we finalized a methodology to spread clustered measures when setting quality benchmarks to promote a clinically meaningful assessment of ACO quality. Specifically, we finalized a policy that CMS would set quality benchmarks using flat percentages for a clustered measure when the national FFS data results in the 60th percentile for the measure are equal to or greater than 80.00 percent. We noted that the methodology would not apply to measures whose performance rates are calculated as ratios, for example, measures such as the two ACO Ambulatory Sensitive Conditions Admissions and the All Condition Readmission measures. Similarly, in the CY 2015 PFS final rule with comment period (79 FR 67925), we finalized a

policy to address ''topped out'' measures by also setting benchmarks using flat percentages when the 90th percentile is equal to or greater than 95 percent. Although similar to the ''cluster'' policy finalized in the CY 2014 PFS final rule with comment period, we included measures whose performance rates are calculated as ratios. We believed this policy was appropriate because measures calculated and reported as ratios may become topped out and expressed our desire to treat all topped out measures consistently.

Since the CY 2015 PFS final rule with comment period, we have determined that converting measures calculated and reported as ratios into benchmarks expressed as percentiles and percentages creates confusion in the interpretation of quality results and may yield results that are contrary to the intended purpose of using flat percentages. As a result, we propose no longer applying the flat percentage policy to performance measures calculated as ratios, such as the Ambulatory Sensitive Conditions Admissions measures and the All-Cause Readmission measure. In addition, we propose two technical changes to address typographical errors in § 425.502(a)(1), which contains a duplicative reference to CMS, and in § 425.502(b)(2)(ii), which contains an extra ''t'' at the end of ''percent.''

e. Incorporation of Other Reporting Requirements Related to the PQRS

The Affordable Care Act gives the Secretary authority to incorporate reporting requirements and incentive payments from certain Medicare programs into the Shared Savings Program, and to use alternative criteria to determine if payments are warranted. Specifically, section 1899(b)(3)(D) of the Act affords the Secretary discretion to incorporate reporting requirements and incentive payments related to the physician quality reporting initiative (PQRI), under section 1848 of the Act, including such requirements and such payments related to electronic prescribing, electronic health records, and other similar initiatives under section 1848, and permits the Secretary to use alternative criteria than would otherwise apply (under section 1848 of the Act) for determining whether to make such payments. Under this authority, in the November 2011 final rule, we incorporated certain reporting requirements and payment rules related to the PQRS into the Shared Savings Program at § 425.504 for ''eligible professionals'' (EPs) who bill under the TIN of an ACO participant within an ACO. Thus, the Shared Savings Program rules provide that EPs who bill under the TIN of an ACO participant within an ACO may only participate under their ACO participant TIN as a group practice under PQRS under the Shared Savings Program for purposes of qualifying for a PQRS incentive (prior to 2015) or avoiding the payment adjustment (starting in 2015). In other words, the current regulations prohibit ACO participant TINs and the EPs billing through those TINs from participating in PQRS outside of the Shared Savings Program such that these entities may not independently report for purposes of PQRS apart from the ACO.

An ACO, reporting on behalf of its EPs for purposes of PQRS, is required to satisfactorily submit through the CMS web interface all of the ACO GPRO measures that are part of the Shared Savings Program quality performance standard. Under § 425.504(c), for 2016 and subsequent years, if an ACO fails to satisfactorily report all of the ACO GPRO measures through the CMS web interface each EP who bills under the TIN of an ACO participant within the ACO will receive a downward adjustment, as described in § 414.90(e) for that year. The current regulations do not provide any mechanism for these EPs to report separately or otherwise avoid the downward payment adjustment if the ACO fails to satisfactorily report on their behalf.

We stated in the November 2011 final rule that there were two main reasons for not allowing EPs who bill under the TIN of an ACO participant to report outside of their ACO for purposes of PQRS: (1) The Shared Savings Program is concerned with measuring the quality of care furnished by the ACO to its patient population as a whole, and not that of individual ACO providers/suppliers, and (2) allowing EPs that bill under the TIN of an ACO participant to earn more than one PQRS incentive goes against the rules of traditional PQRS (76 FR 67901 through 67902).

Since publication of the November 2011 final rule, we have gained experience with these policies and program operations and believe it is necessary to propose a change in policy in order to be able to accept and use data that is separately reported outside the ACO by EPs billing through the TIN of an ACO participant within an ACO for purposes of PQRS under limited circumstances for the final two years of PQRS before it sunsets and is replaced by the Quality Payment Program (QPP). We continue to believe that in most cases it is appropriate to assess EPs that bill through the TIN of an ACO participant under the PQRS as a group practice because as noted in the November 2011 final rule, the Shared Savings Program is concerned with measuring the quality of care furnished to an assigned population of FFS beneficiaries by the ACO, as a whole, and not that of individual ACO providers/suppliers. We believe this framework promotes clinical integration among the ACO providers/suppliers, which is an important aspect of the Shared Savings Program. In addition, it is consistent with the requirement under § 425.108(d) that each ACO provider/supplier must demonstrate a meaningful commitment to the mission of the ACO to ensure its likely success. Because an ACO cannot be successful in the Shared Savings Program without satisfying the quality reporting requirements, we believe a meaningful commitment by ACO providers/suppliers to the mission of the ACO includes assisting with and engaging in annual quality reporting through the ACO. Further, ACO reporting reduces burden for those in small or solo practices, and places a focus on population health by encouraging care coordination by ACO providers/suppliers to improve the health of the broader patient population for which they are responsible. Finally, we believe that such group reporting is consistent with group reporting under various other CMS initiatives and therefore, we do not intend to remove the requirement that ACOs report on behalf of the EPs who bill under the TIN of an ACO participant. As a corollary, we would continue to use ACO data preferentially for purposes of assessing or determining an EP's quality performance for purposes of programs such as PQRS or, by extension, the VM.

However, we believe that when an ACO does not satisfactorily report for purposes of PQRS, it may be appropriate to accept and use data that is reported outside the ACO. For PQRS to be able to accept and use data reported outside the ACO, however, we must modify the provision at § 425.504 prohibiting EPs that bill under the TIN of an ACO participant in an ACO to report separately for purposes of PQRS. We are therefore proposing to modify § 425.504 to lift the prohibition on separate reporting for purposes of the 2017 and 2018 PQRS payment adjustment. We believe this change to our program rules is necessary for several reasons.

First, we believe it is necessary to protect EPs that participate in ACOs that fail to satisfactorily report all of the ACO GPRO measures. Although 98 percent of ACOs successfully complete required quality reporting annually, there have been a few instances where

an ACO has failed to report all of the required measures, for example, where an ACO has terminated its participation in the Shared Savings Program and did not quality report on behalf of the EPs that bill under the TIN of an ACO participant at the end of the performance year as required under our close-out procedures. In other instances, some ACOs continued to participate in the Shared Savings Program but failed to complete quality reporting in a timely manner. In these instances, the lack of complete quality reporting by the ACO translated into a failure for the EPs within the ACO to receive a PQRS incentive (or to avoid the PQRS downward adjustment) for that year.

Second, PQRS has transitioned away from providing incentive payments to applying only downward payment adjustments to payments under the Medicare Physician Fee Schedule, making it even more important for EPs to ensure they comply with the reporting requirements for PQRS. Under the current rules, EPs who bill under the TIN of an ACO participant within an ACO must ultimately rely on the ACO to report on their behalf. These EPs are only able to encourage and facilitate ACO reporting, but lack the ability to ensure that the ACO satisfactorily reports in order to prevent application of the payment adjustment. The proposed change to allow EPs to report separately would provide them a mechanism over which they have direct control to ensure satisfactory reporting occurs. Additionally, we note that because there are no more payment incentives under the PQRS, there is no longer any concern that an EP may inadvertently receive duplicative PQRS incentive payments from CMS. Specific issues and policies related to data reported by EPs apart from an ACO for purposes of avoiding the PQRS payment adjustment for payment years 2017 and 2018 are addressed in section III.H. of this proposed rule.

Third, under the VM, if the ACO satisfactorily reports quality data on their behalf, groups and solo practitioners that bill under the TIN of an ACO participant will be evaluated under the quality tiering methodology and could qualify for an upward payment adjustment if the ACO satisfactorily reports on their behalf. However, if the ACO does not satisfactorily report quality data as required under § 425.504 then groups and solo practitioners that bill under the TIN of an ACO participant fall into Category 2 for the VM and are subject to a downward payment adjustment. In section III.G. of this proposed rule, we make proposals for how quality data reported by EPs billing under the TINs of ACO participants that is reported apart from the ACO for purposes of avoiding the VM downward payment adjustment for 2017 and 2018.

For the reasons noted above, we believe it is appropriate to retain the provisions under § 425.504 that require the ACO to report all of the ACO GPRO measures to satisfactorily report on behalf of the EPs who bill under the TIN of an ACO participant for purposes of the PQRS payment adjustment, however, we are proposing to modify the provisions that prohibit EPs that bill under the TIN of an ACO participant to report apart from the ACO. Specifically, we propose to add a redesignated and revised paragraph at § 425.504(d) to address the requirement that the ACO report on behalf of the eligible professionals who bill under the TIN of an ACO participant for purposes of the of the 2017 and 2018 PQRS payment adjustment. Under this revised provision the prohibition on separate quality reporting for purposes of the PQRS payment for 2017 and 2018 would be removed. We also propose to make a technical change to § 425.504 to move existing § 425.504(d) to § 425.504(c)(5) because the intent of this provision was to parallel the language of § 425.504(b)(6) for purposes of the payment adjustment for 2016 and subsequent years. We reiterate our intent that data reported by an ACO would continue to be preferentially used for purposes of other CMS initiatives that rely on such data, including the PQRS and the VM, as discussed in sections III.I. and III.M., respectively. If an EP who bills under the TIN of an ACO participant chooses to report apart from the ACO, the EP's data may be used for purposes of PQRS and VM only when complete ACO reported data is not available.

Additionally, we note that under the Shared Savings Program, only the quality data reported by the ACO as required under § 425.500 would be used to assess the ACO's performance under the Shared Savings Program. In other words, quality data submitted separately from the ACO will not be considered under the Shared Savings Program. We request comments on this proposal.

f. Alignment With the Quality Payment Program (QPP)

1. Background and Introduction to the Quality Payment Program

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015), amended title XVIII of the Act to repeal the Medicare sustainable growth rate (SGR) and strengthen Medicare access by improving physician payments and making other improvements, to reauthorize the Children's Health Insurance Program, and for other purposes. The statute established the Merit-Based Incentive Payment System (MIPS), a new program for certain Medicare-participating practitioners. MIPS consolidates components of three existing programs, the PQRS, the Physician Value Modifier (VM), and the Medicare Electronic Health Record (EHR) Incentive Program for EPs. The statute also established incentives for participation in certain alternative payment models (APMs). On April 27, 2016, the Department of Health and Human Services (HHS) issued a proposed rule to implement key provisions of the MACRA and establish a new Quality Payment Program (QPP) (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 (81 FR 28162 through 28586) (the QPP proposed rule)). The QPP proposed rule proposes to implement a Quality Payment Program (QPP) that replaces a patchwork system of Medicare reporting programs with a flexible system that allows practitioners to choose from two paths that link quality to payments: the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs). As proposed, MIPS and the APM incentive will impact practitioner payments beginning in payment year 2019 based on 2017 reporting. MIPS is a new program that combines parts of the Physician Quality Reporting System (PQRS), Value Modifier (VM) and Medicare Electronic Health Record (EHR) Incentive Program into a single program in which eligible clinicians (ECs) will be measured over 4 categories which include quality, resource use, clinical practice improvement, and advancing care information. The QPP proposed rule specifically addresses ECs that participate in APMs and Advanced APMs, such as the Shared Savings Program. Specifically, for ECs participating in APMs, the QPP proposed rule proposes to:

- Establish criteria for reporting under each of the 4 categories. For example, the QPP proposed rule proposes for the quality performance category to use quality information submitted by the ACO through the CMS web interface to assess each EC billing under the TIN of an ACO participant. For assessing performance in the

category of advancing care information for ECs billing under the TIN of an ACO participant, the QPP proposed rule proposes to aggregate EC-reported data to calculate an ACO score which is applied to each participating EC.

• Define an Advanced APM as one that meets several criteria including requiring participants to use certified EHR technology (CEHRT). As proposed under the QPP proposed rule, only Tracks 2 and 3 of the Shared Savings Program have the potential to meet all criteria necessary for designation as an Advanced APM. As proposed, in order to meet the CEHRT requirement, the Medicare Shared Savings Program must hold ACOs accountable for their participating eligible clinicians' use of CEHRT by applying a penalty or reward based on the degree of use of CEHRT (such as the percentage of EPs that are using CEHRT or the care coordination or other activities they perform using CEHRT).

We therefore reviewed the Shared Savings Program rules and identified several modifications to program rules that we believe must be proposed in order to support and align with this effort. These proposed modifications are discussed in more detail below and include:

• Revisions to §§ 425.504 and 425.506 to sunset Shared Savings Program alignment with PQRS and the EHR Incentive Program starting with quality reporting period 2017 (corresponding to payment year 2019).

• Addition of new paragraph § 425.506(e) and section § 425.508 to align with the proposed Quality Payment Program, including rules addressing annual assessment of an ACO ECs' use of CEHRT and for ACO reporting of certain quality measures to satisfy the quality performance category on behalf of the eligible clinicians who bill under the TIN of an ACO participant.

• Modifications to the EHR measure title and specifications necessary to align with the proposed QPP criteria for determining Advanced APM status, including scoring requirements for the limited circumstances when the measure is designated as pay for reporting.

2. Proposals Related to Sunsetting PQRS and EHR Incentive Program Alignment and Alignment With APM Reporting Requirements Under the Quality Payment Program

The Shared Savings Program has established rules at §§ 425.504 and 425.506 incorporating reporting requirements related to PQRS and the EHR Incentive Program. The current provision at § 425.504(c), addresses the PQRS payment adjustment for 2016 and subsequent years. Under the existing Shared Savings Program rules, which we propose to modify as discussed in the immediately preceding section, EPs who bill under the TIN of an ACO participant within an ACO may only participate under their ACO participant TIN as a group practice under the PQRS Group Practice Reporting Option for purposes of the PQRS payment adjustment under the Shared Savings Program. ACOs must submit all of the ACO GPRO measures to satisfactorily report on behalf of their eligible professionals for purposes of the PQRS payment adjustment. Under the current rules, if an ACO does not satisfactorily report, each EP participating in the ACO receives a payment adjustment under PQRS. As discussed in this rule, we have proposed to revise the rules to allow EPs who bill under the TIN of an ACO participant within an ACO to report separately from their ACO for purposes of the PQRS payment adjustment for 2017 and 2018.

At § 425.506, we address alignment with the EHR Incentive Program. Specifically, at § 425.506(a), we assert that ACOs, ACO participants, and ACO providers/suppliers are encouraged to develop a robust EHR infrastructure, which aligns with our eligibility criteria under § 425.112 that require ACOs to define care coordination processes, which may include the use of enabling technologies such as CEHRT. At § 425.506(b) and (c) we state that the quality measure regarding EHR adoption is measured based on a sliding scale and that it is weighted twice that of any other measure for scoring purposes and determining compliance with quality performance requirements for domains. To align with the EHR incentive program we state in § 425.506(d), that EPs participating in an ACO under the Shared Savings Program satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program when the EP extracts data necessary for the ACO to satisfy the quality reporting requirements under the Shared Savings Program from CEHRT and when the ACO reports the ACO GPRO measures through a CMS web interface. EPs are responsible for meeting the rest of the EHR incentive program requirements apart from the ACO.

As noted in this section of the proposed rule, the VM, PQRS and the EHR incentive programs are sunsetting and the last quality reporting period under these programs is proposed to be 2016, which would impact payments in 2018. Quality reporting under the QPP, as proposed, would begin in 2017 for payment year 2019. In order to align with the policies proposed in the QPP proposed rule, we propose to amend §§ 425.504 and 425.506 to indicate that these reporting requirements apply to ACOs and their EPs through the 2016 performance year. Specifically, at § 425.504(c) we propose to remove the phrase ''for 2016 and subsequent performance years'' each time it appears and add in its place the phrase ''for 2016.'' As noted in section III.H. of this rule, we propose a technical change to redesignate paragraph (d) as paragraph (c)(5) and then to add new paragraph (d) to address PQRS alignment rules for the 2017 and 2018 PQRS payment adjustment. Similarly, at § 425.506, we propose to revise paragraph (d) to indicate that the last reporting year for the EHR Incentive program is 2016. As stated in this section of the proposed rule, the PQRS and EHR incentive programs are sunsetting and we have proposed that the Quality Payment Program will begin with the 2017 reporting year, and payment adjustments will take effect in 2019 for eligible clinicians.

In addition, we propose to require ACOs, on behalf of the ECs who bill under the TIN of an ACO participant, to report quality measures through the CMS web interface in order to satisfy the QPP quality performance category. Currently, ACOs are required under § 425.504 to report measures on behalf of the EPs who bill under the TIN of an ACO participant for purposes of PQRS. Under the QPP proposed rule, the quality data submitted to the CMS web interface by ACOs would satisfy the quality performance category for ECs participating in the ACO. Therefore, in order to align with the QPP proposals, we propose to add a new paragraph at § 425.508(a) that parallels the current requirement at § 425.504 for reporting on behalf of EPs who bill under the TIN of an ACO participant for purposes of PQRS. Specifically, we propose to require that ACOs, on behalf of ECs who bill under the TIN of an ACO participant, must submit all the ACO CMS web interface measures required by the Shared Savings Program using a CMS web interface, to meet reporting requirements for the quality performance category under MIPS. We also propose to maintain flexibility for EPs to report quality performance category data separately from the ACO, and therefore, do not propose to include a provision that would restrict an EP from reporting outside the ACO. The intent is to permit flexibility in reporting quality data. Under the Shared

Savings Program, however, no quality data reported apart from the ACO will be considered for purposes of assessing the quality performance of the ACO. We note that the QPP proposed rule does not address what, if any, separately reported EC quality performance category data might be considered, however, we believe it is important to retain flexibility in the event we finalize a policy under the QPP that would permit consideration of quality performance category data that is submitted separately by ECs participating in ACOs.

3. Proposals Related to Alignment With the Quality Payment Program (QPP)

In the QPP proposed rule (81 FR 28296) we outlined and defined the proposed criteria for Advanced APMs, APMs through which ECs would have the opportunity to become Qualified Participants as specified in section 1833(z)(3)(C) and (D) of the Act. First, under MACRA, for an APM to be considered an Advanced APM, it must meet three requirements: (1) Require participants to use certified EHR technology; (2) provide payment for covered professional services based on quality measures comparable to those used in the quality performance category of MIPS; and (3) be either a Medical home Model expanded under section 1115A(c) of the Act or bear more than an nominal amount of risk for monetary losses. In the QPP proposed rule, we proposed criteria for each of these requirements (81 FR 28296). As proposed under the QPP proposed rule, significant distinctions between the design of different tracks or options within an APM mean that certain tracks or options could meet the proposed Advanced APM criteria while other tracks or options may not. Because of this, only Tracks 2 and 3 of the Shared Savings Program would have the potential to meet all criteria necessary for designation as an Advanced APM. Under the approach discussed in the QPP proposed rule, while all ACOs would meet the criterion for provider payment based on quality measures comparable to those used in the quality performance category of MIPS, only Tracks 2 and 3 would appear to the meet the proposed financial risk standard to bear more than a nominal amount of risk for monetary losses.

For purposes of meeting the CEHRT requirement, we proposed in the QPP proposed rule to adopt for Advanced APMs the definition of CEHRT that is proposed for MIPS and the APM incentive under § 414.1305 (see 81 FR 28299 for more detailed information). We also noted in the QPP proposed rule that the statute does not specify the number of ECs who must use CEHRT or how CEHRT must be used in an Advanced APM. For this reason, we stated we believed it was reasonable to use discretion when proposing details on how APMs might meet criteria. In the QPP proposed rule, we proposed that an Advanced APM must require at least 50 percent of ECs who are enrolled in Medicare (or each hospital if hospitals are the APM participants) to use the certified health IT functions outlined in the proposed definition of CEHRT to document and communicate clinical care with patients and other health care professionals. However, we stated we believed it was appropriate to propose an alternative criterion for CEHRT use for the Shared Savings Program because, although the Shared Savings Program requires ACOs to encourage and promote the use of enabling technologies (such as EHRs) to coordinate care for assigned beneficiaries, the Shared Savings Program does not require a specific level of CEHRT use for participation in the program. Instead, the Shared Savings Program, as noted above, includes an assessment of EHR use as part of the quality performance standard which directly impacts the amount of shared savings/shared losses generated by the ACO. We therefore proposed an alternative criterion available only to the Shared Savings Program. Specifically, we proposed that the alternative criterion would allow the Shared Savings Program to satisfy the EHR criterion if it holds APM Entities accountable for their ECs' use of CEHRT by applying a financial penalty or reward based on the degree of CEHRT use (such as the percentage of ECs that use CEHRT or the engagement in care coordination or other activities using CEHRT). We noted that the current EHR quality measure at ACO #11, as noted above, assesses the degree to which certain ECs in the ACO successfully meet the requirements of the EHR Incentive Program, which requires the use of CEHRT by certain ECs in the ACO, and we stated that ''[s]uccessful reporting of the measure for a performance year gives the ACO points toward its overall quality score, which in turn affects the amount of shared savings or shared losses an ACO could earn or be liable for, respectively.'' (81 FR 28300). Finally, we stated that we believed the alternative criterion meets the statutory requirement because the ''proposed alternative criterion builds on established Shared Savings Program rules and incentives that directly tie the level of CEHRT use to the ACO's financial reward which in turn has the effect of directly incentivizing ever-increasing levels of CEHRT use among EPs.''

In light of these QPP proposals, we are proposing several modifications to our program rules in order to align with the QPP proposals.

First, we propose to modify the title and specifications of the EHR quality measure (ACO #11). This measure is currently titled Percent of PCPs Who Successfully Meet Meaningful Use Requirements. Under the current Shared Savings Program rules, ACOs must report on and are held accountable for certain measures that make up the quality reporting standard. One of these measures, ACO #11, assesses the degree of CEHRT use by primary care physicians participating in the ACO and performance on this measure is weighted twice that of any other measure for scoring purposes. To calculate this measure, CMS collects information submitted by PCPs through the EHR Incentive Program and determines the rate of CEHRT use by PCPs participating in the ACO. Specifically, as explained in our guidance [*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/2015-ACO11-Percent-PCP-Successfully-Meeting-Meaningful-Use-Requirement.pdf*], the denominator is based on all PCPs who are participating in the ACO in the reporting year under the Shared Savings Program and the numerator for the measure is based on the PCPs included in the denominator who successfully qualify to participate in either the Medicare or Medicaid EHR Incentive Program in the year indicated. Results of this measure are used in determining the ACO's overall quality score which in turn determines the ACO's final sharing/loss rate and the amount of shared savings earned (or shared losses owed) by the ACO.

Additionally, under the proposed policies included in the QPP proposed rule, ECs participating in an ACO would satisfy the Advancing Care Information category by reporting meaningful use of EHRs apart from the ACO (81 FR 28247, Table 15). Similar to the process currently used under the Shared Savings Program to determine what practitioners have met criteria for meaningful use for the ACO #11 measure, we anticipate accessing EC-reported data under the Advancing Clinical Information category to assess the ACO's overall use of CEHRT. Because the current measure only assesses the degree of use of CEHRT by primary care physicians participating in the ACO, we propose to modify the EHR

measure to align with the QPP proposals. Specifically, we propose to change the specifications of the EHR measure to assess the ACO on the degree of CEHRT use by all providers and suppliers designated as ECs under the QPP proposed rule that are participating in the ACOs rather than narrowly focusing on the degree of use of CEHRT of only the primary care physicians participating in the ACO. We believe this modification to the specifications for ACO #11 would better align with the QPP proposals and ensure a subset of ACOs in the Shared Savings Program could qualify to be Advanced APM entities. We would also modify the title of the measure to remove the reference to PCPs. We believe the modification in the specifications of ACO #11 will be extensive and will require ECs to gain familiarity with the reporting requirements under the QPP proposed rule. We therefore propose that this measure would be considered a newly introduced measure and set at the level of complete and accurate reporting for the first two reporting period for which reporting of the measures is required according to our rules at § 425.502(a)(4). Therefore, the measure would be pay for reporting for the 2017 and 2018 performance years. We further propose to define requirements specific to this measure for the limited circumstances in which it is designated as pay for reporting. Specifically, we propose to include the requirement at § 425.506(e)(1) that during years in which ACO #11 is designated as a pay for reporting measure, in order for us to determine that the ACO has met requirements for complete and accurate reporting, at least one EC as we have proposed to define the term in the Proposed QPP rule, participating in the ACO must meet the reporting requirements under the Advancing Clinical Information category under the QPP, as proposed under the QPP proposed rule. We believe this proposal would safeguard the ability of Tracks 2 and 3 to fully meet all criteria for designation as Advanced APMs as proposed in the QPP proposed rule by ensuring the letter and spirit of the statutory criteria are met, even in the limited circumstances when ACO #11 is designated as pay for reporting under the Shared Savings Program. Beginning in the 2019 performance year, ACO #11 would be assessed according to the phase-in schedule noted in Table 36 which remains consistent with the current phase-in schedule under which the measure will be phased in to pay for performance starting with PY2 of an ACO's first agreement period and for all performance years of any subsequent agreement periods, assuming no major changes to the measure that would cause us to consider the measure to be a newly introduced measure and revert it to pay for reporting. We therefore further propose to add § 425.506(e)(2) reiterating our current requirement at § 425.506(b) that during pay for performance years, assessment of EHR adoption is measured based on a sliding scale. We do not intend that our proposal to use this measure to assess the degree of CEHRT use by ECs participating in the ACO for purposes of meeting the CERHT criterion for Advanced APMs under the QPP to change the way we treat the measure under pay for performance now. Similar to the current method used by the Shared Savings Program to calculate the EHR measure, the data will continue to be derived using EC reported EHR data that is required and collected by MIPS as proposed in the QPP proposed rule. Additionally, the measure will remain double weighted. We propose to retain the existing EHR measure requirements at § 425.506(a)–(c) and to modify § 425.506(d) to sunset the current EHR reporting requirement as noted in the prior section.

Finally, consistent with our statements in the QPP proposed rule as noted above, we do not believe that any additional modifications or exceptions to current program rules (other than the ones proposed here, specifically, that the measure specifications and title of ACO #11 be modified to include all ECs and not just PCPs, and the proposal for how an ACO would demonstrate complete and accurate reporting) must be made in order to be consistent with the spirit and intent of the statute and the QPP proposed criteria. Rather, the existing Shared Savings Program rules are sufficient to meet the QPP proposed criteria for Tracks 2 and 3 to be designated as eligible APMs because the EHR quality measure will always be used to impact the amount of shared savings or losses of an ACO, regardless of whether it is designated as pay for performance or pay for reporting. We note that the EHR measure has an especially significant impact on the overall quality scoring for an ACO because it is double-weighted compared to any other measure. In spite of this, we are considering additional options regarding the treatment of the EHR measure under the Shared Savings Program in order to further enhance the importance of this measure and its impact on an ACO's quality performance score and to improve alignment with the intent of the policies proposed in the QPP proposed rule. Specifically, we are considering whether to finalize a policy that would require the EHR measure to be P4P in all performance years, including the first year of an ACO's first agreement period. Additionally, we are considering whether to finalize a policy that would require the EHR measure to remain P4P, even when a new EHR measure is introduced or there are significant modifications to the specifications for the measure. Such modifications may require additional changes or alternative approaches to certain current Shared Savings Program rules related to quality benchmarking and scoring. We anticipate that if such modifications are made, they would only apply to the EHR measure and would not impact current scoring and benchmarking rules for other quality measures that make up the quality performance standard. For example, if a final policy is adopted that requires the EHR measure to remain P4P in the face of changes to the measure, we anticipate that we would need to establish a benchmark appropriate for the measure that does not depend on FFS or ACO generated data and distributing points on a sliding scale according to the benchmark because no FFS or ACO generated data would be available to do so in the first 2 years of the use of the new measure. For example, we may use a flat rate to assess performance or create a scale that aligns with our final QPP policies (for example, assessing ACO performance on a scale from 0–50 percent or 0–75 percent) and incrementally making points available depending on level of attainment. Additionally, we would consider exempting the EHR measure from ''minimum attainment level'' rules that would normally apply to a pay for performance measure, at least for the first 2 years of implementation and/or the first year of the first agreement period since the measure would be new to the ACO. Finally, we would consider whether these modifications should apply to the EHR measure only for tracks that could meet the requirements for designation as Advanced APMs under the forthcoming QPP final rule; we note that under the QPP proposed rule, only Tracks 2 and 3 would be designated as Advanced APMs. We seek comment on how best to conform to the intent and spirit of the QPP requirements to ensure that clinicians have assurance they are participating in an Advanced APM. We specifically seek comment on our proposals and the alternatives considered.

Finally, we note that the CMS web interface measures, including those proposed in the QPP proposed rule, are consistent across CMS reporting programs. We do not believe it is beneficial to propose CMS web interface measures for ACO quality reporting separately. Therefore, to avoid confusion and duplicative rulemaking, we propose that any future changes to the CMS web interface measures would be proposed through rulemaking for the QPP and would be applicable to ACO quality reporting under the Shared Savings Program.

4. Incorporating Beneficiary Preference Into ACO Assignment

a. Background

Under section 1899(c) of the Act, beneficiaries are required to be assigned 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. Medicare FFS beneficiaries do not enroll in the Shared Savings Program, and they retain the right to seek Medicare-covered services from any Medicare-enrolled provider or supplier of their choosing. No exclusions or restrictions based on health conditions or similar factors are applied in the assignment of Medicare FFS beneficiaries. Thus, a beneficiary's choice to receive primary care services furnished by physicians and certain non-physician practitioners that are ACO professionals in the ACO, determines the beneficiary's assignment to an ACO under the Shared Savings Program. As discussed in detail in the November 2011 Medicare Shared Savings Program final rule (76 FR 67851 through 67870), we finalized a claims-based hybrid approach (called preliminary prospective assignment with retrospective reconciliation) for assigning beneficiaries to an ACO. Under this approach, beneficiaries are preliminarily assigned to an ACO at the beginning of a performance year to help the ACO refine its care coordination activities, but final beneficiary assignment is determined at the end of each performance year based on where beneficiaries chose to receive a plurality of their primary care services during the performance year. We adopted this policy because we believe that the methodology balances beneficiary freedom to choose healthcare providers under FFS Medicare with the ACO's desire to have information about the FFS beneficiaries that are likely to be assigned at the end of the performance year. We believe this methodology accomplishes an appropriate balance because ACOs have the greatest opportunities to impact the quality and cost of the care of beneficiaries that choose to receive care from providers and suppliers participating in the ACO during the course of the year.

A beneficiary is eligible for assignment to an ACO under § 425.402 if the beneficiary had a primary care service with a physician who is an ACO professional, and thus, is eligible for assignment to the ACO under the statutory requirement to base assignment on ''utilization of primary care services'' furnished by physicians who are ACO professionals in the ACO. The beneficiary is then assigned to the ACO if the allowed charges for primary care services furnished to the beneficiary by all primary care physicians who are ACO professionals and non-physician ACO professionals in the ACO are greater than the allowed charges for such services provided by primary care physicians, nurse practitioners, physician assistants, and clinical nurse specialists who are ACO professionals in another ACO or not affiliated with any ACO and are identified by a Medicare-enrolled TIN. The second step of the assignment process considers the remainder of beneficiaries who have received at least one primary care service from an ACO physician with a specialty designation specified in § 425.402(c) , but have received no services from a primary care physician, nurse practitioner, physician assistant, or clinical nurse specialist either inside or outside the ACO. These beneficiaries are assigned to the ACO if the allowed charges for primary care services furnished by physicians who are ACO professionals in the ACO with one of the specialty designations specified in § 425.402(c) are greater than the allowed charges for primary care services furnished by physicians with such specialty designations in another ACO or who are not affiliated with any ACO and are identified by a Medicare-enrolled TIN. The ''two step'' assignment process simultaneously maintains the requirement to focus on primary care services in beneficiary assignment, while recognizing the necessary and appropriate role of specialists and non-physician practitioners in providing primary care services, such as in areas with primary care physician shortages. We revised this two-step claims based methodology in the June 2015 Final Rule as discussed in detail in that final rule (80 FR 32743 through 32758) and finalized a policy that would exclude services provided by certain physician specialties from step 2 of the assignment process.

Additionally, in the June 2015 final rule, and in response to stakeholders, we implemented an option for ACOs to participate in a new two-sided performance-based risk track, Track 3. Under Track 3, beneficiaries are prospectively assigned to the ACO at the beginning of the performance year using the same two-step methodology, based on the most recent 12 months for which data are available, which reflects where beneficiaries have chosen to receive primary care services during that period. The ACO is held accountable for beneficiaries that are prospectively assigned to it for the performance year. Under limited circumstances, a beneficiary may be excluded from the prospective assignment list, for example, if the beneficiary enrolls in Medicare Advantage or no longer lives in the United States or U.S. territories and possessions, based on the most recent available data in our beneficiary records at the end of the performance year. A beneficiary is not excluded from the ACO's prospective assignment list at the time of reconciliation because the beneficiary chose to receive most or all of his or her primary care during the performance year from providers and suppliers outside the ACO. Additionally, no beneficiaries are added to the ACO's prospective assignment list at the time of reconciliation because a beneficiary chose to receive a plurality of his or her primary care during the performance year from ACO professionals participating in the ACO. Offering this alternative approach to beneficiary assignment responds to stakeholders who expressed a desire for a prospective assignment approach. These stakeholders believe prospective assignment will provide more certainty about the beneficiaries for whom the ACO will be held accountable during the performance year, thus enabling ACOs to redesign their patient care processes to more efficiently and effectively improve care for specific FFS beneficiaries rather than for all FFS beneficiaries. We note, however, that such certainty is limited because prospectively aligned beneficiaries who meet the exclusion criteria specified in § 425.401(b) during the performance year will not be aligned to the ACO at the end of the year; and further, as noted, beneficiaries remain free under FFS Medicare to choose the healthcare providers from whom they receive services.

Because of uncertainty inherent in FFS Medicare where there is no beneficiary lock-in or enrollment, both patient advocacy groups and ACOs have expressed interest in and support for

enhancing claims-based assignment of beneficiaries to ACOs by taking into account beneficiary attestation regarding the healthcare provider that they consider to be responsible for coordinating their overall care. Stakeholders believe that incorporating this information and giving beneficiaries the opportunity to voluntarily ''align'' with the ACO in which their primary healthcare provider participates will improve the patient centeredness of the assignment methodology. In theory, active beneficiary acknowledgement of the practitioner they believe to be responsible for their overall care could enhance engagement and the beneficiary's commitment to receive the bulk of his or her primary care from the designated practitioner. In turn, some stakeholders believe this could reduce year-to-year ''churn'' in beneficiary assignment lists and, in the case of prospective assignment, potentially increase certainty further because the increase in beneficiary engagement may encourage the beneficiary to receive care during the performance year from ACO providers/suppliers, to the extent that the beneficiary is aware of which providers and suppliers participate in the ACO. However, we note that such a process would not obligate the beneficiary to receive care from ACO providers/suppliers because the beneficiary would retain freedom under FFS Medicare to receive services from whichever provider or supplier the beneficiary chooses. Thus, while taking beneficiary attestation into account in the assignment algorithm may improve beneficiary engagement and therefore reduce year-to-year ''churn'' in beneficiary assignment of such patients, it may not result in the sort of certainty that some ACOs desire, particularly with respect to where beneficiaries choose to receive services.

To begin to address these concerns, the Center for Medicare & Medicaid Innovation (Innovation Center) began conducting a test of beneficiary attestation (which was referred to as voluntary alignment, a term that we will also use in the context of the Shared Savings Program) in the Pioneer ACO Model (see *https://innovation.cms.gov/initiatives/Pioneer-aco-model/*) for the 2015 performance year.

In the Pioneer ACO Model, for a Pioneer ACO to participate in voluntary alignment for performance year four (Pioneer ACO contract year 2015), the Pioneer ACO was required to submit an application to CMS in the summer of performance year three (Pioneer ACO contract year 2014) in which the ACO explained its plan for contacting beneficiaries. ACOs that were approved to participate in voluntary alignment were limited to contacting only those beneficiaries who appeared on the ACO's then current (Pioneer ACO contract year 2014) and prior year's (Pioneer ACO contract year 2013) prospective assignment lists.

The ACOs sent letters to beneficiaries during a specified period asking the beneficiaries to confirm whether a listed Pioneer Provider/Supplier was their ''main doctor.'' The Innovation Center imposed certain safeguards on the participating ACOs to protect against actions that could improperly influence a beneficiary's decision to complete the voluntary alignment form. The ACOs collected responses and turned them in to CMS in fall 2014, before the start of the 2015 performance year. Beneficiaries who confirmed a care relationship with the Pioneer Provider/Supplier listed on the form, and met all other eligibility criteria for alignment, were prospectively aligned to the Pioneer ACO for the upcoming performance year, regardless of whether or not the practitioners participating in the Pioneer ACO rendered the plurality of the beneficiary's primary care services during the alignment period. We refer to the procedures used under the Pioneer ACO Model as ''the manual process.''

Because the testing of beneficiary attestation in the Pioneer ACO Model was just beginning at the time of the publication of the December 2014 proposed rule, in that proposed rule we indicated our interest in beneficiary attestation, but did not make any specific proposals. However, we welcomed comments on whether it would be appropriate to offer a beneficiary attestation process to ACOs participating under two-sided risk financial arrangements under the Shared Savings Program in the future (79 FR 72826 through 72829). We noted that if we were to offer a beneficiary attestation process for ACOs in performance-based risk tracks, we would anticipate initially implementing beneficiary attestation in a manner consistent with the beneficiary attestation process tested under the Pioneer ACO Model (79 FR 72829).

Beneficiary and ACO participation in and experience with voluntary alignment under the Pioneer ACO Model to date has been mixed. Initially, beneficiaries often seemed confused about the implications of attesting to a care relationship with a Pioneer Provider/Supplier, based on the letters they received from Pioneer ACOs. Beneficiaries, for example, were often unfamiliar with the name of the Pioneer ACO. Although most Pioneer ACOs initially expressed high interest in beneficiary attestation, only half participated. Those that did not participate cited cost/benefit concerns. To address concerns expressed by ACOs and beneficiaries, the beneficiary attestation process was updated for the Pioneer ACO Model for PY 2016, with letters sent to beneficiaries during the summer of 2015. The new beneficiary attestation process includes updated language in the letters to beneficiaries and the attestation form to reduce beneficiary confusion. The letters now include plainer language, refer to a specific healthcare provider (in addition to the ACO), and Pioneer Providers/Suppliers are permitted to discuss beneficiary attestation with beneficiaries and respond to questions. Other significant changes to the process include a longer voluntary alignment period and the ability for ACOs to provide the letter/form to beneficiaries via email, patient portal, or other electronic method (in which case the forms must be returned with a ''wet-ink'' signature, such as by returning the original signed form by mail. (We continue to view this updated process to be a manual process.) In addition there was a change to the voluntary alignment eligibility criteria. For performance year four (Pioneer ACO contract year 2015), only those beneficiaries who were identified on a Pioneer ACO's prospective alignment list from performance year two (Pioneer ACO contract year 2013) or performance year three (Pioneer ACO contract year 2014) were eligible to voluntarily align with the Pioneer ACO for performance year four, assuming all other eligibility criteria were met. For performance year five (Pioneer ACO contract year 2016), CMS changed the criteria to allow beneficiaries to voluntarily align into the performance year five aligned population if, among other requirements, the beneficiary had at least one paid claim for a Qualified E/M service, as defined in section 2.4 of Appendix C of the Pioneer ACO Agreement, furnished by a Pioneer Provider/Supplier on or after January 1, 2013. Based on some initial feedback, beneficiaries appear to be wary of the implications of designating a ''main doctor'' but are much more amenable to this type of information request when it comes from their physician or other practitioner, rather than from an ACO. However, information is not yet available on the impact or results of the modifications made to the beneficiary attestation process in the Pioneer ACO Model. The Next Generation ACO Model, which started operation on

January 1, 2016, includes a beneficiary attestation policy similar to the updated manual process used under the Pioneer ACO model. In order for a Medicare FFS beneficiary to be eligible to voluntarily align with a Next Generation ACO for performance year two (Next Generation ACO contract year 2017), the beneficiary must have had at least one paid claim for a qualified evaluation and management service on or after January 1, 2014, with an entity that was a Next Generation Participant during performance year one, among other requirements.

To date, the Innovation Center has done limited analyses of the updated voluntary alignment process for effects on beneficiary engagement. Early experience indicates that for the participating ACOs, the number of prospectively assigned beneficiaries per ACO increased by 0.2 to 2.7 percent relative to the number of beneficiaries who would have otherwise been assigned. However, there is not yet enough information to determine whether beneficiary attestation under the manual process has had an impact on increasing certainty that a beneficiary will continue to choose to receive primary care or other services from practitioners participating in an ACO. For example, we would like to know how many of the beneficiaries who ''attested'' into alignment to the ACO continued to seek primary care services from ACO professionals during the performance year, which might demonstrate increased engagement on the part of the beneficiary. The Innovation Center found that ACOs were implementing the beneficiary attestation process under the Pioneer ACO Model as they described in their applications, and no marketing abuses have been observed to date.

Based on valuable experience gained through development and testing of beneficiary attestation processes through the Pioneer ACO Model, the manual process developed thus far appears to be resource intensive and may not significantly impact beneficiary assignment to ACOs. We also note that a similar manual process for sending letters to beneficiaries to provide them notice of their opportunity to opt out of claims data sharing was removed from the Shared Savings Program in the June 2015 final rule (see 80 FR 32743). This data sharing opt out process was removed because it was resource intensive and cumbersome for ACOs and CMS, and was confusing for beneficiaries. Instead, based on stakeholder comments, we finalized a process to provide beneficiaries the opportunity to decline claims data sharing directly by contacting the Medicare program (through 1–800–MEDICARE) rather than through the ACO. This more direct process started at the end of 2015 and so far appears to be working well, as it has not generated the number of complaints and concerns raised by the initial manual process.

b. Proposals

We continue to believe that it may be desirable to incorporate beneficiary attestation into the assignment of beneficiaries to ACOs participating in the Shared Savings Program, to supplement and enhance the current claims-based algorithm driven methodology as described in more detail in this section of the proposed rule. We agree with stakeholders that supplementing the current assignment process with a voluntary alignment process that incorporates beneficiary attestation about their ''main doctor'' could help ACOs to increase patient engagement, improve care management and health outcomes, and lower expenditures for beneficiaries. Incorporating beneficiary attestation into the beneficiary assignment process could further strengthen the current claims-based, two-step assignment process. For example, although we defined certain HCPCS codes at § 425.20 as being ''primary care services,'' the use of these codes may not fully capture the extent of the primary care relationship a beneficiary has with his or her provider. Supplementing the claims-based assignment algorithm with beneficiary attestations could further assure that beneficiaries are assigned to ACOs based on their relationship with providers that they believe to be truly responsible for their overall care.

We believe that it would be appropriate to implement, at a minimum, a voluntary alignment process under the Shared Savings Program that would be similar to the updated manual process we have implemented under the Pioneer ACO Model and that will be used under the Next Generation ACO Model. However, based on the valuable knowledge and experience we have gained through these Innovation Center models, we are concerned that the manual voluntary alignment process used for the Pioneer ACO Model and that will be used under the Next Generation ACO Model is resource intensive for both ACOs and CMS. The voluntary alignment process under the Pioneer ACO Model requires individual ACOs to directly obtain information from beneficiaries by sending them a form letter approved by CMS that includes a copy of a CMS-approved form that the beneficiary may complete to confirm their care relationship with a provider or supplier that is participating in the ACO (that is, their ''main doctor''), whose services are considered in the alignment process. The ACOs then communicate these beneficiary attestations to CMS. However, not all beneficiaries that submit an attestation form may be eligible to be aligned to the ACO. Accordingly, we must review the submissions, and provided the beneficiary is otherwise eligible for alignment to the ACO, this confirmation (or attestation) is then used to align the beneficiary to the ACO. If we were to implement a similar manual process under the Shared Savings Program, we believe it would be appropriate to limit voluntary alignment to Track 3 ACOs for the reasons explained later in this section. Additionally, the timing and requirements of the process would prohibit beneficiaries from voluntarily aligning to ACOs that initially join the Shared Savings Program under Track 3 for the ACO's first performance year because, consistent with the coluntary alignment process under the Pioneer ACO and Next Generation ACO models explained above, an ACO would only be permitted to contact beneficiaries that were aligned prospectively to the ACO in the current or prior years. Thus, a beneficiary's designation of an ACO professional as responsible for coordinating their overall care would impact an ACO's prospective assignment list starting in PY2, assuming the ACO met all requirements necessary for the incorporation of this information during PY1, including applying for participation in voluntary alignment, sending letters, collecting beneficiary preferences, and timely submitting all required information to CMS.

Because of the limitations of the manual process, we have considered ways that voluntary alignment might be implemented in a more automated and direct way under the Shared Savings Program, potentially having a more significant impact on beneficiary engagement while reducing burdens on ACOs, ACO participants, ACO providers/suppliers, ACO professionals, beneficiaries, and CMS. Automating a process for Medicare FFS beneficiaries to designate their ''main doctor'' or the other healthcare provider they believe is responsible for their overall care could align with agency goals to provide increased focus on patient centered care, and improve beneficiary engagement. We believe strengthening primary care is critical to an effective health care system. Automating a

process for beneficiaries to designate their ''main doctor'' or the healthcare provider they believe is responsible for their overall care could encourage beneficiaries to partner with a healthcare provider to better coordinate their care, including care with specialists, and would help to support the continued development of a health care system that results in healthier people and smarter spending of our health care dollars. Incorporating beneficiary preferences through voluntary alignment could also help to increase the accuracy of the assignment process. If a beneficiary is aligned to the ACO in which the healthcare provider who they believe is responsible for coordinating their overall care is participating, there may be an increased probability that the beneficiary's care will be coordinated, resulting in smarter spending of health care dollars, including spending on care by specialists.

We are therefore proposing to implement an automated approach under which we could determine which healthcare provider a FFS beneficiary believes is responsible for coordinating their overall care (their ''main doctor'') using information that is collected in an automated and standardized way directly from beneficiaries (through a system established by us, such as *MyMedicare.Gov*), rather than requiring individual ACOs, ACO participants, or ACO professionals to directly obtain this information from beneficiaries annually and then communicate these beneficiary attestations to CMS. We believe such an approach would be more efficient for ACOs and their participants, beneficiaries, and CMS. We anticipate that, to the extent feasible, the operational process for beneficiaries to voluntarily align with an ACO by designating a ''main doctor'' or primary healthcare provider would be incorporated into existing processes. For example, currently Medicare FFS beneficiaries already have the ability to obtain an account at *www.MyMedicare.gov* and save information about their ''favorite'' providers from that Web site's Physician Compare function, so one possibility would be to include an additional feature in *MyMedicare.Gov* that would allow beneficiaries to indicate which of their ''favorite'' healthcare providers they consider to be responsible for their overall care. Another possibility would be to permit beneficiaries to directly choose their ''main doctor'' through 1–800–Medicare or through Physician Compare with a link to *MyMedicare.Gov*, similar to the mechanism that is currently available to select a ''favorite'' healthcare provider through Physician Compare. We would notify beneficiaries of this opportunity and encourage them to designate their primary healthcare provider and explain how to do this through beneficiary outreach materials such as through the Medicare & You Handbook (see *https://www.medicare.gov/medicare-and-you/medicare-and-you.html*), the required Shared Savings Program notifications under § 425.312, and/or other beneficiary outreach activities or materials. CMS would issue, either directly or indirectly through template language, all written communications to beneficiaries detailing the automated process for voluntary alignment.

We propose to make such an automated mechanism available for beneficiaries to voluntarily align with the provider or supplier that they believe is responsible for coordinating their overall care starting early in 2017, making it possible for us to use beneficiary attestations for assigning beneficiaries to ACOs in all three tracks for the 2018 performance year. For example, if the automated mechanism is available for beneficiaries in early 2017, we would be able to use the information in the fall of 2017 to develop ACO assignment lists for 2018 for ACOs that are currently participating in the Shared Saving Program, as well as those applying for participation. Voluntary alignment data would be accessed and incorporated in the beneficiary assignment process each time we run the assignment algorithm. Under the automated approach, beneficiaries would be able to change their attestation about their ''main doctor'' at any time, however, we note there may be a lag in using the information to update an ACO's assignment list depending on the timing of the beneficiary's updated designation and the track under which the ACO is participating. For example, we propose that beneficiaries who designate an ACO professional in a Track 3 ACO as their ''main doctor'' would be prospectively assigned to that Track 3 ACO based on their designation prior to the start of the performance year as currently provided under § 425.400(a)(3). These beneficiaries would remain assigned to the Track 3 ACO until the end of the benchmark or performance year, even if they subsequently designate a practitioner outside the ACO as their ''main doctor'', unless they meet any of the exclusion criteria under § 425.401(b). We considered incorporating voluntary alignment as part of the exclusion criteria under 425.401(b), however, we believe it would be appropriate, when incorporating voluntary alignment for Track 3 ACOs, to continue the current prospective assignment policy provided under § 425.400(a)(3) because the intent of prospective assignment is to provide stability in ACOs' beneficiary assignment lists to allow ACOs to coordinate care appropriately for the patients assigned to them. This policy would also align with our policy regarding the SNF 3-day rule waiver under § 425.612, which is limited to eligible beneficiaries who have been prospectively aligned to a Track 3 ACO, because it is important for the ACO to have clear information about which beneficiaries are eligible to receive SNF services pursuant to the waiver. The updated designation would, however, be considered when conducting beneficiary assignment for the subsequent benchmark or performance year.

Further, we propose to incorporate voluntary alignment for ACOs in Tracks 1 and 2 on a quarterly basis; that is, beneficiaries who are not currently assigned to a Track 3 ACO and who voluntarily align with a healthcare provider that is an ACO professional participating in an ACO under Track 1 or 2 would be reflected in the ACO's next preliminary prospective or final assignment list as provided under § 425.400(a)(2). We believe this policy would be appropriate because it aligns with the current timing for updates to Track 1 and 2 ACO assignment lists.

Finally, we propose that if a beneficiary voluntarily aligns with a provider or supplier whose services would be considered in assignment but who is not participating in an ACO as an ACO professional, the beneficiary would not be eligible for alignment to an ACO, even if the beneficiary would have otherwise been assigned to an ACO under our claims-based approach.

We further propose that, if this automated voluntary alignment process is not operationally ready for implementation under the proposed timeframe, we would implement a manual voluntary alignment process for Track 3 ACOs only that builds upon experience previously gained under the Pioneer ACO Model. Because a manual voluntary alignment process is resource intensive for both ACOs and CMS, we believe that if it were necessary to adopt a manual voluntary alignment process under the Shared Savings Program, it would be appropriate to initially limit it to ACOs participating in the Shared Savings Program under Track 3 because beneficiaries are prospectively aligned to Track 3 ACOs (as they are to ACOs under the Pioneer ACO Model and the

Next Generation Model). The process and timing for sending letters to beneficiaries regarding voluntary alignment under the manual process was developed specifically for prospective alignment and for a limited number ACOs. It is likely that attempting to implement such a manual process for the hundreds of ACOs in Track 1 and Track 2, whose beneficiaries are only preliminarily prospectively aligned with retrospective reconciliation, would result in operational challenges for ACOs and CMS and could have unintended consequences that could be confusing or harmful to beneficiaries. Because it is impossible to anticipate what issues might arise if we were to try to implement a manual process across a large number of ACOs operating under a preliminary prospective assignment methodology with retrospective reconciliation, we are not confident at this time that we can propose appropriate procedures and any additional safeguards that might be necessary to allow implementation in all tracks. Therefore, we propose that if an automated process is not available to allow beneficiaries to designate their primary healthcare provider in time to allow the information to be considered for beneficiary assignment for performance year 2018, we would implement voluntary alignment in a step-wise fashion over time, beginning with ACOs in Track 3, whose beneficiaries are prospectively assigned. Limiting voluntary alignment to ACOs to which beneficiaries are prospectively aligned would permit ACOs and CMS to initially focus limited resources on voluntary alignment efforts on a population of beneficiaries that can be identified for targeting and outreach regarding the voluntary alignment process and the benefits of designating an ACO professional as responsible for coordinating their overall care.

More specifically, we propose that if we determine, by no later than spring 2017, that an automated voluntary alignment process is not ready for implementation to allow beneficiaries to voluntarily align with ACO across all three Tracks for the 2018 performance year, then we would implement an alternative manual voluntary alignment process to allow beneficiaries to align with Track 3 ACOs for the 2018 performance year and until such time as an automated process is available. This proposed alternative manual voluntary alignment process for Track 3 ACOs would be similar to the updated process that was used under the Pioneer ACO Model to allow beneficiaries to voluntarily align with participating ACOs for the 2016 performance year and that we will follow under the Next Generation ACO Model for the 2017 performance year. Early each year, starting in 2017, Track 3 ACOs would notify us as to whether they want to participate in voluntary alignment for the upcoming performance year. Specifically, similar to the process used under the Pioneer ACO Model and the Next Generation ACO Model, each spring starting in 2017, those Track 3 ACOs that have notified CMS that they would like to participate in voluntary alignment would be required to provide us with a list of the beneficiaries they plan to contact to request that the beneficiary designate an ACO professional whose services are considered in assignment as their ''main doctor.'' The ACOs must also submit to CMS for approval the criteria used to identify the listed beneficiaries. We would review these beneficiary lists to determine if the beneficiary is eligible to be contacted regarding voluntary alignment depending on whether the beneficiary was prospectively assigned yo the ACO in prior performance years, similar to the approach used under the Pioneer ACO Model and the Next Generation ACO Model approach as described above. ACOs could then contact the eligible beneficiaries by sending them a form letter approved by CMS, similar to the letter ACOs sent under the Pioneer ACO Model for 2016, that would include a copy of a CMS-approved form that the beneficiary could complete to confirm their care relationship with an ACO professional, whose services are considered in the assignment process, who the ACO believes may be their ''main doctor.'' Alternatively, the ACO could provide an opportunity for beneficiaries to obtain a copy of the CMS-approved form in the offices of ACO professionals that furnish primary care services on which assignment is based.

Under the manual voluntary alignment process, by September of each year, Track 3 ACOs participating in voluntary alignment for the upcoming performance year would notify CMS as to which beneficiaries had agreed to voluntarily align with their ACO for the upcoming performance year by submitting a form designating an ACO professional whose services are considered in alignment as responsible for coordinating their overall care. We would verify that the beneficiaries are still eligible for assignment to the ACO, and prospectively assign all eligible beneficiaries to the Track 3 ACO for the upcoming performance year. We would repeat this process annually; that is, under this process, beneficiaries would be required to voluntarily align each year by submitting a new form confirming a care relationship with an ACO professional whose services are used in assignment. This approach would enable us to begin the process of incorporating beneficiary attestations into the assignment of beneficiaries to Track 3 ACOs until a more automated, direct method of voluntary alignment is operationally feasible. We believe even this more limited approach to voluntary alignment may increase patient centeredness over the current approach of assigning beneficiaries to ACOs based only on the claims-based algorithm driven methodology for the reasons discussed above and because some level of additional beneficiary engagement in the alignment process may be preferable to no beneficiary engagement.

Therefore, regardless of process (manual or automatic), we are proposing to begin to incorporate beneficiary attestation into the assignment methodology for the Shared Savings Program, effective for assignment for the 2018 performance year. In brief, under the proposal, an eligible beneficiary would be assigned to an ACO based on the existing claims-based assignment process unless the beneficiary has designated a healthcare provider as being responsible for their overall care. If an eligible beneficiary has made such a designation then the voluntary alignment would override the claims based assignment process. Under an automated process, beneficiaries would be able to modify their designation at any time (not just annually, as under a manual process), however, as noted above, there may necessarily be a lag before that information can be incorporated into the assignment methodology for purposes of determining an ACO's assignment list, depending on the timing of the designation and the track in which the ACO is participating. The latest that the information would be updated would be prior to the start of the next performance year at a timepoint designated by CMS in cases where beneficiaries are prospectively aligned to a Track 3 ACO. There may also be a lag when a beneficiary voluntarily aligns with a practitioner identified by an NPI who is an ACO professional in an ACO, but chooses to leave the ACO during a performance year. For example, there may be situations in which an eligible beneficiary voluntarily aligns to a practitioner billing under ACO participant TIN A in ACO A participating in Track 3 and becomes

prospectively assigned for performance year 2018 on that basis. In the first quarter of 2018, the practitioner reassigns billing rights to ACO participant TIN B in ACO B, thus switching ACOs. Under our proposal, the beneficiary would remain prospectively aligned to ACO A for the duration of performance year 2018. Similarly, there may be situations in which an eligible beneficiary voluntarily aligns to a practitioner billing under ACO participant TIN in ACO C participating in Track 1 using an automated process and becomes preliminarily prospectively aligned during the first quarter of a performance year. In the second quarter of the performance year, the practitioner reassigns billing rights to a non-ACO participant TIN. Under our proposals, the next time a preliminary prospective assignment list is issued, the beneficiary would no longer appear on ACO C's list. Moreover, voluntary alignment in no way limits or changes benefits under FFS Medicare. Because of this, a beneficiary that meets the eligibility criteria may voluntarily align with a practitioner participating in an ACO, become aligned to the ACO, but subsequently choose to receive all his or her primary care from a practitioner that is unaffiliated with the ACO. In this case, the beneficiary would continue to be assigned to the ACO based upon the beneficiary's designation of an ACO professional as their ''main doctor'' for the remainder of the performance year under the manual process, and indefinitely until the beneficiary changes his or her designation under the automated process. Finally, we can imagine a scenario where a beneficiary designates as their ''main doctor'' a practitioner that is unaffiliated with any ACO and therefore the beneficiary is not assigned to an ACO even though the ACO's practitioners provided a plurality of the beneficiary's primary care services and would have otherwise been held accountable for the beneficiary's care. Given the high interest in taking beneficiary preferences for alignment into account and the potential for improving beneficiary engagement, we believe these scenarios, which may involve undesirable effects on the accuracy of beneficiary alignment, can be limited when beneficiaries are provided sufficient information about the importance of keeping the designation of their ''main doctor'' up to date.

We emphasize that we do not intend for the voluntary alignment process (whether automated or manual) to be used as a mechanism for ACOs (or their ACO participants, ACO providers/suppliers, ACO professionals or other individuals or entities performing functions or services on behalf of the ACO) to target beneficiaries for whose treatment the ACO might expect to earn shared savings, or to avoid those for whose treatment the ACO might be less likely to generate shared savings. Further, as discussed in more detail later in this section, we do not believe ACOs or others should be permitted to offer gifts or other inducements to beneficiaries, nor should they be allowed to withhold or threaten to withhold services, for the purposes of coercing or influencing beneficiaries' voluntary alignment decisions. However, we believe it is important to promote engagement and discussion between beneficiaries and their healthcare providers and therefore do not propose to prohibit an ACO or its ACO participants, ACO providers/suppliers, or ACO professionals from providing a beneficiary with accurate descriptive information about the potential patient care benefits of designating an ACO professional as responsible for the beneficiary's overall care.

Accordingly, we propose to revise the regulations governing the assignment methodology to add a new paragraph (e) to § 425.402. Under this paragraph, if an automated system is available by spring of 2017 to allow a beneficiary to designate an ACO professional whose services are used in alignment as responsible for coordinating their overall care and for CMS to process the designation electronically, then the voluntary alignment process would be available for ACOs participating in Track 1, Track 2, or Track 3, as specified in § 425.600(a) of this part. However, if such an electronic system is not available by spring of 2017, then CMS will specify the form and manner in which a beneficiary may designate an ACO professional whose services are used in assignment as responsible for coordinating their overall care using a manual process, but the voluntary alignment process will be limited to ACOs participating in Track 3 until an automated system is available. In either case, under the proposal, beginning in performance year 2018 beneficiaries that have voluntarily aligned with an ACO by designating an ACO professional whose services are used in assignment as responsible for coordinating their overall care will be added to the ACO's list of assigned beneficiaries, for a performance year under the following conditions:

- The beneficiary must have had at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 of this subpart or who has one of the primary specialty designations included in § 425.402(c).
- The beneficiary must meet the assignment eligibility criteria established in § 425.401, and must not be excluded by the criteria at § 425.401(b).
- The beneficiary must have designated an ACO professional who is a primary care physician as defined at § 425.20 of this part, a physician with a specialty designation included at § 425.402(c) of this subpart, or a nurse practitioner, physician assistant, or clinical nurse specialist as responsible for their overall care.
- The designation must be made in the form and manner and by a deadline determined by CMS. In contrast, if a beneficiary designates a provider or supplier outside the ACO, who is a primary care physician as defined at § 425.20 of this part, a physician with a specialty designation included at § 425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist, as responsible for coordinating their overall care, the beneficiary will not be added to the ACO's list of assigned beneficiaries for a performance year, even if the beneficiary would otherwise be included in the ACO's assigned beneficiary population under the assignment methodology in § 425.402(b).

Further, we propose that the ACO, ACO participants, ACO providers/suppliers, ACO professionals, and other individuals or entities performing functions or services related to ACO activities are prohibited from directly or indirectly, committing any act or omission, or adopting any policy that coerces or otherwise influences a Medicare beneficiary's decision to designate or not designate an ACO professional as responsible for coordinating their overall care, including but not limited to the following:

- Offering anything of value to the Medicare beneficiary as an inducement for influencing the Medicare beneficiary's decision to designate or not to designate an ACO professional as responsible for coordinating their overall care. Any items or services provided in violation of this prohibition will not be considered to have a reasonable connection to the medical care of the beneficiary, as required under § 425.304(a)(2);

• Withholding or threatening to withhold medical services or limiting or threatening to limit access to care; and

• Including any voluntary alignment or change of preference forms requiring a beneficiary signature with any other materials or forms, including but not limited to any other materials requiring the signature of the Medicare beneficiary. (We note this requirement would only be applicable if we implement a manual process);

To maintain flexibility for ACOs, ACO participants, ACO providers/suppliers, ACO professionals, beneficiaries, and CMS, we would intend to provide further operational details regarding the voluntary alignment process and the applicable implementation timelines through subregulatory guidance and other outreach activities.

We seek comments on this proposal, on the effective date, and on any other related issues that we should consider for the final rule to address issues related to voluntary alignment under the Shared Savings Program. In particular, we seek comment on whether voluntary alignment is an appropriate mechanism for assigning beneficiaries retrospectively to an ACO. Specifically, is it appropriate to retrospectively align a beneficiary to an ACO, if the beneficiary designated an ACO professional whose services are used in assignment as responsible for the beneficiary's overall care, but did not receive a plurality of primary care services from ACO professionals in the ACO during the performance year? We seek comment on whether including voluntary alignment information in our assignment algorithm should be discretionary, that is, whether ACOs should be permitted to opt into or out of voluntary alignment. We seek comment on whether we should exclude a beneficiary from an ACO's prospective assignment list for a performance year if later during the performance year the beneficiary voluntarily aligns with a healthcare provider that is not an ACO professional in the ACO. We also seek input on how concerns about ACO avoidance of at risk beneficiaries might be addressed.

We also note that under the proposed automated voluntary alignment process, a beneficiary's designation of a healthcare provider as responsible for coordinating their overall care would stay in effect until the beneficiary chose to make a subsequent change. We have concerns that in some cases a beneficiary may develop a closer healthcare relationship with a primary care provider who is different than the one they initially designated but the beneficiary might not necessarily change their designation to reflect this new choice. However, requiring a beneficiary to update his or her designation annually seems burdensome. Therefore, under the proposal we would continue to use their designation and rely on appropriate information shared with beneficiaries at the point of care to ensure the beneficiary's designation is kept up to date. We seek comment on this issue and our proposal under the automated system to continue to use a beneficiary's designation of the healthcare provider responsible for coordinating their overall care until it is changed.

In addition, although we are not proposing to specify operational processes in regulations, nevertheless we also welcome suggestions regarding the operational process, implementation timelines, and related issues regarding the process for beneficiaries to voluntarily align with an ACO, including how to strengthen ACOs' beneficiary engagement activities. We note that although we are proposing to establish a process under which beneficiaries may designate their ''main doctor'' who they consider responsible for coordinating their overall care, in establishing the operational processes for allowing beneficiaries to designate their ''main doctor'' we may not explicitly use the phrase ''responsible for coordinating overall care'' which we have included in the proposed provision at § 425.402(e). Instead, we may consider using other terminology based on focus group testing and/or other feedback from beneficiary representatives. We welcome comments on what terminology would be preferable to ensure beneficiaries understand the significance of designating a provider or supplier as responsible for coordinating their overall care. We will consider such suggestions further as we develop program guidance and outreach activities for beneficiaries and ACOs.

3. SNF 3-Day Rule Waiver Beneficiary Protections

a. 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 three 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), 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 for their prospectively assigned beneficiaries when they are admitted to certain ''SNF affiliates,'' that is, SNFs with whom the ACO has executed SNF affiliate agreements. (See § 425.612(a)(1)). Waivers are effective upon CMS notification of approval for the waiver or the start date of the ACO's participation agreement, whichever is later. (See § 425.612(c)). We stated in the June 2015 final rule that the SNF 3-day rule waiver would be effective for services furnished on or after January 1, 2017. Program requirements for this waiver are codified at § 425.612. These requirements are primarily based on criteria previously developed under the Pioneer ACO Model. Specifically, under § 425.612(a)(1), we waive the requirement in section 1861(i) of the Act for a 3-day inpatient hospital stay prior to a Medicare covered post-hospital extended care service for eligible beneficiaries prospectively assigned to ACOs participating in Track 3 that have been approved to implement the waiver that receive otherwise covered post-hospital extended care services furnished by an eligible SNF that has entered into a written agreement to partner with the ACO for purposes of this waiver. All other provisions of the statute and regulations regarding Medicare Part A post-hospital extended care services continue to apply.

We believe that clarity regarding whether a waiver applies to SNF services furnished to a particular beneficiary is important to help ensure compliance with the conditions of the waiver and also improve our ability to monitor waivers for misuse. Therefore, in the June 2015 final rule, we limited the waiver to ACOs in Track 3 because under the prospective assignment methodology used in Track 3, beneficiaries are assigned in advance to the ACO for the entire performance year (unless they meet any of the exclusion criteria under § 425.401(b) during the performance year), so it will be clearer to a Track 3 ACO whether the waiver applies to SNF services furnished to a particular beneficiary than it would be to an ACO in Track 1 or 2, where beneficiaries are assigned using a preliminary prospective assignment methodology with retrospective reconciliation (80 FR 32804). An ACO's use of the SNF 3-day rule waiver will be associated with a distinct and easily identifiable event, specifically, admission of a prospectively assigned beneficiary to a previously identified SNF affiliate without prior inpatient

hospitalization or after an inpatient hospitalization of fewer than 3 days.

Based on our experiences under the Pioneer ACO Model, and in response to comments, we established certain requirements under § 425.612 for ACOs, ACO providers/suppliers, SNF affiliates, and beneficiaries with respect to the SNF 3-day rule waiver under the Shared Savings Program. All ACOs electing to participate in Track 3 will be offered the opportunity to apply for a waiver of the SNF 3-day rule for their prospectively assigned beneficiaries at the time of their initial application to participate in Track 3 of the program and annually thereafter while participating in Track 3. We anticipate accepting the first SNF 3-day rule waiver applications from Track 3 ACOs later this summer. As set forth at § 425.612(a)(1)(i), in their waiver applications, ACOs must demonstrate that they have 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. As part of the application process, the ACO will be required to submit a list of the SNFs with which the ACO will partner (called ''SNF affiliates'') along with executed SNF affiliate agreements for each listed SNF. These SNF affiliates will be subject to program integrity screening under § 425.612(b). Additionally, the ACO must submit narratives describing how the ACO plans to implement the waiver, including the communication plan between the ACO and its SNF affiliates; a care management plan for beneficiaries admitted to a SNF affiliate; a beneficiary evaluation and admission plan approved by the ACO medical director and the healthcare professional responsible for the ACO's quality improvement and assurance processes; and a description of any financial relationships between the ACO, SNF, and acute care hospitals.

To be eligible to receive covered SNF services under the waiver, a beneficiary must be prospectively assigned to the ACO for the performance year in which he or she is admitted to the SNF affiliate, may not reside in a SNF or other long-term care setting, must be medically stable and have an identified skilled nursing or rehabilitation need that cannot be provided as an outpatient, and must meet the other requirements set forth at § 425.612(a)(1)(ii).

For a SNF to be eligible to partner with ACOs for purposes of the waiver, a SNF must have an overall quality rating of 3 or more stars under the CMS 5 Star Quality Rating System, must sign a written agreement with the ACO, which we refer to as the ''SNF affiliate agreement,'' that includes elements determined by CMS, including: A clear indication of the effective dates of the SNF affiliate agreement; agreement to comply with Shared Savings Program rules, including but not limited to those specified in the participation agreement between the ACO and CMS; agreement to validate beneficiary eligibility to receive covered SNF services under the waiver prior to admission; remedial processes and penalties for noncompliance with the terms of the waiver, and other requirements set forth at § 425.612(a)(1)(iii). The SNF affiliate agreement must include these elements to ensure that the SNF affiliate understands its responsibilities related to implementation of the SNF 3-day rule waiver.

We indicated in the June 2015 final rule that the SNF 3-day rule waiver would be effective no earlier than January 1, 2017; thereafter, the waiver will be effective upon CMS notification to the ACO of approval for the waiver or the start date of the ACO's participation agreement, whichever is later, and will not extend beyond the term of the ACO's participation agreement. If CMS terminates the participation agreement under § 425.218, then the waiver will end on the date specified by CMS in the notice of termination. If the ACO terminates its participation agreement, then the waiver will end on the effective date of termination as specified in the written notification required under § 425.220.

We also indicated in the June 2015 final rule that we established the timeline for implementation of the SNF 3-day rule waiver to allow for development of additional subregulatory guidance, including necessary education and outreach for ACOs, ACO participants, ACO providers/suppliers, and SNF affiliates. We noted that we would continue to evaluate the waiver of the SNF 3-day rule, including further lessons learned from Innovation Center models in which a waiver of the SNF 3-day rule is being tested. We indicated that in the event we determined that additional safeguards or protections for beneficiaries or other changes were necessary, such as to incorporate additional protections for beneficiaries into the ACO's participation agreement or SNF affiliate agreements, we would propose the necessary changes through future rulemaking.

In considering additional beneficiary protections that may be necessary to ensure proper use of the SNF 3-day rule waiver under the Shared Savings Program, we note that there are existing, well established payment and coverage policies for SNF services based on sections 1861(i), 1862(a)(1), and 1879 of the Act that include protections for beneficiaries from liability for certain non-covered SNF charges. These existing payment and coverage policies for SNF services continue to apply to SNF services furnished to beneficiaries assigned to ACOs participating in the Shared Savings Program, including services furnished pursuant to the SNF 3-day rule waiver. (For example, see the Medicare Claims Processing Manual, Chapter 30—Financial Liability Protections, section 70, available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c30.pdf*; Medicare Coverage of Skilled Nursing Facility Care beneficiary booklet, Section 6: Your Rights & Protections, available at *https://www.medicare.gov/Pubs/pdf/10153.pdf*; and Medicare Benefit Policy Manual, Chapter 8—Coverage of Extended Care (SNF) Services Under Hospital Insurance available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c08.pdf*). In general, CMS requires that the SNF inform a beneficiary in writing about services and fees before the beneficiary is admitted to the SNF (§ 483.10(b)(6)); the beneficiary cannot be charged by the SNF for items or services that were not requested (§ 483.10(c)(8)(iii)(A)); a beneficiary cannot be required to request extra services as a condition of continued stay (§ 483.10(c)(8)(iii)(B)); and the SNF must inform a beneficiary that requests an item or service for which a charge will be made that there will be a charge for the item or service and what the charge will be (§ 483.10(c)(8)(iii)(C)). (See also section 6 of Medicare Coverage of Skilled Nursing Facility Care at *https://www.medicare.gov/Pubs/pdf/10153.pdf*.)

b. Proposals

Since publication of the June 2015 final rule, we have continued to learn from implementation and refinement of the SNF 3-day rule waiver in the Pioneer ACO Model (see *https://innovation.cms.gov/initiatives/Pioneer-aco-model/*) and the Next Generation ACO Model (see *https://innovation.cms.gov/initiatives/Next-Generation-ACO-Model*). Based on these experiences, we believe there are situations where it would be appropriate to require additional beneficiary financial protections under the SNF 3-day rule waiver for the Shared Savings Program. Specifically, we are concerned about potential

beneficiary financial liability for non-covered Part A SNF services that might be directly related to use of the SNF 3-day rule waiver under the Shared Savings Program.

First, one example of a scenario under which a beneficiary may be at financial risk relates to the quarterly exclusions from a Track 3 ACO's prospective assignment list. For example, assume a beneficiary was prospectively assigned to a Track 3 ACO that has been approved for the SNF 3-day rule waiver (a waiver-approved ACO), but during the first quarter of the year, the beneficiary's Part B coverage terminated and the beneficiary is therefore no longer eligible to be assigned to the ACO. As a result, the beneficiary would be excluded from the ACO's prospective assignment list because the beneficiary meets one or more of the exclusion criteria specified at § 425.401(b). That is, although SNF services are covered under Part A, not Part B, the beneficiary would be dropped from the ACO's prospective assignment list if during the performance year the beneficiary is no longer enrolled in Part B and thus no longer eligible to be assigned to the ACO. We are concerned about some very limited situations, such as when a beneficiary's Part B coverage terminates during a quarter when the beneficiary is also receiving SNF services. The beneficiary may be admitted to a SNF without a prior 3-day inpatient hospital stay after his or her Part B coverage ended, but before the beneficiary appears on a quarterly exclusion list. It is not operationally feasible for CMS to notify the ACO and for the ACO, in turn, to notify its SNF affiliates, ACO participants, and ACO providers/suppliers immediately of the beneficiary's exclusion. The lag in communication may then cause the SNF affiliate to unknowingly admit a beneficiary who no longer qualifies for the waiver without a prior 3-day inpatient hospital stay. Absent specific beneficiary protections, we are concerned that the beneficiary could be charged for such non-covered SNF services. We do not believe it would be appropriate for CMS to hold the beneficiary or the SNF affiliate financially liable for such services. We believe we should allow for a reasonable amount of time for CMS to communicate beneficiary exclusions to an ACO and for the ACO to communicate the exclusions to its SNF affiliates, ACO participants, and ACO providers/suppliers. Typically there would be no way for the SNF affiliate to verify in real-time that a beneficiary continues to be prospectively assigned to the ACO; the SNF affiliate must rely upon the assignment list and quarterly exclusion lists provided by CMS to the ACO and communicated by the ACO to its SNF affiliates, ACO participants, and ACO providers/suppliers. Further, the beneficiary does not receive a notification regarding his or her eligibility for the SNF 3-day rule waiver prior to receiving SNF services under the waiver, so beneficiaries are not able to check their own eligibility.

To address delays in communicating beneficiary exclusions from the prospective assignment list, the Pioneer ACO Model and Next Generation ACO Model provide for a 90-day grace period that functionally acts as an extension of beneficiary eligibility for the SNF 3-day rule waiver and permits some additional time for the ACO to receive quarterly exclusions lists from CMS and communicate beneficiary exclusions to its SNF affiliates. We believe that it would be appropriate, in order to protect beneficiaries from potential financial liability related to the SNF 3-day rule waiver under the Shared Savings Program, to establish a similar 90-day grace period in the case of a beneficiary who was prospectively assigned to a waiver-approved ACO at the beginning of the performance year but is later excluded from assignment to the ACO.

Therefore, we believe it is necessary for purposes of carrying out the Shared Savings Program to allow these formerly assigned beneficiaries to receive covered SNF services under the SNF 3-day rule waiver when the beneficiary is admitted to a SNF affiliate within a 90-day grace period following the date that CMS delivers the quarterly beneficiary exclusion list to an ACO. The equitable and efficient implementation of the SNF 3-day rule waiver is necessary to further support ACOs' efforts to increase quality and decrease costs under two-sided performance-based risk arrangements. (See 80 FR 32804 for a detailed discussion of the rationale for establishing the SNF 3-day rule waiver). Based upon the experience in the Pioneer ACO Model, we believe it is not possible to adopt such a waiver without providing some protection for certain beneficiaries who were prospectively assigned to the ACO at the start of the year, but are subsequently excluded from assignment. Accordingly, we are proposing to modify the waiver to include a 90-day grace period to allow sufficient time for CMS to notify the ACO of any beneficiary exclusions, and for the ACO then to inform its SNF affiliates, ACO participants, and ACO providers/suppliers of those exclusions.

More specifically, we propose to modify the waiver under § 425.612(a)(1) to include a 90-day grace period that would permit payment for SNF services provided to beneficiaries who were initially on the ACO's prospective assignment list for a performance year but were subsequently excluded during the performance year. CMS would make payments for SNF services furnished to such a beneficiary under the terms of the SNF 3-day rule waiver if the following conditions are met:

- The beneficiary was prospectively assigned to a waiver-approved ACO at the beginning of the performance year but was excluded in the most recent quarterly exclusion list.
- The SNF affiliate services are furnished to a beneficiary admitted to the SNF affiliate within 90 days following the date that we deliver the quarterly exclusion list to the ACO.
- We would have otherwise made payment to the SNF affiliate for the services under the SNF 3-day rule waiver, but for the beneficiary's exclusion from the waiver-approved ACO's prospective assignment list.

We further note that we anticipate that there would be very few instances where it would be appropriate for SNF services to qualify for payment under this 90-day grace period. This is because this waiver only allows for payment for claims that meet all applicable requirements except the requirement for a prior 3-day inpatient hospital stay. For example, assume that a beneficiary who had been assigned to a waiver-approved ACO was admitted to a SNF without a prior 3-day inpatient hospital stay after his or her enrollment in an MA Plan, but before the beneficiary appears on a quarterly exclusion list. In this case, these SNF services would not be covered under FFS because the waiver does not expand coverage to include services furnished to Medicare beneficiaries enrolled in MA Plans. Both beneficiaries and healthcare providers are expected to know that the beneficiary is covered under an MA plan and not FFS Medicare.

Second, we are concerned that there could be other more likely scenarios where a beneficiary could be charged for non-covered SNF services that were a result of an ACO's or SNF's inappropriate use of the SNF 3-day rule waiver. Specifically, we are concerned that a beneficiary could be charged for non-covered SNF services if a SNF affiliate were to admit a FFS beneficiary who is not prospectively assigned to the waiver-approved ACO, and payment for SNF services is denied for lack of a qualifying inpatient hospital stay.

We believe this situation could occur as a result of a breakdown in one or more of processes the ACO and SNF affiliate are required to have in place to implement the waiver. For example, the SNF affiliate and the admitting ACO provider/supplier may not verify that the beneficiary appears on the ACO's prospective assignment list prior to admission, as required under the SNF 3-day rule waiver (§ 425.612(a)(1)(iii)(B)(4)) and the terms of the SNF's affiliate agreement with the ACO. In this scenario, Medicare would deny payment of the SNF claim under existing FFS rules because the beneficiary did not have a qualifying inpatient hospital stay. We are concerned that, once the claim is rejected, the beneficiary may not be protected from financial liability, and thus could be charged by the SNF affiliate for these non-covered SNF services that were a result of an inappropriate attempt to use the waiver, potentially subjecting the beneficiary to significant financial liability. However, in this scenario, a SNF with a relationship to the ACO submitted the claim that was rejected for lack of a qualifying inpatient hospital stay, but that otherwise would have been paid by Medicare. In this circumstance, we propose to assume the SNF's intent was to rely upon the SNF 3-day waiver, but the waiver requirements were not met. We believe it is reasonable to assume the SNF's intent was to use the SNF 3-day rule waiver because, as a SNF affiliate, the SNF should be well aware of the ability to use the SNF 3-day rule waiver and, by submitting the claim, demonstrated an expectation that CMS would pay for SNF services that would otherwise have been rejected for lack of a 3-day inpatient hospital stay. We believe that in this scenario, the rejection of the claim under the SNF 3-day rule waiver could easily have been avoided if the ACO, the admitting ACO provider/supplier, and the SNF affiliate had confirmed that the requirements for use of the SNF 3-day rule waiver were satisfied. Because each of these entities is in a better position to know the requirements of the waiver and ensure that they are met than the beneficiary is, we believe that the ACO and/or the SNF affiliate should be accountable for such rejections and the SNF affiliate should be prevented from attempting to charge the beneficiary for the non-covered SNF stay.

To address situations similar to this scenario where the beneficiary may be subject to financial liability due to an eligible SNF submitting a claim that is not paid only as a result of the lack of a qualifying inpatient hospital stay, the Next Generation ACO Model generally places the financial responsibility on the SNF, where the SNF knew or reasonably could be expected to have known that payment would not be made for the non-covered SNF services. In such cases, CMS makes no payment for the services and the SNF may not charge the beneficiary for the services and must return any monies collected from the beneficiary. Additionally, under the Next Generation ACO Model, the ACO must indemnify and hold the beneficiary harmless for payment for the services. We believe it is appropriate to propose to adopt a similar policy under the Shared Savings Program because, under § 425.612(a)(1)(iii)(B), to be a SNF affiliate, a SNF must agree to validate the eligibility of a beneficiary to receive covered SNF services in accordance with the waiver prior to admission to the SNF, and otherwise comply with the requirements and conditions of the Shared Savings Program. SNF affiliates are required to be familiar with the SNF 3-day rule and the terms and conditions of the SNF 3-day rule waiver for the Shared Savings Program, and should know to verify that a FFS Medicare beneficiary who is a candidate for admission has completed a qualifying hospital stay or that the admission meets the criteria under a waiver of the SNF 3-day rule that is properly in place. Additionally, ACOs and their SNF affiliates are required to develop plans that will govern communication and beneficiary evaluation and admission prior to use of the SNF 3-day rule waiver. In these circumstances, we believe it is reasonable that the ultimate responsibility and liability for a non-covered SNF admission should rest with the admitting SNF affiliate.

Therefore, to protect FFS beneficiaries from being charged in certain circumstances for non-covered SNF charges related to the waiver of the SNF 3-day rule under the Shared Savings Program, potentially subjecting such beneficiaries to significant financial liability, we are proposing to add certain beneficiary protection requirements in § 425.612(a)(1). These requirements would apply to SNF services furnished by a SNF affiliate that would otherwise have been covered except for the lack of a qualifying hospital stay preceding the admission to the SNF affiliate. Specifically, we propose that we would make no payment to the SNF, and the SNF may not charge the beneficiary for the non-covered SNF services, in the event that a SNF that is a SNF affiliate of a Track 3 ACO that has been approved for the SNF 3-day rule waiver admits a FFS beneficiary who was never prospectively assigned to the waiver-approved ACO (or was assigned but later excluded and the 90 day grace period has lapsed), and the claim is rejected only for lack of a qualifying inpatient hospital stay.

In this situation, we propose that we would apply the following rules:

- We would make no payment to the SNF affiliate for such services.
- The SNF affiliate must not charge the beneficiary for the expenses incurred for such services; and the SNF affiliate must return to the beneficiary any monies collected for such services.
- The ACO may be required to submit a corrective action plan to CMS for approval as specified at § 425.216(b) addressing what actions the ACO will take to ensure that the SNF 3-day rule waiver is not misused in the future. If after being given an opportunity to act upon the corrective action plan the ACO fails to come into compliance, approval to use the waiver will be terminated in accordance with § 425.612(d). We note that in accordance with our existing program rules at §§ 425.216 and 425.218, CMS retains the authority to take corrective action, including terminating an ACO for non-compliance with program rules. A misuse of a waiver under § 425.612 would constitute non-compliance with program rules. Accordingly, we propose to codify at new provision § 425.612(d)(4) that misuse of a waiver under § 425.612 may result in CMS taking remedial action against the ACO under §§ 425.216 and 425.218, up to and including termination of the ACO from the Shared Savings Program.

We propose that if the SNF submitting the claim is a SNF affiliate for a waiver-approved ACO, and the only reason for the rejection of the claim is lack of a qualifying inpatient hospital stay, then CMS would assume the SNF intended to rely upon the SNF 3-day rule waiver. We would not assume the SNF intended to rely upon the SNF 3-day rule waiver if the SNF is not a SNF affiliate of a waiver-approved ACO because the waiver is not available to SNFs more broadly. We believe intended reliance on the waiver is an important factor in determining whether the additional beneficiary protections proposed here should apply as explained above. Outside the context of an intent to rely on the SNF 3-day rule waiver, we do not believe it would be necessary to include additional beneficiary protections under the Shared Savings Program because there is no reason for either the beneficiary or the SNF to expect that different coverage rules would apply to SNF services. In these other situations,

the beneficiary protections generally applicable under traditional FFS Medicare, noted earlier in this section, continue to apply.

As previously noted in this section, we anticipate accepting the first SNF 3-day rule waiver applications from Track 3 ACOs later this summer. We strongly believe it is important to ensure that beneficiaries have appropriate financial protections against misuse of the waiver prior to approving any SNF 3-day rule waiver applications. We also recognize that ACOs and their SNF affiliates could be reluctant to enter into a SNF affiliate agreement without there being clarity as to their potential responsibility for non-covered SNF services related to the waiver. For these reasons, although we will still accept applications from Track 3 ACOs for the SNF 3-day rule waiver later this summer, in the event we finalize any of the proposed beneficiary protections in the CY 2017 PFS final rule with comment period, we plan to develop a process for ACOs to confirm that they and their SNF affiliates agree to comply with all requirements related to the SNF 3-day rule waiver, including any new requirements adopted in this rulemaking. ACOs and SNF affiliates that do not agree to comply with all requirements would be ineligible for the SNF 3-day rule waiver. We note that this confirmation process may delay approval of ACOs' applications for the SNF 3-day rule waiver; however, we do not anticipate approval would be delayed beyond the first quarter of 2017.

We seek comments on these proposals. We note that under our proposed beneficiary protection provision, a SNF affiliate would be prohibited from charging a beneficiary for non-covered SNF services even in cases where the beneficiary explicitly requested or agreed to being admitted to the SNF in the absence of a qualifying 3-day hospital stay if all other requirements for coverage are met. We therefore specifically seek comment on whether it is reasonable to hold SNFs that are SNF affiliates responsible for all claims that are rejected solely as a result of lack of a qualifying inpatient hospital stay. We also seek comment on whether the ACO rather than or in addition to the SNF affiliate, should be held liable for such claims and under what circumstances. We also seek comment on our proposal to modify the waiver under § 425.612(a)(1) to include a 90-day grace period for beneficiaries prospectively assigned to a waiver-approved ACO at the start of the performance year but later excluded. We seek comment on the proposed length of the grace period, and in particular whether the grace period should be less than 90 days, given our expectation that ACOs will share the quarterly beneficiary exclusion lists with their SNF affiliates, ACO participants, and ACO providers/suppliers in a timely manner. Finally, we seek comment on any other related issues that we should consider in connection with these proposals to protect beneficiaries from significant financial liability for non-covered SNF services related to the waiver of the SNF 3-day rule under the Shared Savings Program.

4. Technical Changes

a. Financial Reconciliation for ACOs That Fall Below 5,000 Assigned Beneficiaries

Section 1899(b)(2)(D) of the Act includes a requirement that a participating ACO must have a minimum of 5,000 Medicare FFS beneficiaries assigned to it. Currently, the regulations at § 425.110(b) indicate that if at any time during the performance year, an ACO's assigned population falls below 5,000, the ACO may be subject to the actions described in §§ 425.216 and 425.218; the regulations further indicate at § 425.110(b)(1) that while under a CAP, the ACO remains eligible for shared savings and losses and the MSR and MLR (if applicable) is set ''at a level consistent with the number of assigned beneficiaries.'' We have applied this rule in the past to perform financial reconciliation for ACOs that fell below 5,000 assigned beneficiaries. In these cases, the ACO was subject to a CAP and financial reconciliation was based on a variable MSR/MLR that was determined by the number of assigned beneficiaries. For example, we have calculated the ACO's MSR based on an expanded sliding scale that include a range of 3,000 to 4,999 assigned beneficiaries with a corresponding MSR range of 5.0 to 3.9 percent.

However, ACOs under risk-based tracks are not limited to financial reconciliation under a variable MSR/MLR that is based on the number of assigned beneficiaries. In the June 2015 final rule (see 80 FR 32769– 32771, and 32779–32780), we finalized a policy that provides ACOs under two-sided performance-based risk tracks with an opportunity to choose among several options for establishing their MSR/MLR. In addition to being able to choose a symmetrical MSR/MLR that varies based on the ACO's number of assigned beneficiaries, ACOs under two-sided performance-based risk tracks can also choose from a menu of non-variable MSR/MLR options (either a 0 percent MSR/MLR or a symmetrical MSR/MLR in a 0.5 percent increment between 0.5 through 2.0 percent).

We believe it is important to clarify the policy regarding situations where an ACO under a two-sided performance-based risk track has chosen a non-variable MSR/MLR at the start of the agreement period but has fallen below 5,000 assigned beneficiaries at the time of financial reconciliation. As discussed in detail in the June 2015 final rule, we continue to believe that ACOs under two-sided performance-based risk tracks are best positioned to determine the level of risk that they are prepared to accept. Therefore, we are proposing to update the regulations at § 425.110(b)(1) to be consistent with the regulatory changes in the June 2015 final rule that permit ACOs under a two-sided performance-based risk track (Track 2 and Track 3) to choose their own MSR/MLR from a menu of options. Specifically, we are proposing to update the regulations at § 425.110(b)(1) to indicate that in the event an ACO falls below 5,000 assigned beneficiaries at the time of financial reconciliation, the ACO participating under a two-sided risk track will be eligible to share in savings (or losses) and the MSR/MLR will be set at a level consistent with the choice of MSR/MLR that the ACO made at the start of the agreement period. If the Track 2 or Track 3 ACO selected a symmetrical MSR/MLR option based on a fixed percentage (for example, zero percent or a percentage between 0.5 and 2 percent) regardless of ACO size, then the current methodology for use of a variable MSR/MLR based on the ACO's number of assigned beneficiaries would not apply. For example, if at the beginning of the agreement period the ACO chose a 1.0 percent MSR/MLR and the ACO's assigned population falls below 5,000, the MSR/MLR will remain 1.0 percent for purposes of financial reconciliation while the ACO is under a CAP. Further, as we noted in earlier rulemaking, if the ACO has elected a variable MSR/MLR, the methodology for calculating the variable MSR/MLR under a two-sided model is consistent with the methodology for calculating the variable MSR that is required under the under the one-sided model (Track 1) (see 80 FR 32769 through 32771; 32779 through 32780). Under the one-sided shared savings model (Track 1), we have accounted for circumstances where an ACO's number of assigned beneficiaries falls below 5,000, by expanding the variable MSR range based on input from the CMS Office of the Actuary (OACT). Thus, in the case where a Track 2 or Track 3 ACO selects a variable MSR/MLR based on its number of assigned

beneficiaries, and the ACO's number of assigned beneficiaries falls below 5,000, we would continue to use an approach for determining the MSR/MLR range consistent with the approach for calculating the MSR range under the one-sided model.

b. Requirements for Merged or Acquired TINs

ACOs frequently request that we take into account the claims billed by the TINs of practices that have been acquired by sale or merger for the purpose of meeting the minimum assigned beneficiary threshold, establishing a more accurate financial benchmark, and determining the prospective or preliminary prospective assignment list for the upcoming performance year. In response to these inquiries, we initially developed subregulatory guidance that allowed claims billed under the TIN of a merged or acquired entity to be considered in certain circumstances. In that guidance we indicated that the merged or acquired entity's TIN may no longer be used to bill Medicare. In the June 2015 final rule, we codified the policies outlined in this guidance allowing for consideration of claims billed under merged or acquired entities' TINs for purposes of beneficiary assignment and establishing the ACO's benchmark, provided certain requirements were met (§§ 425.204(g), 425.118(a)(2)). However, the regulation at § 425.204(g) indicates that an ACO may request that CMS consider, for purposes of beneficiary assignment and establishing the ACO's benchmark under § 425.602, claims billed by ''Medicare-enrolled'' entities' TINs that have been acquired through sale or merger by an ACO participant. Because the regulation at § 425.204(g) refers to such merged or acquired TINs as ''Medicare-enrolled,'' we have received inquiries from ACOs regarding whether such merged or acquired TINs must continue to be Medicare-enrolled after the merger or acquisition has been completed and the TINs are no longer used to bill Medicare.

It was not our intent to establish such a requirement. We do not believe there would be a program purpose to require the TIN of a merged or acquired entity to maintain Medicare enrollment if it is no longer used to bill Medicare. Therefore, to address this issue, we are proposing a technical change to § 425.204(g) to clarify that the merged/acquired TIN is not required to remain Medicare enrolled after it has been merged or acquired and no longer used to bill Medicare.

L. Value-Based Payment Modifier and Physician Feedback Program

1. Overview

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. 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 program continue CMS' 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 MACRA 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 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 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.

3. Provisions of This Proposed Rule

As a general summary, we are proposing to update the VM informal review policies and establish how the quality and cost composites under the VM would be affected for the CY 2017 and CY 2018 payment adjustment periods in the event that unanticipated program issues arise.

a. Expansion of the Informal Inquiry Process To Allow Corrections for the VM

Section 1848(p)(10) of the Act provides that there shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

- The establishment of the VM.
- The evaluation of the quality of care composite, including the establishment of appropriate measures of the quality of care.
- The evaluation of the cost composite, including the establishment of appropriate measures of costs.
- The dates of implementation of the VM.
- The specification of the initial performance period and any other performance period.
- The application of the VM.
- The determination of costs.

These statutory requirements regarding limitations of review are reflected in § 414.1280. We previously indicated in the CY 2013 PFS final rule with comment period (77 FR 69326) that we believed an informal review mechanism is appropriate for groups of physicians to review and to identify any possible errors prior to application of the VM, and we established an informal inquiry process at § 414.1285.

In the CY 2015 PFS final rule with comment period (79 FR 67960), for the CY 2015 payment adjustment period, we finalized: (1) A February 28, 2015 deadline for a group to request

correction of a perceived error made by CMS in the determination of its VM; and (2) a policy to classify a TIN as ''average quality'' in the event we determined that we have made an error in the calculation of the quality composite. Beginning with the CY 2016 payment adjustment period: (1) We finalized a deadline of 60 days that would start after the release of the Quality and Resource Use Reports (QRURs) for the applicable performance period for a group or solo practitioner to request a correction of a perceived error related to the VM calculation, and (2) we stated we would take steps to establish a process for accepting requests from physicians to correct certain errors made by CMS or a third-party vendor (for example, PQRS-qualified registry). Our intent was to design this process as a means to recompute a TIN's quality composite and/or cost composite in the event we determine that we initially made an erroneous calculation. We noted that if the operational infrastructure was not available to allow this recomputation, we would continue the approach for the CY 2015 payment adjustment period to classify a TIN as ''average quality'' in the event we determine that we have made an error in the calculation of the quality composite. We finalized that we would recalculate the cost composite in the event that an error was made in the cost composite calculation. We noted that we would provide additional operational details as necessary in subregulatory guidance.

Moreover, for both the CY 2015 payment adjustment period and future adjustment periods, we finalized a policy to adjust a TIN's quality-tier if we make a correction to a TIN's quality and/or cost composites because of this correction process. We further noted that there is no administrative or judicial review of the determinations resulting from this expanded informal inquiry process under section 1848(p)(10) of the Act. In the CY 2015 PFS final rule for the CY 2016 payment adjustment period, we noted that if the operational infrastructure is not available to allow the recomputation of quality measure data we would continue the approach of the initial corrections process to classify a TIN as ''average quality'' in the event we determine a third-party vendor error or CMS made an error in the calculation of the quality composite.

In the CY 2016 PFS final rule with comment period (80 FR 71294 through 71295), for the CY 2017 and CY 2018 payment adjustment periods, we finalized a deadline of 60 days that would start after the release of the QRURs for the applicable performance period for a group or solo practitioner to request a correction of a perceived error related to the VM calculation. We also finalized the continuation of the process for accepting requests from groups and solo practitioners to correct certain errors made by CMS or a third-party vendor (for example, PQRS-qualified registry). We stated we would continue the approach of the initial corrections process to classify a TIN as ''average quality'' in the event we determine a third-party vendor error or CMS made an error in the calculation of the quality composite and the infrastructure was not available to allow for recomputation of the quality measure data. Additionally, we finalized that we would reclassify a TIN as Category 1 when PQRS determines on informal review that at least 50 percent of the TIN's EPs meet the criteria to avoid the PQRS downward payment adjustment for the relevant payment adjustment year. If the group was initially classified as Category 2, then we would not expect to have data for calculating their quality composite, in which case they would be classified as ''average quality''; however, if the data is available in a timely manner, then we would recalculate the quality composite.

As a result of issues that we became aware of prior to and during the CY 2016 VM informal review process that are discussed below, we have learned that re-running QRURs and recalculating the quality composite is not always practical or possible, given the diversity and magnitude of the errors, timing of when we become aware of an error, and practical considerations in needing to compute a final VM upward payment adjustment factor after the performance period has ended based on the aggregate amount of downward payment adjustments. Furthermore, this approach can create uncertainty for groups and solo practitioners about their final VM payment adjustment making it difficult for them to plan and make forecasts.

- *Electronic Health Record (EHR) and Qualified Clinical Data Registry (QCDR) Issues:* CMS was unable to determine the accuracy of PQRS data submitted via EHR and QCDR for the CY 2014 performance period due to data integrity issues. Consequently, if a group (as identified by its Medicare Taxpayer Identification Number (TIN)) or the EPs in a group reported PQRS measures *only* through the EHR or QCDR reporting mechanism, then the TIN's quality composite score for the CY 2016 VM was based on the TIN's performance on the CMS-calculated quality outcome measures and the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for PQRS survey measures (if applicable). If a TIN was classified as ''low quality'' based on its performance on these measures, then we reclassified the TIN as ''average quality.'' If the TIN's initial quality tier designation was ''average quality'' or ''high quality'', then that quality tier designation was retained. Without the additional PQRS data submitted via EHR and QCDR, we were concerned that a low quality designation based on the three CMS-calculated quality outcome measures and CAHPS for PQRS survey measures (if applicable) may not necessarily represent a TIN's quality performance If the TIN also reported PQRS measures for the CY 2014 performance period through reporting mechanisms other than EHR or QCDR, then those PQRS quality measures, along with CMS-calculated quality outcome measures, and CAHPS for PQRS survey measures (if applicable), were used to calculate the TIN's quality composite score for the CY 2016 VM.
- *Incomplete Claims Identification Issue:* After the release of the 2014 Annual QRURs in September 2015, we discovered a defect in the program used to identify the claims from CY 2014, which is the performance period for the VM CY 2016 payment adjustment period: Only claims from January 12 through December 31 were identified; claims from January 1 through January 11 were incorrectly omitted from 2016 VM calculations. These missing claims accounted for 2.73 percent of the CY 2014 claims. We re-ran all of the 2014 annual QRURs to correct this issue, including recalculating benchmarks and standard deviations for the cost measures to avoid disadvantaging groups as a result of using artificially low cost benchmarks. Of the approximately 13,800 TINs subject to the CY 2016 VM, 28 TINs received a lower VM and 8 TINs received a higher VM. There were also 27 TINs newly subject to the CY 2016 VM. Out of these 27 TINs, 12 were classified as Category 1 TINs and 15 were classified as Category 2 TINs. TINs were not held harmless from a lower VM resulting from these corrections. We notified the TINs that were affected by this issue.
- *Specialty Adjustment Issue:* In the course of performing quality assurance for the 2015 Mid-Year QRURs, we discovered a defect in the program used to specialty-adjust the cost measures. As a result of this defect, we determined that the CY 2016 VM for 28 TINs (out of approximately 13,800 TINs subject to the CY 2016 VM) were incorrectly calculated. Holding the benchmarks for the cost measures and the mean cost

composite score constant, 8 TINs would have had a lower VM and 20 TINs would have had a higher VM in CY 2016. We corrected the cost composite designation for the 20 TINs whose CY 2016 VM was higher after the recalculation and left the original cost composite designation for the 8 TINs whose VM was adversely affected by the recalculation.

Due to the volume and complexities of the informal review issues, the inconsistency of available PQRS data to calculate a TIN's quality composite, the case-by-case nature of the informal review process, and the condensed timeline to calculate an accurate VM upward payment adjustment factor, we believe that we need to update the VM informal review policies and establish in rulemaking how the quality and cost composites under the VM would be affected if unanticipated issues arise (for example, the program issues described above, errors made by a third-party such as a vendor, or errors in our calculation of the quality and/or cost composites). The intent of these proposals are not to provide relief for EPs and groups who fail to report under PQRS, but rather to provide a mechanism for addressing unexpected issues such as the data integrity issues discussed above.

Recalculating the quality composite is operationally complex, and does not align with the current timeline given the volume of informal reviews and the need to calculate the VM upward payment adjustment factor as close to the beginning of the payment adjustment period as possible. We want to close out as many informal reviews as possible before the VM upward payment adjustment factor is calculated, to lend confidence to the adjustment factor and to provide finality for the clinicians, and to minimize claims reprocessing. Limiting the potential movement of TINs between VM quality tiers based on informal review may result in a more accurate adjustment factor calculation and provide greater predictability for the CMS' Office of the Actuary (OACT) in making assumptions around the adjustment factor including assumptions around the impact of outstanding informal reviews at the time of the calculations. We believe that our proposals would help groups and solo practitioners to better predict the outcome of their final VM adjustment and reduce uncertainty as we continue to improve our systems.

Table 38 summarizes our proposals.

TABLE 38—PROPOSED QUALITY AND COST COMPOSITE STATUS FOR TINS DUE TO INFORMAL REVIEW DECISIONS AND WIDESPREAD QUALITY AND COST DATA ISSUES

	Scenario 1: TINS moving from Category 2 to Category 1 as a result of PQRS or VM informal review process		Scenario 2: Non-GPRO Category 1 TINs with additional EPs avoiding PQRS payment adjustment as a result of PQRS informal review process		Scenario 3: Category 1 TINs with widespread quality data issues		Scenario 4: Category 1 TINs with widespread claims data issues	
	Initial composite	Revised composite	Initial composite	Revised composite	Initial composite	Revised composite	Recalculated composite	Revised composite
Quality	N/A	Average	Low	Average	N/A	Average	Low	Average.
	N/A	Average	Average	Average	N/A	Average	Average	Average.
	N/A	Average	High	High	N/A	Average	High	High.
Cost	Low	Low	Low	Low	Low	Low	Low	Low.
	Average	Average	Average	Average	Average	Average	Average	Average.
	High	Average	High	High	High	Average	High	Average.

Scenario 1: TINs Moving From Category 2 to Category 1 as a Result of PQRS or VM Informal Review Process

For the CY 2017 VM, Category 1 will include those groups that meet the criteria to avoid the CY 2017 PQRS payment adjustment as a group practice participating in the PQRS Group Practice Reporting Option (GPRO) in CY 2015 and groups that have at least 50 percent of the group's EPs meet the criteria to avoid the CY 2017 PQRS payment adjustment as individuals (80 FR 71280). Category 1 also includes those solo practitioners that meet the criteria to avoid the CY 2017 PQRS payment adjustment as individuals. Category 2 will include groups and solo practitioners that are subject to the CY 2017 VM and do not fall within Category 1 (79 FR 67939). We finalized a similar two-category approach for the CY 2018 VM based on participation in the PQRS by groups and solo practitioners in 2016 (80 FR 71280 through 71281).

If a TIN is initially classified as Category 2, and subsequently, through the PQRS or VM informal review process, the TIN is classified as Category 1 then we propose to classify the TIN's quality composite as ''average quality'' instead of attempting to calculate the quality composite. We also propose to calculate the TIN's cost composite using the quality-tiering methodology. If the TIN is classified as ''high cost'' based on its performance on the cost measures, then we propose to reclassify the TIN's cost composite as ''average cost.'' If the TIN is classified as ''average cost'' or ''low cost'', then we propose that the TIN would retain the calculated cost tier designation. We note that in the CY 2016 PFS final rule with comment period (80 FR 71280), we finalized a policy for the CY 2017 and 2018 payment adjustment periods that when determining whether a group will be included in Category 1, we will consider whether the 50 percent threshold has been met regardless of whether the group registered to participate in the PQRS GPRO for the relevant performance period. We believe this policy will allow groups that register for a PQRS GPRO, but fail as a group to meet the criteria to avoid the PQRS payment adjustment an additional opportunity for the quality data reported by individual EPs in the group to be taken into account for the purposes of applying the VM. Consequently, because of this policy we anticipate that the number of TINs who could fall into Scenario 1 would be minimal; however, we believe it is necessary to have a policy in the event that CMS determines on informal review that Category 2 TINs were negatively impacted by a third-party vendor error or CMS made an error in the calculation of the quality composite. We propose to apply these policies for the CY 2017 VM and CY 2018 VM.

Calculating the quality composite for a TIN that was initially classified as Category 2 would be operationally complex given the timeline for determining and applying the VM adjustments for all TINs subject to the VM, the volume of informal reviews, the need to calculate the VM upward payment adjustment factor as close to the beginning of the payment adjustment period as possible, and uncertainty about the availability of the

PQRS quality data. Therefore, classifying the quality composite as ''average quality'' would offer a predictable decision for all informal reviews where a TIN changes classification from Category 2 to Category 1.

Our proposal to calculate the cost composite and assign ''average cost'' if the cost composite is initially classified as ''high cost'' would alleviate concerns from stakeholders that a TIN may receive a downward VM payment adjustment under the quality-tiering methodology as a result of being classified as average quality and high cost. Under our proposal discussed above, for TINs in Scenario 1, we would not consider a TIN's actual performance on the quality measures or calculate a quality composite score; rather, we would classify the TIN's quality composite as average quality for the reasons stated above. In this scenario, we do not believe that we should retain a TIN's ''high cost'' designation when the TIN's actual cost performance is not being compared to the TIN's actual quality performance, as it is possible the TIN might have scored high quality if actual performance had been considered. We believe that these proposals would help groups and solo practitioners to better predict the outcome of their final VM adjustment and reduce uncertainty about the impact of the informal review. Additionally, it is important to note that groups or solo practitioners who submit an informal review request would not automatically be covered by the policy proposed for Scenario 1. We would verify on informal review that the group or solo practitioner did submit complete and accurate data and did meet the criteria to avoid the PQRS payment adjustment to be included in Category 1.

We request comments on these proposals.

Scenario 2: Non-GPRO Category 1 TINs With Additional EPs Avoiding PQRS Payment Adjustment as a Result of PQRS Informal Review Process

For the CY 2017 VM, Category 1 will include groups that have at least 50 percent of the group's EPs meet the criteria to avoid the CY 2017 PQRS payment adjustment as individuals (80 FR 71280). A similar policy was finalized for the CY 2018 VM (80 FR 71280). If a TIN is classified as Category 1 for the CY 2017 VM by having at least 50 percent of the group's EPs meet the criteria to avoid the CY 2017 PQRS payment adjustment as individuals, and subsequently, through the PQRS informal review process, it is determined that additional EPs that are in the TIN also meet the criteria to avoid the CY 2017 PQRS payment adjustment as individuals, then we propose the following policies to determine the TIN's quality and cost composites:

- If the TIN's quality composite is initially classified as ''low quality'', then we propose to reclassify the TIN's quality composite as ''average quality.'' If the TIN's quality composite is initially classified as ''average quality'' or ''high quality'', then we propose that the TIN would retain that quality tier designation.
- We would maintain the cost composite that was initially calculated.

We propose to apply these policies for the CY 2017 VM and CY 2018 VM. Under these policies, we would not recalculate the TIN's quality composite to include the additional EPs that were determined to have met the criteria to avoid the PQRS payment adjustment as individuals through the PQRS informal review process. As discussed under Scenario 1, recalculating the quality composite is operationally complex, and we may not have PQRS data for the additional EPs because they did not meet the criteria to avoid the PQRS payment adjustment during the initial determination. In addition, we seek to avoid a situation where by recalculating the quality composite, a TIN may be subject to a lower quality tier designation because a few EPs in the TIN independently pursued PQRS informal reviews. As stated above, we are proposing to reclassify a TIN's quality composite as average quality if it is initially classified as ''low quality'' in order to avoid a situation where we do not have the PQRS quality data for those few EPs whose quality performance could have bumped the TIN up from a low quality designation as the EPs did not meet the criteria to avoid the PQRS payment adjustment during the initial determination. Additionally, it is important to note that TINs whose EPs submit an informal review request would not automatically be covered by the policy proposed for Scenario 2. We would verify on informal review that an EP did submit complete and accurate data and did meet the criteria to avoid the PQRS payment adjustment as an individual in order for the TIN to be included in Category 1.

We request comments on these proposals.

Scenario 3: Category 1 TINs With Widespread Quality Data Issues

In cases where there is a systematic issue with any of a Category 1 TIN's quality data that renders it unusable for calculating a TIN's quality composite, we propose to classify the TIN's quality composite as average quality. For this proposal, we consider widespread quality data issues, as issues that impact multiple TINs and we are unable to determine the accuracy of the data submitted via these TINs (for example, the EHR and QCDR issues for the CY 2014 performance period as described above). This proposal would offer a predictable designation for all TINs under this scenario.

We also propose to calculate the TIN's cost composite using the quality-tiering methodology. If the TIN is classified as ''high cost'' based on its performance on the cost measures, then we propose to reclassify the TIN's cost composite as ''average cost.'' If the TIN is classified as ''average cost'' or ''low cost'', then we propose that the TIN would retain the calculated cost tier designation. We propose to apply these policies for the CY 2017 VM and CY 2018 VM.

As discussed under Scenario 1, our proposal to calculate the cost composite and assign ''average cost'' if the cost composite is initially classified as ''high cost'' would alleviate concerns from stakeholders that a TIN may receive a downward VM payment adjustment under the quality-tiering methodology as a result of being classified as average quality and high cost. Similarly, for TINs in Scenario 3, we would not consider a TIN's actual performance on the quality measures or calculate a quality composite score; rather, we would classify the TIN's quality composite as average quality for the reasons stated above. In this scenario, we do not believe that we should retain a TIN's high cost designation when the TIN's actual cost performance is not being compared to the TIN's actual quality performance, as it is possible the TIN might have scored high quality if actual performance had been considered. We would continue to show and designate these groups as high cost in their annual QRURs so they have the opportunity to understand and improve their performance, but under our proposal, we would classify their cost composite as average cost for purposes of determining their VM adjustment. Additionally, it is important to note that groups or solo practitioners would only be covered by the policy proposed for Scenario 3 once we verify that the group or solo practitioner did submit complete and accurate data and did meet the criteria to avoid the PQRS payment adjustment in order to be included in Category 1.

We request comments on these proposals.

Further, we note that we expect quality data issues such as these to be

significantly limited moving forward. We have included new front-end edits to the data submission process to catch errors that result in such quality data issues early enough to be corrected. Additionally, we note that TINs are ultimately responsible for the data that are submitted by their third-party vendors and expect that TINs are holding their vendors accountable for accurate reporting. While we understand that data submission requirements are evolving and that both vendors and CMS are developing capabilities for reporting and assessing performance, we are considering further policies to promote complete and accurate reporting by registries and other third-party entities that submit data on behalf of groups and EPs.

Scenario 4: Category 1 TINs With Widespread Claims Data Issues

If we determine after the release of the Quality and Resource Use Reports (QRURs) that there is a widespread claims data issue that impacts the calculation of the quality and/or cost composites for Category 1 TINs, we propose to recalculate the quality and cost composites for affected TINs. For this proposal, we consider widespread claims data issues, as issues that impact multiple TINs and require the recalculation of the quality and/or cost composites (for example, the incomplete claims identification and specialty adjustment issues described above).

After recalculating the composites, if the TIN's quality composite is classified as low quality, then we propose to reclassify the quality composite as average quality, and conversely, if the TIN's cost composite is classified as high cost, we propose to reclassify the cost composite as average cost. If the TIN is classified as average quality, high quality, average cost or low cost, then we propose that the TIN would retain the calculated quality or cost tier designation. We are proposing to assign average quality if the quality composite is classified as low quality and assign average cost if the cost composite is classified as high cost after recalculating the quality and cost composites because, after a claims data issue is identified, it would take approximately 6 weeks to recalculate the composites and notify groups and solo practitioners about their recalculated VM. Given that the VM informal review period lasts for 60 days after the release of the QRURs and the timing of when we become aware of an error, we would likely not be able to notify groups and solo practitioners about their recalculated VM before the end of the informal review period. We believe these proposed policies are necessary to provide certainty for groups and solo practitioners about their final VM payment adjustment and due to the condensed timeline to calculate an accurate VM upward payment adjustment factor.

We propose to apply these policies for the CY 2017 VM and CY 2018 VM.

We request comments on these proposals.

The proposals described in this section would allow us to make predictable decisions as a result of informal reviews and unanticipated issues that may arise, providing greater certainty for groups and solo practitioners about impact of their results, as we foresee that several of the issues that impacted the CY 2016 VM, as described above, may continue to impact the CY 2017 and CY 2018 VM and/or new unanticipated issues may be identified. The proposals would also minimize the need to use PQRS data to recalculate the quality composite and prevent situations where we are making decisions on a case-by-case basis based on the TIN's PQRS reporting mechanism.

b. Application of the VM to Participant TINs in Shared Savings Program ACOs That Do Not Complete Quality Reporting

In the CY 2015 PFS final rule with comment period (79 FR 67946), for groups and solo practitioners, as identified by their TIN, that participate in a Shared Savings Program ACO, we finalized the same policy that is generally applicable to groups and solo practitioners that fail to satisfactorily report or participate under PQRS and thus fall in Category 2 and are subject to an automatic downward adjustment under the VM in CY 2017. We stated that, consistent with the application of the VM to other groups and solo practitioners that report under PQRS, if the ACO does not successfully report quality data as required by the Shared Savings Program under § 425.504, all groups and solo practitioners participating in the ACO will fall in Category 2 for the VM, and therefore, will be subject to a downward payment adjustment. We finalized this policy for the 2017 payment adjustment period for the VM. In the CY 2016 PFS proposed rule with comment period (80 FR 41899), we proposed to continue this policy in the CY 2018 payment adjustment period for all groups and solo practitioners subject to the VM that participate in a Shared Savings Program ACO and finalized our proposal in the CY 2016 PFS final rule (80 FR 71285).

As discussed in sections III.I. and III.L.1.e. of this proposed rule, we are proposing to remove the prohibition on EPs who are part of a group or solo practitioner that participates in a Shared Savings Program ACO, for purposes of PQRS reporting for the CY 2017 and CY 2018 payment adjustments, to report outside the ACO. As a result of this proposed policy, the EPs in groups and those who are solo practitioners would be allowed to report to the PQRS as a group (using one of the group registry, QCDR, or EHR reporting options) or individually (using the registry, QCDR, or EHR reporting option) outside of the ACO. This section addresses how we propose to use the PQRS data reported by EPs outside of the ACO for the CY 2018 VM when the ACO does not successfully report quality data on behalf of their EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504.

For the CY 2018 payment adjustment period, if a Shared Savings Program ACO does not successfully report quality data on behalf of their EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504, then we propose to use the data reported to the PQRS by the EPs (as a group (using one of the group registry, QCDR, or EHR reporting options) or as individuals (using the registry, QCDR, or EHR reporting option) under the participant TIN) outside of the ACO to determine whether the TIN would fall in Category 1 or Category 2 under the VM. We propose to apply the two-category approach finalized for the CY 2018 VM (80 FR 71280) 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. This proposed policy is consistent with our policy for groups and solo practitioners who are subject to the VM and do not participate in the Shared Savings Program, and we believe it would further encourage quality reporting by EPs in the event the ACO does not successfully report quality data as required by the Shared Savings Program under § 425.504. For example, if groups that participate in a Shared Savings Program ACO in 2016 report quality data to the PQRS outside of the ACO and meet the criteria to avoid PQRS payment adjustment for CY 2018 as a group using one of the group registry, QCDR, or EHR reporting options or have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals using the registry, QCDR, or EHR reporting option by

reporting quality data to PQRS outside of the ACO, then they would be included in Category 1 for the CY 2018 VM. If solo practitioners that participate in a Shared Savings Program ACO in 2016 report quality data to the PQRS outside of the ACO and meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals using the registry, QCDR, or EHR reporting option, then they would also be included in Category 1. Category 2 would include those groups and solo practitioners subject to the CY 2018 VM that participate in a Shared Savings Program ACO and do not fall within Category 1.

As finalized for the CY 2018 payment adjustment period (80 FR 71285), all groups and solo practitioners that participate in a Shared Savings Program ACO and fall in Category 2 will be subject to an automatic downward payment adjustment under the VM. For groups and solo practitioners that participate in a Shared Savings Program ACO that did not successfully report quality data as required by the Shared Savings Program under § 425.504 and are in Category 1 as a result of reporting quality data to the PQRS outside of the ACO, we propose to classify their quality composite for the VM for the CY 2018 payment adjustment period as ''average quality.'' As finalized in the CY 2015 PFS final rule with comment period (79 FR 67943), the cost composite for groups and solo practitioners that participate in a Shared Savings Program ACO will be classified as ''average cost.'' Because we would not have the ACO's quality data for these groups and solo practitioners, we believe it would be appropriate to use the quality data they reported to the PQRS outside the ACO to determine whether they avoided the PQRS payment adjustment and whether they would be in Category 1 or 2 for purposes of the VM, but not to calculate a quality composite using the quality-tiering methodology. As we stated previously, we continue to believe that it is appropriate to calculate a quality composite for groups and solo practitioners participating in the Shared Savings Program based on the ACO's quality data (79 FR 67944). This proposal is not intended to encourage groups and solo practitioners that participate in a Shared Savings Program ACO to report to the PQRS outside the ACO, but in the event the ACO does not successfully report quality data on behalf of their EPs for purposes of PQRS, to provide them with a safeguard that would allow them to avoid the PQRS payment adjustment and the automatic downward adjustment under the VM. We encourage groups and solo practitioners to continue to report through the ACO in order to promote clinical and financial integration within the ACO and for the Medicare beneficiaries they treat. For groups and solo practitioners that participate in a Shared Savings Program ACO that successfully reports quality data on behalf of their EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504, we will calculate their VM for the CY 2018 payment adjustment period according to the policies established in the CY 2015 PFS final rule with comment period (79 FR 67941 to 67947 and 79 FR 67956 to 67957) and CY 2016 PFS final rule with comment period (80 FR 71283 to 71286 and 80 FR 71294). We solicit comment on these proposals. We are also proposing corresponding revisions to § 414.1210(b)(2).

As discussed in section III.H. of this proposed rule, to allow affected EPs that participate in an ACO to report separately for the CY 2017 PQRS payment adjustment, we are proposing a secondary PQRS reporting period for EPs that were in an ACO that did not successfully report quality data on behalf of the EPs in the group and those who are solo practitioners. Specifically, we are proposing that affected individual EPs or groups, who report under an ACO, may separately report outside the ACO either as individual EPs (using the registry, QCDR, or EHR reporting option) or using one of the group registry, QCDR, or EHR reporting options (note these EPs and groups would not need to register for one of these group reporting options, but rather mark the data as group data in their submission) during a secondary PQRS reporting period for the CY 2017 PQRS payment adjustment if they were a participant in an ACO that did not successfully report quality data on their behalf during the established reporting period for the CY 2017 PQRS payment adjustment. We are proposing the secondary PQRS reporting period for the CY 2017 PQRS payment adjustment would coincide with the reporting period for the CY 2018 PQRS payment adjustment (that is, January 1, 2016 through December 31, 2016).

This section addresses how we propose to use, for purposes of the CY 2017 VM, the PQRS data reported by the EPs in the group and those who are solo practitioners outside of the ACO using the secondary PQRS reporting period when the ACO did not successfully report quality data on behalf of their EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504 for the CY 2017 PQRS payment adjustment. For the CY 2017 payment adjustment period, if a Shared Savings Program ACO did not successfully report quality data on behalf of their EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504 for the CY 2017 PQRS payment adjustment, then we propose to use the data reported to the PQRS by the EPs (as a group using one of the group registry, QCDR, or EHR reporting options or as individuals using the registry, QCDR, or EHR reporting option) under the participant TIN) outside of the ACO during the secondary PQRS reporting period to determine whether the TIN would fall in Category 1 or Category 2 under the VM. We propose to apply the two-category approach finalized for the CY 2017 VM (79 FR 67938 to 67939 and as revised in 80 FR 71280 to 71281) 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. In section III.H. of this proposed rule, we are proposing to 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. Therefore, we propose that groups that meet the criteria to avoid PQRS payment adjustment for CY 2018 as a group practice participating in the PQRS GPRO (using one of the group registry, QCDR, or EHR reporting options) or have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals (using the registry, QCDR, or EHR reporting option), based on data submitted outside the ACO and during the secondary PQRS reporting period, would be included in Category 1 for the CY 2017 VM. We also propose that solo practitioners that meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals using the registry, QCDR, or EHR reporting option, based on data submitted outside the ACO and during the secondary PQRS reporting period, would be included in Category 1 for the CY 2017 VM. Category 2 would include those groups and solo practitioners subject to the CY 2017 VM that participate in a Shared Savings Program ACO and do not fall within Category 1.

As finalized for the CY 2017 payment adjustment period (79 FR 67946), all groups and solo practitioners that

participate in a Shared Savings Program ACO and fall in Category 2 will be subject to an automatic downward payment adjustment under the VM. For groups and solo practitioners that participate in a Shared Savings Program ACO that did not successfully report quality data as required by the Shared Savings Program under § 425.504 and are in Category 1 as a result of reporting quality data to the PQRS outside of the ACO using the secondary PQRS reporting period, we propose to classify their quality composite for the VM for the CY 2017 payment adjustment period as ''average quality'' for the same reasons described above for the CY 2018 payment adjustment period. As finalized in the CY 2015 PFS final rule with comment period (79 FR 67943), the cost composite for groups and solo practitioners that participate in a Shared Savings Program ACO will be classified as ''average cost.''

If EPs who are part of a group or a solo practitioner that participated in a Shared Savings Program ACO in 2015 that did not successfully report quality data on their behalf decide to use the secondary PQRS reporting period, it is important to note that such groups and solo practitioners should expect to be initially classified as Category 2 and receive an automatic downward adjustment under the VM for items and services furnished in CY 2017 until CMS is able to determine whether the group or solo practitioner met the criteria to avoid the PQRS payment adjustment as described above. First, we would need to process the data submitted for 2016. Second, we would need to determine whether or not the group or solo practitioner would be classified as Category 1 or Category 2 for the CY 2017 VM and notify the group or solo practitioner if there is a change in the VM status. Third, we would need to update the group or solo practitioner's status so that they will stop receiving an automatic downward adjustment under the VM for items and services furnished in CY 2017 and reprocess all claims that were previously paid. Since groups and solo practitioners taking advantage of this secondary reporting period for the 2017 VM will have missed the deadline for submitting an informal review request for the 2017 VM, we propose the informal review submission periods for these groups and solo practitioners would occur during the 60 days following the release of the QRURs for the 2018 VM.

We request comment on these proposals. We are also proposing corresponding revisions to § 414.1210(b)(2).

M. Physician Self-Referral Updates

1. Unit-Based Compensation in Arrangements for the Rental of Office Space or Equipment

a. The Physician Self-Referral Statute and Regulations

(1) Section 1877 of the Act

Section 6204 of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239) (OBRA 1989), enacted on December 19, 1989, added section 1877 to the Act. Section 1877 of the Act, also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. The statute establishes a number of specific exceptions, and grants the Secretary the authority to create regulatory exceptions for financial relationships that pose no risk of program or patient abuse. Additionally, the statute mandates refunding any amount collected under a bill for an item or service furnished under a prohibited referral. Finally, the statute imposes reporting requirements and provides for sanctions, including civil monetary penalty provisions. Section 1877 of the Act became effective on January 1, 1992.

Section 4207(e) of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) (OBRA 1990), enacted on November 5, 1990, amended certain provisions of section 1877 of the Act to clarify definitions and reporting requirements relating to physician ownership and referrals and to provide an additional exception to the prohibition. Several subsequent laws further changed section 1877 of the Act. Section 13562 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66) (OBRA 1993), enacted on August 10, 1993, expanded the referral prohibition to cover certain other ''designated health services'' in addition to clinical laboratory services, modified some of the existing statutory exceptions, and added new exceptions. Section 152 of the Social Security Act Amendments of 1994 (SSA 1994) (Pub. L. 103–432), enacted on October 31, 1994, amended the list of designated health services, changed the reporting requirements at section 1877(f) of the Act, and modified some of the effective dates established by OBRA 1993. Some provisions relating to referrals for clinical laboratory services were effective retroactively to January 1, 1992, while other provisions became effective on January 1, 1995.

(2) Regulatory History

(a) General Background

The following discussion provides a chronology of our more significant and comprehensive rulemakings; it is not an exhaustive list of all rulemakings related to the physician self-referral law.

Following the passage of section 1877 of the Act, we proposed rulemakings in 1992 (related only to referrals for clinical laboratory services) (57 FR 8588) (the 1992 proposed rule) and 1998 (addressing referrals for all DHS) (63 FR 1659) (the 1998 proposed rule). We finalized the proposals from the 1992 proposed rule in 1995 (60 FR 41914) (the 1995 final rule), and issued final rules following the 1998 proposed rule in three stages. The first final rulemaking (Phase I) was published in the January 4, 2001 **Federal Register** (66 FR 856) as a final rule with comment period. The second final rulemaking (Phase II) was published in the March 26, 2004 **Federal Register** (69 FR 16054) as an interim final rule with comment period. Due to a printing error, a portion of the Phase II preamble was omitted from the March 26, 2004 **Federal Register** publication. That portion of the preamble, which addressed reporting requirements and sanctions, was published on April 6, 2004 (69 FR 17933). The third final rulemaking (Phase III) was published in the September 5, 2007 **Federal Register** (72 FR 51012) as a final rule. In addition to Phase I, Phase II, and Phase III, we issued final regulations on August 19, 2008 in the ''Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates'' final rule with comment period (73 FR 48434) (the FY 2009 IPPS final rule). That rulemaking made various revisions to the physician self-referral regulations, including provisions that prohibited certain per unit-of-service (often referred to as ''per-click'') and percentage-based compensation formulas for determining the rental charges for office space and equipment lease arrangements.

We issued additional final regulations after passage of the Affordable Care Act. In the CY 2011 PFS final rule with comment period (75 FR 73170), we codified a disclosure requirement established by the Affordable Care Act for the in-office ancillary services exception. We also issued regulations in the CY 2011 OPPS final rule with comment period (75 FR 71800), the CY

2012 OPPS final rule with comment period (76 FR 74122), and the CY 2015 OPPS final rule with comment period (79 FR 66770) that established or revised certain regulatory provisions concerning physician-owned hospitals to codify and interpret the Affordable Care Act's revisions to section 1877 of the Act. Finally, in the CY 2016 PFS final rule (80 FR 70886), we issued regulations to accommodate delivery and payment system reform, reduce burden, and to facilitate compliance. In that rulemaking, we established two new exceptions, clarified certain provisions of the physician self-referral law, updated regulations to reflect changes in terminology, and revised definitions related to physician-owned hospitals. One of the new exceptions, the exception for timeshare arrangements at § 411.357(y), includes a prohibition on certain per unit-of-service compensation formulas.

(b) Unit-Based Compensation

We have addressed the issue of unit-based compensation in several rulemakings. Sections 1877(e)(1)(A)(iv) and (B)(iv) of the Act provide that, for an arrangement for the rental of office space or equipment to satisfy the relevant exceptions to the physician self-referral law, the rental charges over the term of the lease must be set in advance, be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. Interpreting this ''volume or value'' standard in the 1998 proposed rule, we proposed that compensation could be based on units of service (for example, ''per-use'' equipment rentals) provided that the units of service did not include services provided to patients who were referred by the physician receiving the payment. For example, a physician who owned a lithotripter could rent it to a hospital on a per-procedure basis, except for lithotripsies for patients referred by the physician owner. Instead, payments for the use of the lithotripter for those patients would have to use a methodology that did not vary with referrals. (63 FR 1714; *see also* 66 FR 876). We further proposed that arrangements in which a physician rents equipment to an entity that furnishes a designated health service, such as a hospital that rents an MRI machine, with the physician receiving rental payments on a ''per-use'' or ''per-click'' basis (that is, a rental payment is generated each time the machine is used) do not prohibit the physician from otherwise referring to the entity, provided that these kinds of arrangements are typical and comply with the fair market value and other standards that are included under the rental exception. However, because a physician's compensation under this exception cannot reflect the volume or value of the physician's own referrals, we proposed that the rental payments may not reflect ''per-use'' or ''per-click'' payments for patients who are referred for the service by the physician lessor. (63 FR 1714)

After reviewing the public comments in response to the 1998 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) Importantly, we permitted unit-based compensation formulas, even when the physician receiving the payment has generated the payment through a DHS referral. To reach this position, we reviewed the legislative history with respect to the statutory exceptions for the rental of office space and equipment and concluded that Congress intended that unit-of-service-based payments be protected under certain circumstances. (66 FR 878) Specifically, with respect to the exceptions for the rental of office space and equipment, the Conference Committee report, H. Rep. No. 213, 103rd Cong., 1st Sess. (1993) (the House Conference Report) states at page 814 that the conferees ''intend[ed] that rental charges for [office] space and equipment leases may be based on daily, monthly, or other time-based rates, or rates based on units of service furnished, so long as the amount of the time-based or units of service rates does not fluctuate during the contract period based on the volume or value of referrals between the parties to the lease or arrangement.'' However, we stated our unequivocal belief that arrangements in which the lessor is compensated each time that the lessor refers a patient to the lessee for a service performed in the leased office space or using the leased equipment have an obvious potential for abuse and could incent overutilization (66 FR 878). We indicated that we would continue to monitor financial arrangements in the health care industry and would revisit particular regulatory decisions if we determine that there has been abuse or overutilization (66 FR 860).

In the CY 2008 PFS proposed rule (72 FR 38122), we stated that arrangements between a physician lessor and an entity lessee under which the physician lessor receives unit-of-service payments are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee. We proposed that space and equipment leases may not include per-click payments to a physician lessor for services rendered by an entity lessee to patients who are referred by a physician lessor to the entity (72 FR 38183). We also solicited comments on the question of whether we should prevent per-click payments in situations in which the physician is the lessee and a DHS entity is the lessor. The CY 2008 PFS proposed rule also included eight other significant proposed revisions to the physician self-referral regulations. Due to the large number of physician self-referral proposals, the significance of the provisions both individually and in concert with each other, and the volume of public comments received in response to the CY 2008 PFS proposed rule, we declined to finalize our proposals, including our proposal to prohibit certain per unit-of-service compensation formulas in arrangements for the rental of office space and equipment, in the CY 2008 PFS final rule (72 FR 66222).

After consideration of the public comments and our independent research, we finalized regulations prohibiting certain per-unit of service compensation formulas for determining office space and equipment rental charges in the FY 2009 IPPS final rule (73 FR 48434). Specifically, we revised § 411.357(a)(4) and (b)(4) to prohibit rental charges for the rental of office space or equipment that are determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. In doing so, we relied on our authority in section 1877(e)(1)(A)(vi) and (B)(vi) of the Act, which permits the secretary to impose by regulation other requirements needed to protect against program or patient abuse. We also revised the exceptions at §§ 411.357(l) and (p) for fair market value compensation and indirect compensation arrangements, respectively, to include similar limitations on the formula for determining office space and equipment rental charges, as applicable. We did so using our authority at section 1877(b)(4) of the Act, as those exceptions were established using that authority. (*See* 73 FR 48713 through 48721) We determined it necessary to limit the type

of per-click compensation formulas available for arrangements for the rental of office space and equipment because we believe that arrangements under which a lessor receives unit-of-service payments are inherently susceptible to abuse. Specifically, we believe that the lessor has an incentive to profit from referring a higher volume of patients to the lessee and from referring patients to the lessee that might otherwise go elsewhere for services.

b. Development of This Rulemaking

(1) Council for Urological Interests v. Burwell

On June 12, 2015, the D.C. Circuit (the Court) issued an opinion in *Council for Urological Interests* v. *Burwell,* 790 F.3d 212 (D.C. Cir. 2015), that addressed the prohibition on per-click rental charges for the lease of equipment found at § 411.357(b)(4)(ii)(B). In its ruling, the Court agreed with CMS that section 1877(e)(1)(B)(vi) of the Act provides the Secretary the authority to prohibit per-click leasing arrangements. The Court concluded that—

> The text of the statute does not unambiguously preclude the Secretary from using her authority to add a requirement that bans per-click leases. To the contrary, the statutory text of the exception clearly provides the Secretary with the discretion to impose any additional requirements that she deems necessary ''to protect against program or patient abuse.'' (*Council for Urological Interests,* 790 F.3d at 219.)

The Court further concluded that the relevant language in the House Conference Report merely interpreted section 1877(e)(1)(B)(iv) of the Act, and thus did not preclude CMS from imposing additional requirements under section 1877(e)(1)(B)(vi) of the Act. It stated that the legislative history ''simply indicates that, as written, the rental-charge clause [in section 1877(e)(1)(B)(iv) of the Act] does not preclude per-click leases'' and stated further that ''[n]othing in the legislative history suggests a limit on [the Secretary's] authority to prohibit per-click leases under section 1877(e)(1)(B)(vi) of the Act).'' *Id.* at 222.

The Court also concluded, however, that CMS's discussion of the House Conference Report in the FY 2009 IPPS final rule contained an unreasonable interpretation of the conferees' statements concerning sections 1877(e)(1)(A)(iv) and (B)(iv) of the Act, and it remanded the case to the agency to permit a fuller consideration of the legislative history. This rulemaking addresses that decision.

(2) The FY 2009 IPPS Final Rule

As discussed above, in the FY 2009 IPPS final rule, we revised the exceptions for the rental of office space and equipment to include in each a requirement that the rental charges for the office space or equipment are not determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. We explained that our decision to add this requirement was ultimately based on our authority under section 1877(e)(1)(B)(vi) of the Act to promulgate ''other requirements'' needed to protect against program or patient abuse. However, we also discussed certain legislative history contained in the House Conference Report addressing sections 1877(e)(1)(A)(iv) and 1877(e)(1)(B)(iv) of the Act, which establish requirements that rental charges over the term of a lease for office space or rental equipment be set in advance, be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. With respect to those statutory conditions, the language in the House Conference Report states that—

> The conferees intend that charges for space and equipment leases may be based on daily, monthly, or other time-based rates, or rates based on units of service furnished, so long as the amount of time-based or units of service rates does not fluctuate during the contract period based on the volume or value of referrals between the parties to the lease or arrangement. (H.R. Rep. No. 103–213, at 814 (1993).)

In the FY 2009 IPPS final rule, we noted that CMS had previously concluded that this language indicated that Congress intended to permit leases that included per-click payments, even for patients referred by the physician lessor (66 FR 940), but asserted that the language could also be interpreted as excluding from the office space and equipment lease exceptions those lease arrangements that include per-click payments for services provided to patients referred from one party to the other (73 FR 48716). Specifically, we stated that, where the total amount of rent (that is, the rental charges) over the term of the lease is directly affected by the number of patients referred by one party to the other, those rental charges can arguably be said to ''take into account'' or ''fluctuate during the contract period based on'' the volume or value of referrals between the parties. The Court found this revised interpretation to be an unreasonable reading of the language of the House Conference Report. The Court remanded § 411.357(b)(4)(ii)(B) to the Secretary for further proceedings consistent with its opinion, and directed that the Secretary should consider whether a ban on per-click equipment leases is consistent with the House Conference Report.

c. Re-proposal of Limitation on the Types of Per-Unit of Service Compensation Formulas for Determining Office Space and Equipment Rental Charges

In this proposed rule, we are re-proposing certain requirements for arrangements involving the rental of office space or equipment. Specifically, using the same language in existing §§ 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B), we are proposing to include at §§ 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B) a requirement that rental charges for the office space or equipment are not determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. We are using the authority granted to the Secretary in sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act to re-propose this requirement in the exceptions at § 411.357(a) and (b) for the rental of office space and equipment, respectively. We are using the authority granted to the Secretary in section 1877(b)(4) of the Act to re-propose this requirement in the exceptions at § 411.357(l) and (p) for fair market value compensation and indirect compensation arrangements, respectively.

We emphasize that we are not proposing an absolute prohibition on rental charges based on units of service furnished. In general, per-unit of service rental charges for the rental of office space or equipment are permissible. We are proposing to limit the general rule by prohibiting per-unit of service rental charges where the lessor generates the payment from the lessee through a referral to the lessee for a service to be provided in the rented office space or using the rented equipment. Thus, per-unit of service rental charges for the rental of office space or equipment would be permissible, but only in those instances where the referral for the service to be provided in the rented office space or using the rented equipment did not come from the lessor.

(1) Authority

In accordance with the Court's opinion in *Council for Urological*

Interests, we set forth below the Secretary's authority to include in the exceptions applicable to office space and equipment leases a requirement that rental charges are not determined using a formula based on per-unit of service rental charges that reflect services provided to patients referred by the lessor to the lessee. Our determination follows the Court's reasoning, which we excerpt below, in rejecting the Council for Urological Interests' assertion that the Secretary lacks the authority to impose a ban on ''per-click'' equipment—and by correlation—office space leases. We also describe why limiting the types of per-click rental charges that would not violate the physician self-referral law's referral and claims submission prohibitions is consistent with the language of the House Conference Report.

As the Court stated, the physician self-referral law gives the Secretary power to add requirements as needed to protect against program or patient abuse, even if Congress did not anticipate such abuses at the time of enactment of the statute. Specifically, although Congress may not have originally included a ban on per-click rental charges in office space and equipment lease arrangements, it ''empowered the Secretary to make her own assessment of the needs of the Medicare program and regulate accordingly.'' (*Council for Urological Interests,* 790 F.3d at 220.) The statute explicitly permits the Secretary to impose additional conditions on arrangements for the rental of office space or equipment, and nowhere expressly states that per-click rates must always be permitted. Thus, as the Court confirmed, the Secretary's regulation ''can properly be classified as an 'other' requirement expressly permitted by sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act.'' (*Id.*)

The Secretary's authority to impose requirements regarding the type of compensation formulas upon which office space and equipment rental charges may be based is not constrained by the House Conference Report. As discussed elsewhere in this proposed rule, we acknowledge that the language in the House Conference Report states Congress' intent at the time of enactment of the physician self-referral law that sections 1877(e)(1)(A)(iv) and (B)(iv) of the Act not be interpreted as prohibiting charges for the rental of office space or equipment that are based on units of service furnished. We do not purport here to interpret this language as implying anything other than the conferees' understanding—at the time of enactment of the statute—that the statute as written did not prohibit rental charges based on units of service rates. But Congress also gave the Secretary the authority in sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act to impose by regulation other requirements as needed to protect against program or patient abuse, which could only happen *after* the enactment of the statute. Nowhere in the House Conference Report did Congress express an intent to limit the authority granted to the Secretary in sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act (as enacted). In fact, the House Conference Report was completely silent regarding sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act, leaving the express words of the statute to speak for themselves. As the Court noted—

> The conference report . . . states only that rental charges ''may'' be based on units of service. The language is not obligatory. Instead, it simply indicates that, as written, the rental-charge clause [(section 1877(e)(1)(B)(iv) of the Act)] does not preclude per-click leases. But, as we have already explained, there is more to the statute than this clause, and to qualify for the exception, a rental agreement must comply with all six clauses, not merely the rental-charge clause alone. The final clause [(section 1877(e)(1)(B)(vi) of the Act)] gives the Secretary the authority to add further requirements. Nothing in the legislative history suggests a limit on this authority. We conclude that the statute does not unambiguously forbid the Secretary from banning per-click leases as she evaluates the needs of the Medicare system and its patients. (790 F.3d at 221–22 (*footnote omitted*))

Moreover, as the Court further noted, a statement that unit of service-based rental charges are not precluded by sections 1877(e)(1)(A)(iv) and (B)(iv) of the Act as they are written is not equivalent to a statement that the Secretary must continue to permit such charges as she reevaluates, in light of experience, the operation of the statute and the need to protect the Medicare program and its beneficiaries against abuse. (*Id.* at 222 n.7; *see also id.* at 222 n.6 (''Congress has expressly delegated to the Secretary the authority to promulgate additional requirements, as she has done here, and the legislative history does not clearly impose a constraint on that power.'')).

The Secretary has broad authority under sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act to impose conditions on arrangements for the rental of office space or equipment in order to protect against program or patient abuse. That authority is not limited by the express words of the statute as it is in other provisions of section 1877 of the Act. In agreement, the Court in *Council for Urological Interests* explained—

> . . . Congress knew how to limit the Secretary's authority to impose additional requirements to the various exceptions [to the physician self-referral law]. In [section 1877(e)(2) of the Act], Congress excludes bona fide employment relationships from the definition of compensation arrangements. This provision states that the employment relationship must comply with various requirements, including that the pay not be determined ''in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.'' This employment exception also allows the Secretary to impose ''other requirements,'' just as the equipment rental exception. But the statute then goes on to say that the listed requirements ''shall not prohibit the payment of remuneration in the form of a productivity bonus based on services performed personally by the physician.'' This language shows that Congress knew how to cabin the Secretary's authority to impose ''other'' requirements and that it knew how to further clarify what it meant by compensation that does not take into account the volume of business generated between parties. That Congress employed neither of these tools with reference to the [exception for the rental of office space or equipment] again supports reading the statute as giving the Secretary broad discretion as she regulates in this area. (790 F.3d at 221 (citations omitted))

The Secretary's authority to limit the use of per-unit of service rental charges in arrangements for the rental of office space or equipment is particularly clear when the exceptions for the rental of office space and equipment are compared to other provisions in section 1877 of the Act. According to the Court in *Council for Urological Interests*—

> [T]he statute elsewhere expressly permits charging per-click fees in other contexts, showing that Congress knew how to authorize such payment terms when it wanted to. In [section 1877(e)(7)(A) of the Act], Congress created an exception to the [physician self-referral law] that allows the continuation of certain group practice arrangements with a hospital. . . . The provision states that ''[a]n arrangement between a hospital and a group under which designated health services are provided by the group but are billed by the hospital'' is excepted from the ban on referrals if, among other things, ''the compensation paid over the term of the agreement is consistent with fair market value and the compensation *per unit of services* is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.'' Comparing this provision to the [exceptions for the rental of office space and equipment] shows that Congress knew how to permit per-click payments explicitly, suggesting that the omission in this particular context was deliberate. . . . In other words, Congress's decision not to include similar language in the [exceptions for the rental of

office space and equipment] supports our conclusion that the statute is silent regarding the permissibility of per-click leases for equipment rentals. (790 F.3d at 220–21 (citations omitted))

In summary, as we stated in the FY 2009 IPPS final rule (73 FR 48716), the physician self-referral statute responds to the context of the times in which it was enacted (by addressing known risks of overutilization and, in particular, by creating exceptions for common business arrangements), and also incorporates sufficient flexibility to adapt to changing circumstances and developments in the health care industry. For example, in section 1877(b)(4) of the Act, Congress authorized the Secretary to protect additional beneficial arrangements by promulgating new regulatory exceptions. In addition, Congress included the means to address evolving fraud risks by inserting into many of the exceptions—and notably, for our purposes, in the lease exceptions—specific authority for the Secretary to add conditions as needed to protect against abuse. This design reflects a recognition that a fraud and abuse law with sweeping coverage over most of the health care industry could not achieve its purpose over the long term if it were frozen in time. In short, the statute evidences Congress' foresight in anticipating that the nature of fraud and abuse—and of beneficial industry arrangements—might change over time. (73 FR 48716 (citations omitted))

As we did in 2007 when we first proposed to impose additional requirements for rental charges in arrangements for the rental of office space and equipment, and in 2008 when we finalized regulations incorporating such additional requirements, we are relying in this proposal on the Secretary's clear authority in sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act to impose such other requirements needed to protect against program or patient abuse. With respect to our proposal to include the same requirements at § 411.357(l) and (p), we have determined that the proposed revisions to § 411.357(l) and (p) are necessary to meet the standard set forth in section 1877(b)(4) of the Act, which authorizes the Secretary to establish exceptions to the statute's referral and billing prohibitions only where the excepted financial relationships do not pose a risk of program or patient abuse.

(2) Rationale for Proposal

As we discussed in prior rulemakings, including the 1998 proposed rule, a number of studies prior to the enactment of the physician self-referral law found that physicians who had financial relationships with entities to which they referred patients ordered more services than physicians without such financial relationships (63 FR 1661). Studies conducted since that time, including recent studies by GAO, indicate that financial self-interest continues to affect physicians' medical decision making.

In the FY 2009 IPPS final rule, we discussed in detail our rationale for finalizing the limitation on per-unit of service rental charges in arrangements for the rental of office space or equipment. We noted primary concerns regarding the potential for overutilization, patient steering and other anti-competitive effects, and reduction in quality of care and patient outcomes, as well as concerns regarding the potential for increased costs to the Medicare program. For the reasons set forth in the FY 2009 IPPS final rule, some of which are restated below, we believe that, in order to protect against program or patient abuse, it is necessary to impose additional requirements on arrangements for the rental of office space or equipment. Specifically, we believe that it is necessary to prohibit rental charges that are determined using a formula based on per-unit of service rental charges to the extent that such charges reflect services provided to patients referred by the lessor to the lessee of the office space or equipment.

Commenters responding to our proposal in the CY 2008 PFS proposed rule to impose additional requirements for office space and equipment lease arrangements provided compelling information regarding potential program or patient abuse. We were persuaded in 2008 to finalize requirements limiting per-unit of service rental charges in the exceptions applicable to the rental of office space or equipment, and believe today that these requirements continue to be necessary, due to our concerns that ''per-click'' lease arrangements in which the lessor makes referrals to the lessee that generate payments to the lessor—

- Creates an incentive for overutilization of imaging services (as described by MedPAC in its comments to our proposal in the CY 2008 PFS proposed rule), as well as other services, including therapeutic services;
- Creates an incentive for physicians to narrow their choice of treatment options to those for which they will realize a profit, even where the best course of action may be no treatment;
- Influence physicians to refer to the lessee instead of referring to another entity that utilizes the same or different (and perhaps more efficacious) technology to treat the patient's condition;
- Result in physicians steering patients to equipment they own, even if it means having the patient travel to a non-convenient site for services using the leased equipment; and
- Increase costs to the Medicare program when referring physicians pressure hospitals to use their leasing company despite not being the low cost provider.

Most recently, in the CY 2016 PFS final rule, we expressed our continued concern that, when physicians have a financial incentive to refer a patient to a particular entity, this incentive can affect utilization, patient choice, and competition. Physicians can overutilize by ordering items and services for patients that, absent a profit motive, they would not have ordered. A patient's choice is diminished when physicians steer patients to less convenient, lower quality, or more expensive providers of health care, just because the physicians are sharing profits with, or receiving remuneration from, the providers. And lastly, where referrals are controlled by those sharing profits or receiving remuneration, the medical marketplace suffers if new competitors cannot win business with superior quality, service, or price (80 FR 41926). In that rule, in establishing the exception at § 411.357(y) for timeshare arrangements, we determined it necessary to exclude from the exception any timeshare arrangements that incorporate compensation formulas based on: (1) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the timeshare; or (2) per-unit of service fees, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the timeshare to the party to which the permission is granted. We explained our belief that timeshare arrangements based on percentage compensation or per-unit of service compensation formulas present a risk of program or patient abuse because they may incentivize overutilization and patient steering. We noted, by way of example, that a per-patient compensation formula could incent the timeshare grantor to refer patients (potentially for unnecessary consultations or services) to the party using the timeshare because the grantor will receive a payment each time the premises, equipment, personnel, items, supplies, or services are used. (80 FR 71331 through 71332) Similarly, we believe that arrangements utilizing rental charges for the rental of office space or equipment that are determined

using a formula that rewards the lessor for each service the lessor refers to the lessee are susceptible to this and other abuse.

Finally, we note that we are not alone in our concern regarding overutilization and steering of beneficiaries resulting from arrangements in which a physician's referral may provide future remuneration back to the physician. In two notable advisory opinions, OIG expressed its concern with per-unit of service compensation arrangements. Specifically, in Advisory Opinion 03–08, OIG stated that '' '[p]er patient,' 'per click,' 'per order,' and similar payment arrangements with parties in a position, directly or indirectly, to refer or recommend an item or service payable by a federal health care program are disfavored under the anti-kickback statute. The principal concern is that such arrangements promote overutilization . . . .'' In Advisory Opinion 10–23, OIG noted that the arrangement that was the subject of the opinion ''involves a 'per-click' fee structure, which is inherently reflective of the volume or value of services ordered and provided . . . .''

2. Technical Correction: Advisory Opinions Relating to Physician Referrals, Procedure for Submitting a Request

We are proposing to revise § 411.372(a) by making a minor technical correction to change the instructions for submitting a request for an advisory opinion relating to physician referrals. The current language in this subsection directs a requesting party to submit its request to a physical address that is out of date. In an effort to expedite the receipt and processing of these requests, and to account for any future changes, we are proposing to revise paragraph (a) to state a party or parties must submit a request for an advisory opinion to CMS according to the instructions specified on the CMS Web site.

We note that, at the time of this rulemaking, the correct address for such advisory opinion requests is: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Office of Financial Management, Division of Premium Billing and Collections, Mail Stop C3–09–27, Attention: Advisory Opinions, 7500 Security Boulevard, Baltimore, MD 21244–1850. However, we note that this address is subject to change, per this technical correction, and that parties seeking to submit a request for an advisory opinion relating to physician referrals will need to refer to the instructions on the CMS Web site.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements (ICRs).

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 39 presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 39—National Occupational Employment and Wage Estimates

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefit ($/hr)	Adjusted hourly wage ($/hr)
Compliance Officer	13–1041	33.26	33.26	66.52
Epidemiologist	19–1040	36.97	36.97	73.94
Medical Scientist	19–1042	45.06	45.06	90.12
Medical Secretary	43–6013	16.50	16.50	33.00
Non-Physician Practitioner (Health Diagnosing and Treating Practitioners)	29–1000	46.65	46.65	93.90
Office and Administrative Support Operations	43–0000	17.47	17.47	34.94
Physicians and Surgeons	29–1060	97.33	97.33	194.66
Physicians and Surgeons, All Other	29–1069	95.05	95.05	190.10
Statistician	15–2041	40.60	40.60	81.20

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. Proposed Information Collection Requirements (ICRs) and Burden Estimates

1. ICRs Regarding the Physician Quality Reporting System (PQRS) (§ 414.90)

For individual EPs or group practices, who choose to separately report quality measures during the proposed secondary PQRS reporting period for the 2017 PQRS payment adjustment, who bill under the TIN of an ACO participant if the ACO failed to report on behalf of such EPs or group practices during the previously established reporting period for the 2017 PQRS payment adjustment, we do not believe the individual EP or group practice incurs any additional burden. The associated reporting burden which is currently approved by OMB under control number 0938–1059 (CMS–10276) explains that the PQRS annual burden estimate was calculated separately for (1) individual eligible professionals and group practices using the claims (for eligible professionals only), (2) qualified registry and QCDR,

(3) EHR-based reporting mechanisms, and (4) group practices using the GPRO. We estimated that ALL 1.25 million eligible professionals will participate in the PQRS in 2016 for purposes of meeting the criteria for satisfactory reporting (or, in lieu of satisfactory reporting, satisfactory participation in a QCDR) for the 2018 PQRS payment adjustment. This is a high estimate according to the 2014 PQRS Reporting Experience and Trends Report which found approximately 822,000 EPs participated in PQRS in 2014. Therefore, the additional EPs who choose to report separately from the ACOs have already been accounted for in the PQRS burden. We estimate there were approximately 1,947 EPs that are part of the 218 participant TINs that are under the 8 ACOs that failed to successfully report their 2015 quality data. There is no change in the reporting mechanisms or reporting criteria for PQRS. It is important to note that if the ACO fails to report on behalf of an EP or group practice and the EP or group practice does not utilize this secondary reporting period they may be subject to a downward adjustment.

2. ICRs Regarding Appropriate Use Criteria for Advanced Diagnostic Imaging Services (§ 414.94)

Consistent with section 1834(q) of the Act (as amended by section 218(b) of the PAMA), we have proposed specific requirements for clinical decision support mechanisms (CDSMs) that can be qualified CDSMs under § 414.94 of our regulations as part of the Medicare appropriate use criteria (AUC) program. CDSMs that believe they meet the requirements to be qualified CDSMs (for the purpose of this section) may apply to CMS to be specified as a qualified CDSM.

Applications must be submitted electronically and demonstrate how the CDSM meets the requirements under § 414.94(g)(1). Specifically, applications must demonstrate how the CDSM: (1) Makes available specified applicable AUC and related documentation supporting the appropriateness of the applicable imaging service ordered; (2) identifies the appropriate use criterion consulted in the event the CDSM makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario; (3) makes available, at a minimum, specified applicable AUC that reasonably encompass the entire clinical scope of all priority clinical areas identified in § 414.94(e)(5); (4) has the technical capability to incorporate specified applicable AUC from more than one qualified PLE; (5) determines the extent to which an applicable imaging service is consistent with a specified applicable appropriate use criterion consulted for a patient's specific clinical scenario, or a determination of ''not applicable'' when the mechanism does not contain a criterion applicable to that patient's specific clinical scenario; (6) generates and provides a certification or documentation each time an ordering professional consults a qualified CDSM that includes a unique consultation identifier to the ordering professional that documents which qualified CDSM was consulted, the name and national provider identifier (NPI) of the ordering professional that consulted the CDSM, and whether the service ordered would adhere to specified applicable AUC or whether specified applicable AUC was not applicable to the service ordered; (7) updates AUC content at least every 12 months to reflect revisions or updates made by qualified PLEs to their AUC sets or an individual appropriate use criterion; (8) has a protocol to expeditiously remove AUC determined by the qualified PLE to be potentially dangerous to patients and/or harmful if followed; (9) makes available for consultation specified applicable AUC that reasonably encompass the entire clinical scope of any new priority clinical area within 12 months of the priority clinical area being finalized by CMS; (10) meets privacy and security standards under applicable provisions of law; (11) provides the ordering professional aggregate feedback regarding their consultation with specified applicable AUC in the form of an electronic report on an annual basis; (12) maintains electronic storage of clinical, administrative, and demographic information of each unique consultation for a minimum of 6 years; and (13) complies with modification(s) to any requirements under § 414.94(g)(1) made through rulemaking within 12 months of the effective date of the modification.

To be specified as a qualified CDSM by CMS, mechanism developers must document adherence to the requirements in their application for CMS review and use the application process identified in § 414.94(g)(2) which includes: (1) Applications submitted by CDSMs documenting adherence to each requirement outlined in § 414.94(g)(1) must be received annually by January 1; (2) all approved qualified CDSMs in each year will be included on the list of qualified CDSMs posted to the CMS Web site by June 30 of that year; (3) approved CDSMs are qualified for a period of 5 years; and (4) all qualified CDSMs must re-apply every 5 years and applications must be received by CMS by January 1 of the 5th year after the developer's most recent approval date. If a qualified CDSM is found to be non-adherent to the requirements identified above, CMS may terminate its qualified status or may consider this information during re-qualification.

The one-time burden associated with the requirements under § 414.94(g)(2) is the time and effort it would take each of the approximately 30 CDSM developers (as estimated by CMS, the Office of the National Coordinator (ONC), and the Agency for Healthcare Research and Quality (AHRQ)) that have interests in incorporating AUC consultation into their mechanisms' functionality to compile, review and submit documentation demonstrating adherence to the proposed CDSM requirements. We anticipate 30 respondents based on the number of existing CDSMs that have expressed an interest in incorporating AUC for advanced diagnostic imaging, as well as our estimation of the number of CDSM developers that may be interested in incorporating AUC for advanced diagnostic imaging in the future as their mechanisms develop and evolve. Each respondent will voluntarily compile, review and submit documentation that demonstrates their adherence to the proposed CDSM requirements listed above.

We estimate it would take 10 hours at $68.18/hr for a business operations specialist to compile, prepare and submit the required information, 2.5 hours at $86.72/hr for a computer system analyst to review and approve the submission, 2.5 hours at $135.58/hr for a computer and information systems manager to review and approve the submission, and 5 hours at $131.02/hr for a lawyer to review and approve the submission. In this regard, we estimate 20 hours per submission at a cost of $1,892.65. In aggregate, we estimate 600 hours (20 hr × 30 submissions) at $56,779.50 ($1,892.65 × 30 submissions).

After the anticipated initial 30 respondents, we expect less than 10 applicants to apply to become qualified CDSMs annually. Since we estimate fewer than 10 respondents, the information collection requirements and burden are exempt (5 CFR 1320.2(c)) from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq).

Given that qualified CDSMs must re-apply every 5 years, in years 6–10, we expect the initial 30 entities will re-apply. The ongoing burden for re-applying is expected to be half the

burden of the initial application process. The CDSM developers will be able to make modifications to their original application which should result in a burden of 5 hr at $68.18/hr for a business operations specialist to compile, prepare and submit the required information, 1.25 hr at $86.72/hr for a computer system analyst to review and approve the submission, 1.25 hr at $135.58/hr for a computer and information systems manager to review and approve the submission, and 2.5 hr at $131.02/hr for a lawyer to review and approve the submission. Annually, we estimate 10 hr per submission at a cost of $946.33 per CDSM developer. In aggregate, we estimate 300 hr (10 hr × 30 submissions) at $28,389.90 ($946.33 × 30 submissions).

As regulatory requirements become more complex, we will look to innovative technologies that minimize the burden on an organizations' budget and manpower. To this end, the proposed CDSM functionality requirements identified in § 414.94(g)(1) will help practitioners meet the requirements of the AUC program. While the CDSM application process proposed in § 414.94(g)(2) is a new burden under this program, the CDSM functionality requirements proposed in § 414.94(g)(1) do not add burden as they are functions of the CDSM. These mechanisms function consistently with their voluntary and individualized design so the proposed requirements in § 414.94(g)(1) are either part of a mechanism's functionality or not. If CDSM developers wish to become qualified under this program, they may choose to develop the functionality of their mechanisms consistent with these requirements to be qualified, but all CDSMs are not required to participate in this program. For example, a CDSM that does not incorporate AUC for any advanced diagnostic imaging services would likely choose not to seek to become qualified under this Medicare AUC program. As such, only CDSMs that wish to participate in the Medicare AUC for advanced diagnostic imaging services program are required to apply for qualification and, in choosing to seek qualification, CDSM developers would also choose to incorporate the proposed requirements into their mechanism's functionality.

The proposed requirements and burden will be submitted to OMB under control number 0938—New (CMS–10624).

3. ICRs Regarding the Enrollment of MA Providers, Suppliers, and First-Tier, Downstream, and Related Entities (FDRs) (§ 422.222)

There are approximately 1.9 million providers and suppliers nationwide that are enrolled in Medicare. Through our analysis of currently available encounter data provided by MA organizations, we have found that some providers and suppliers that furnish items or services to MA organization enrollees are not enrolled in Medicare in an approved status. Based on preliminary data, we estimate that 64,000 MA providers and suppliers would have to enroll in Medicare pursuant to proposed § 422.222 in order to treat enrollees.

About half of the approximately 64,000 unenrolled providers and suppliers, or 32,000, are individuals and the other half are organizations. We do not have data at this point to confirm the number of unenrolled individuals who are physicians as opposed to non-physician practitioners. For purposes of fulfilling the requirements of the PRA, we will project that one-half (16,000) are physicians and the other half (16,000) are practitioners.

Consistent with our prior time (per respondent) estimates, we project that it would take 3 hours at $194.66/hr for a physician and $93.30/hr for a non-physician practitioner to complete their individual enrollments. For organizations (office and administrative support personnel), we estimate it would take 6 hours at $34.94/hr, since organizations typically submit more data than individuals. For physicians, we estimate 48,000 hours (16,000 applicants × 3 hours) at a cost of $9,343,680 (48,000 hr × $194.66/hr). For non-physician practitioners, we estimate 48,000 hours (16,000 applicants × 3 hours) at a cost of $4,478,400 (48,000 hr × $93.30/hr). For organizations, we estimate 192,000 hours (32,000 applicants × 6 hours) at a cost of $6,708,480 (192,000 hr × $34.94). In aggregate, we estimate 288,000 hours at $20,530,560.

When projected annually over OMB's maximum 3-year approval period, we estimate 96,000 hours at a cost of $6,843,520.

For physicians and non-physician practitioners, the proposed requirements and annualized burden (32,000 hours) will be submitted to OMB under control number 0938–0685 (Form CMS–855I) because physicians and non-physician practitioners enroll via the Form CMS–855I. For organizations, the proposed requirements and annualized burden (64,000 hours) will be submitted to OMB under control number 0938–0685 (21,333.3 hours for Form CMS–855A and 21,333.3 hours for Form CMS–855B) and control number 0938–1056 (21,333.3 hours for Form CMS–855S). The specific form to be completed would depend upon the provider or supplier type at issue. For instance, and consistent with current enrollment policy, certified providers and certain certified suppliers would complete the Form CMS–855A; group practices, ambulance suppliers, and certain other supplier types would complete the Form CMS–855B; suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) would complete the Form CMS–855S.

Please note that breakout of the organization burden (dividing 64,000 hours by 3 forms) is an estimate. Logistically this is necessary for the purposes of submitting burden for approval. We have no way of estimating the number of providers/suppliers that will complete the individual forms. We welcome comment to help us derive a more reliable breakout.

4. ICRs Regarding Application Requirements (§ 422.501) and Termination of Contract by CMS (§ 422.510)

Changes proposed for §§ 422.501 and 422.510 involve only CMS contract changes and will not result in any external charges or operational costs to MA organizations. Many MA organizations already require Medicare enrollment for all their network providers and suppliers. So there will be no additional costs to most MA and MA- PD plans. The only tangible costs would be to those providers or suppliers that are not enrolled and those costs are estimated above.

5. ICRs Regarding the Release of Medicare Advantage Bid Pricing Data (§ 422.272) and the Release of Part C and Part D Medical Loss Ratio (MLR) Data (§§ 422.2490 and 423.2490)

Section 422.272 proposes an annual public release of MA bid pricing data (with specified exceptions from release), which would occur after the first Monday in October and would contain MA bid pricing data that was approved by CMS for a contract year at least five years prior to the upcoming calendar year. Under Part C, MA organizations (MAOs) are required to submit bid data to CMS each year for MA plans they wish to offer in the upcoming contract year (calendar year), under current authority at § 422.254.

Proposed §§ 422.2490 (for Part C) and 423.2490 (for Part D) would also provide for the public release of Part C and Part

D MLR data for each contract year, which would occur no sooner than 18 months after the end of the contract year for which the MLR Report was submitted. Starting with contract year 2014, if an MAO or Part D sponsor fails to spend at least 85 percent of the revenue received under an MA or Part D contract on incurred claims and quality improving activities, the MAO or Part D sponsor must remit to the Secretary the product of: (1) The contract's total revenue; and (2) the difference between 85 percent and the contract's MLR. For each contract year, each MAO and Part D sponsor must submit an MLR Report to CMS which includes the data needed by the MAO or Part D sponsor to calculate and verify the MLR and remittance amount, if any, for each contract. The proposed rule would allow us to release the Part C and Part D MLR data contained in the MLR Reports that we receive from MAOs and Part D sponsors, with specified exceptions to release.

The proposed provisions on release of MA bid pricing data and release of Part C and Part D MLR data do not change any of the existing requirements regarding submission of bid data and MLR data by MAOs or Part D sponsors. Nor does this rule propose any new or revised reporting, recordkeeping, or third-party disclosure requirements. Although the proposed provisions have no impact on respondent requirements or burden, the changes will be submitted to OMB for approval under control number 0938–0944 (CMS–10142) for MA bid pricing data and 0938–1232 (CMS–10476) for Part C and Part D MLR data.

6. 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, shall not apply to the Shared Savings Program.

C. Summary of Annual Burden Estimates for Proposed Requirements

TABLE 40—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s) under title 42 of the CFR	OMB Control No.	Respondents	Total responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($)	Total cost ($)*
§ 414.94(g)(2)	0938—New	30	30	20	600	varies	56,780
§ 414.94(g)(2) (reapply)	0938—New		30	10	300	varies	28,390
§ 422.222 (physicians and non-physician practitioners).	0938–0685	32,000	10,666.6 (32,000 responses annualized over 3 years).	3	32,000	varies	4,607,360
§ 422.222 (organizations)	0938–0685	32,000	7,111.1 for two CMS–855 forms (21,333.3 responses annualized over 3 years).	6	42,666.6	34.94	1,490,771
§ 422.222 (organizations)	0938–1056		3,555.6 for one CMS–855 form.	6	21,333.3	34.94	745,386
Total		64,030	64,060		96,900	varies	6,928,687

*This rule does not propose any non-labor costs.

D. Associated Information Collections Not Specified in Regulatory Text

In this proposed rule, we make reference to proposed associated information collection requirements that were not discussed in the regulation text contained in this proposed rule. The following is a discussion of those requirements.

1. Global Surgical Services

Section II.D.2. of this proposed rule details our plans for a proposed claims based reporting program for global surgical services. Specifically, that section describes our proposal for claims-based data collection that would be applicable to 10- and 90-day global services furnished on or after January 1, 2017, including who would be required to report, what they would be required to report, and how reports would be submitted. As currently proposed, this data collection would be subject to the PRA. As stated in section 220 of the Protecting Access to Medicare Act (PAMA) of 2014 (Pub. L. 113–93), Chapter 35 of title 44, United States Code, shall not apply to information collected or obtained under this paragraph. Specifically, information collected to ensure the accurate valuation of services under the Physician Fee Schedule which includes but is not limited to surveys of physicians, other suppliers, providers of services, manufacturers, and vendors; surgical logs, billing systems, or other practice or facility records; electronic health records; and, any other mechanism deemed appropriate by the Secretary.

2. Survey of Practitioners

As discussed earlier in section II.D.6. e.(1)–(2) of this document, we are proposing to conduct a survey of providers to help us explore options and collect data with respect to assessing and revaluing the global surgery services. If we finalize this proposal, the associated information collection request will be exempt from the PRA. As stated in stated in section 220 of PAMA of 2014, Chapter 35 of title 44, United States Code, shall not apply to information collected to ensure the accurate valuation of services under the Physician Fee Schedule. Consequently, the information collection requirements associated with this proposed survey need not be reviewed by the Office of Management and Budget.

3. Data Collection for Accountable Care Organizations

In section II.D6.e.(3) of this document, we propose to conduct a survey of ACOs on a number of issues surrounding pre- and post-operative surgical services. Once developed and implemented, the survey would be exempt from the PRA. As stated in section 3022 of the Affordable Care Act, Chapter 35 of title 44, United States Code, shall not apply to the Medicare Shared Savings Program. Similarly, as stated in stated in section 220 of PAMA of 2014, Chapter 35 of title 44, United States Code, shall not apply to information collected to ensure the accurate valuation of services under the Physician Fee Schedule. Consequently, the information collection requirements associated with this proposed survey need not be reviewed by the Office of Management and Budget.

E. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. These 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 proposed collections discussed above, please visit CMS' Web site at *www.cms.hhs.gov/PaperworkReductionActof1995*, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule and identify the rule (CMS–1654–P) the ICR's CFR citation, CMS ID number, and OMB control number.

ICR-related comments are due September 13, 2016.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary to make payment and policy changes under the Medicare PFS and to make required statutory changes under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and the Achieving a Better Life Experience Act of 2014 (ABLE). This proposed rule is also necessary to make 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) and the Congressional Review Act (5 U.S.C. 804(2)).

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 proposed 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 proposed rule is intended to comply with the RFA requirements.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this proposed 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 2016, that threshold is approximately $146 million. This proposed rule would 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.

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 proposed 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 proposed rule, we are proposing to implement a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and to implement statutory provisions. We provide information for each of the policy changes in the relevant sections of this proposed rule. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives 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 2016 with proposed payment rates for CY 2017 using CY 2015 Medicare utilization. The payment impacts in this proposed rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual physician could vary from the average and would depend on the mix of services the practitioner 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 Lab 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 amended section 1848(d) of the Act to specify the update adjustment factors for calendar years 2015 and beyond. For 2017, the specified update is 0.5 percent.

We note that 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 2017 net reduction in expenditures resulting from proposed adjustments to relative values of misvalued codes to be 0.51 percent. Since, if finalized, this amount would exceed the 0.5 percent target established by the Achieving a Better Life Experience Act of 2014 (ABLE) (Division B of Pub. L. 113–295, enacted December 19, 2014), there is no residual difference between the target for the year and the estimated net reduction in expenditures (the ''Target Recapture Amount'') by which to reduce payments made under the PFS. As a result, we estimate that the proposed PFS rates would not produce a CY 2017 Target Recapture Amount applicable to the CY 2017 CF. However, we note that the final Target Recapture Amount will be calculated based on the adjustments to misvalued codes as finalized in the CY 2017 PFS Final Rule.

Effective January 1, 2012, we implemented an MPPR of 25 percent on the professional component (PC) of advanced imaging services. Section 502(a)(2)(A) of the Consolidated Appropriations Act of 2016 (Pub. L 114–113, enacted on December 18, 2015) added a new section 1848(b)(10) of the Act which revises the multiple procedure payment reduction on the professional component of imaging services from 25 percent to 5 percent, effective January 1, 2017. Section 502(a)(2)(B) added a new subclause at section 1848(c)(2)(B)(v)(XI) which exempts the MPPR reductions attributable to the new 5 percent MPPR on the PC of imaging from the PFS budget neutrality provision. However, the provision does not exempt the change from the 25 percent MPPR from PFS budget neutrality. Therefore, for CY 2017 we must calculate PFS rates in a manner that exempts the 5 percent MPPR from budget neutrality but ensures that the elimination of the 25 percent MPPR is included in PFS budget neutrality. We note that the application of the 25 percent MPPR has been applied in a budget neutral fashion to date.

The CY 2017 proposed PFS rates exclude the 5 percent MPPR for the professional component of imaging services by calculating the rates as if the discount does not occur, consistent with our approach to other discounts that occur outside of PFS budget neutrality. In order to implement the change from the 25 percent discount in 2016 to the 5 percent discount in 2017 within PFS budget neutrality, we measured the difference in total RVUs for the relevant services assuming an MPPR of 25 percent and the total RVUs for the same services without an MPPR and then applied that difference as an adjustment to the conversion factor to account for the increased expenditures attributable to the change, within PFS budget neutrality. This approach is consistent with the statutory provision that requires the 5 percent MPPR to be implemented outside of PFS budget neutrality.

To calculate the proposed conversion factor for this year, we multiply the product of the current year conversion factor and the update adjustment factor by the budget neutrality adjustment and the imaging MPPR adjustment described in the preceding paragraphs. We estimate the CY 2017 PFS conversion factor to be 35.7751, which reflects the budget neutrality adjustment, the 0.5 percent update adjustment factor specified under section 1848(d)(18) of the Act, and a the adjustment due to the non-budget neutral 5 percent MPPR for the professional component of imaging services. We did not need to apply an adjustment for atarget recapture for the reasons described above. We estimate the CY 2017 anesthesia conversion factor to be 21.9756, which reflect the same overall PFS adjustments.

TABLE 41—CALCULATION OF THE PROPOSED CY 2017 PFS CONVERSION FACTOR

Conversion factor in effect in CY 2016		35.8043
Update Factor	0.50 percent (1.0050)	
CY 2017 RVU Budget Neutrality Adjustment	−0.51 percent (0.9949)	
CY 2017 Target Recapture Amount	0 percent (1.0000)	
CY 2017 Imaging MPPR Adjustment	−0.07 percent (0.9993)	

TABLE 41—CALCULATION OF THE PROPOSED CY 2017 PFS CONVERSION FACTOR—Continued

Conversion factor in effect in CY 2016		35.8043
CY 2017 Conversion Factor		35.7751

TABLE 42—CALCULATION OF THE PROPOSED CY 2017 ANESTHESIA CONVERSION FACTOR

CY 2016 national average anesthesia conversion factor		21.9935
Update Factor	0.50 percent (1.0050)	
CY 2017 RVU Budget Neutrality Adjustment	−0.51 percent (0.9949)	
CY 2017 Target Recapture Amount	0 percent (1.0000)	
CY 2017 Imaging MPPR Adjustment	−0.07 percent (0.9993)	
CY 2017 Conversion Factor		21.9756

Table 43 shows the payment impact on PFS services of the proposals contained in this proposed 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 43 (CY 2017 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 43.

- *Column A (Specialty):* Identifies the specialty for which data is shown.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2015 utilization and CY 2016 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 2017 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 2017 impact on total allowed charges of the changes in the PE RVUs.
- *Column E (Impact of RVU Changes):* This column shows the estimated CY 2017 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 2017 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 43—CY 2017 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *

Specialty	Allowed Charges (mil)	Impact of Work RVU Changes	Impact of PE RVU Changes	Impact of MP RVU Changes	Combined Impact **
(A)	(B)	(C)	(D)	(E)	(F)
TOTAL	$89,467	0%	0%	0%	0%
ALLERGY/IMMUNOLOGY	230	0	1	0	2
ANESTHESIOLOGY	1,977	0	−1	0	0
AUDIOLOGIST	61	0	0	0	1
CARDIAC SURGERY	322	0	0	0	0
CARDIOLOGY	6,461	0	0	0	1
CHIROPRACTOR	779	0	0	0	0
CLINICAL PSYCHOLOGIST	727	0	0	0	0
CLINICAL SOCIAL WORKER	601	0	0	0	0
COLON AND RECTAL SURGERY	160	0	0	0	0
CRITICAL CARE	308	0	0	0	0
DERMATOLOGY	3,305	0	0	0	1
DIAGNOSTIC TESTING FACILITY	750	0	−2	0	−2
EMERGENCY MEDICINE	3,133	0	0	0	0
ENDOCRINOLOGY	458	1	1	0	2
FAMILY PRACTICE	6,087	1	1	0	3
GASTROENTEROLOGY	1,744	0	0	0	−1
GENERAL PRACTICE	451	1	1	0	2
GENERAL SURGERY	2,157	0	0	0	0
GERIATRICS	211	1	1	0	2
HAND SURGERY	182	0	0	0	0
HEMATOLOGY/ONCOLOGY	1,746	1	1	0	2
INDEPENDENT LABORATORY	701	0	−5	0	−5
INFECTIOUS DISEASE	652	0	0	0	1
INTERNAL MEDICINE	10,849	1	1	0	2
INTERVENTIONAL PAIN MGMT	767	1	0	0	0
INTERVENTIONAL RADIOLOGY	315	−1	−5	0	−7
MULTISPECIALTY CLINIC/OTHER PHYS	128	1	1	0	1

TABLE 43—CY 2017 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *—Continued

Specialty	Allowed Charges (mil)	Impact of Work RVU Changes	Impact of PE RVU Changes	Impact of MP RVU Changes	Combined Impact **
(A)	(B)	(C)	(D)	(E)	(F)
NEPHROLOGY	2,205	0	−1	0	−1
NEUROLOGY	1,514	1	1	0	1
NEUROSURGERY	784	−1	0	0	−1
NUCLEAR MEDICINE	47	0	0	0	0
NURSE ANES/ANES ASST	1,211	0	0	0	0
NURSE PRACTITIONER	2,974	1	1	0	2
OBSTETRICS/GYNECOLOGY	647	0	1	0	1
OPHTHALMOLOGY	5,493	0	−2	0	−2
OPTOMETRY	1,213	0	−1	0	−1
ORAL/MAXILLOFACIAL SURGERY	48	0	0	0	0
ORTHOPEDIC SURGERY	3,685	0	0	0	0
OTHER	26	0	0	0	0
OTOLARNGOLOGY	1,208	0	0	0	0
PATHOLOGY	1,127	0	−2	0	−2
PEDIATRICS	61	1	1	0	2
PHYSICAL MEDICINE	1,062	0	0	0	1
PHYSICAL/OCCUPATIONAL THERAPY	3,395	0	0	0	1
PHYSICIAN ASSISTANT	1,959	0	1	0	1
PLASTIC SURGERY	374	0	0	0	0
PODIATRY	1,954	0	0	0	1
PORTABLE X–RAY SUPPLIER	104	0	−1	0	−1
PSYCHIATRY	1,250	1	1	0	1
PULMONARY DISEASE	1,759	0	0	0	1
RADIATION ONCOLOGY	1,720	0	0	0	0
RADIATION THERAPY CENTERS	43	0	−1	0	−1
RADIOLOGY	4,670	0	−1	0	−1
RHEUMATOLOGY	536	1	1	0	2
THORACIC SURGERY	356	0	0	0	0
UROLOGY	1,764	−1	0	0	−1
VASCULAR SURGERY	1,045	0	−2	0	−2

** Column F may not equal the sum of columns C, D, and E due to rounding.

2. CY 2017 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the proposed RVU changes are generally related to the proposed changes to RVUs for specific services resulting from the Misvalued Code Initiative, including proposed RVUs for new and revised codes. Several specialties, including interventional radiology and independent labs, would experience significant decreases to overall payments for services that they frequently furnish as a result of revisions to the coding structure or the proposed inputs used to develop RVUs for the codes that describe particular services. Other specialties, including endocrinology and family practice, would experience significant increases to payments for similar reasons.

b. Impact

Column F of Table 43 displays the estimated CY 2017 impact on total allowed charges by specialty of all the RVU changes. A table shows the estimated impact on total payments for selected high volume procedures of all of the changes is available under ''downloads'' on CY 2017 PFS proposed 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 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 Proposed Changes in Telehealth List

As discussed in section II.I. of this proposed rule, we proposed to add several new codes to the list of Medicare telehealth services. Although we expect these changes to increase access to care in rural areas, based on recent utilization of similar services already on the telehealth list, we estimate no significant impact on PFS expenditures from the additions relative to overall PFS expenditures.

E. Geographic Practice Cost Indices (GPCIs)

Based upon statutory requirements, we are proposing new GPCIs for each Medicare payment locality. The proposed GPCIs incorporate updated data and cost share weights as discussed in II.E. The Act requires that updated GPCIs be phased in over two years. Addendum D shows the estimated effects of the revised GPCIs on area GAFs for the transition year (CY 2017) and the fully implemented year (CY 2018). The GAFs reflect the use of the updated underlying GPCI data, and the cost share weights remain unchanged from the previous (seventh) GPCI update. The GAFs are a weighted composite of each area's work, PE and malpractice expense GPCIs using the national GPCI cost share weights. While we do not actually use the GAFs in computing the fee schedule payment for a specific service, they are useful in comparing overall areas costs and payments. The actual effect on payment for any actual service will deviate from the GAF to the extent that the proportions of work, PE and malpractice

expense RVUs for the service differ from those of the GAF.

The most significant changes occur in 19 non-California payment localities, where the fully implemented (CY 2018) GAF moves up by more than 1 percent (14 payment localities) or down by more than 2 percent (5 payment localities).

F. Other Provisions of the Proposed Regulation

1. Proposal To Change Direct Supervision Requirement to General Supervision for CCM Services Furnished Incident to RHCs and FQHCs

In section III.A., we proposed to revise § 405.2413(a)(5) and § 405.2415(a)(5) to state that services and supplies furnished incident to TCM and CCM services can be furnished under general supervision of a RHC or FQHC practitioner. In section III.A., we proposed revising the CCM requirements for RHCs and FQHCs to be consistent with the proposed revisions to the CCM requirements for practitioners billing under the PFS. These proposed revisions will allow RHCs and FQHCs to provide TCM and CCM services at the level that was projected when the programs were authorized and therefore no impact on spending is expected.

As outlined in section III.A., we proposed to change the direct supervision requirement to a general supervision for CCM services furnished incident to RHCs and FQHCs. This regulatory change was already made for CCM services furnished by practitioners billing the PFS, and changes to RHC and FQHC regulations have no impact on regulations for practitioners billing under the PFS. The impact on RHCs and FQHCs in 2017 is negligible, as estimates are rounded to the nearest 5 million and 2017 was too small of an impact to have a notable effect on the estimate.

2. FQHC-Specific Market Basket

As discussed in section III.B of this proposed rule, we are proposing to create a 2013-based FQHC market basket to update the FQHC PPS base payment rate. Table 44 shows the 5-year and 10-year fiscal cost estimates from switching from a MEI-adjusted base payment rate to a FQHC PPS market basket-adjusted base payment rate. This was determined by compiling data on historical FQHC spending, projecting it forward, and creating two separate baselines. The first baseline assumed an MEI price update and the second baseline assumed an FQHC specific market basket price update which was created by the Office of the Actuary within CMS. The utilization of services was held constant between the two baselines, and therefore, the impact table specifically captures the change in price from now growing at an FQHC MB update relative to how it was growing at the MEI updates. We estimate that this would cost approximately 170 million dollars over 10 years from FY 2017–2026, 35 million of which would be paid for through beneficiary premiums and the remaining 135 million would be paid for through Part B.

TABLE 44: 5-Year and 10-Year Fiscal Cost Estimates from Switching from an MEI-adjusted Base Payment Rate to a FQHC PPS Market Basket-adjusted Base Payment Rate

Estimate [in millions]	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	5-year impact 2017 - 2021	10-year impact 2017 - 2026
FY Cash Impact (with MC)													
	-	-	-	-	-	-	-	-	-	-	-	-	-
Part B													
Benefits	-	-	5	10	10	15	15	20	25	30	40	40	170
Premium Offset	-	-	-	-	-	(5)	(5)	(5)	(5)	(5)	(10)	(5)	(35)
Total Part B	-	-	5	10	10	10	10	15	20	25	30	35	135

3. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

We are proposing and requesting public comment on clinical decision support mechanism (CDSM) requirements as well as an application process that CDSM developers must comply with for their mechanisms to be specified as qualified under this program. These proposals would not impact CY 2017 physician payments under the PFS.

4. Reports of Payments or Other Transfers of Value to Covered Recipients

We are soliciting comments to inform future rulemaking. We do not intend to finalize any requirements directly as a result of this proposed rule; so there is no impact to CY 2017 physician payments under the PFS.

5. Release of Part C Medicare Advantage Bid Pricing Data and Part C and Part D Medical Loss Ratio (MLR) Data

Under section III.E. of the preamble of this proposed rule, we are proposing to revise the existing regulations by adding § 422.272 to provide for an annual public release of MA bid pricing data (with specified exceptions from release). The annual release would occur after the first Monday in October and would contain MA bid pricing data that was accepted or approved by CMS for a contract year at least 5 years prior to the upcoming calendar year. Under current authority at § 422.254, MA organizations (MAOs) are required to submit bid pricing data to CMS each year for MA plans they wish to offer in the upcoming contract year (calendar year).

In addition, the proposed rule adds § 422.2490 for Part C and § 423.2490 for Part D to provide for an annual public release of Part C and Part D medical loss ratio (MLR) data (with specified exceptions from release). This annual release would occur no sooner than 18 months after the end of the contract year for which MLR data was reported to CMS. Starting with contract year 2014, each MAO or Part D sponsor that fails to spend at least 85 percent of revenue received under an MA or Part D contract on incurred claims and quality improving activities must remit the difference to the government. Under current authority at § 422.2460 and § 423.2460, each year MAOs and Part D sponsors must submit an MLR Report to CMS, which includes the data needed by the MAO or Part D sponsor to calculate and verify the MLR and remittance amount, if any, for each contract.

We are proposing to add regulatory language to authorize CMS' release of such data to the public. We have determined that the proposed regulatory amendments do not impose any mandatory costs on the public or entities that seek to download and use the released data. We expect that this

data will be available to the public from the CMS Web site (*https://www.cms.gov/*). The public may elect to download the data files, which will not impose mandatory costs on any user. Therefore, we have determined that there are not any economically significant effects of the proposed provisions. We also have determined that the proposed regulatory amendments would not impose a burden on the entity requesting or downloading data files.

6. Prohibition on Billing Qualified Medicare Beneficiary Individuals for Medicare Cost-Sharing

We are restating information to inform providers to take steps to educate themselves and their staff about QMB billing prohibitions and to exempt QMB individuals from Medicare cost-sharing billing and related collection efforts. Therefore, there is no impact to CY 2017 physician payments under the PFS.

7. Recoupment or Offset of Payments to Providers Sharing the Same Taxpayer Identification Number

This proposed rule implements section 1866(j) of the Act which grants the Secretary the authority to authority to make any necessary adjustments to the payments of an applicable provider of services or supplier who shares a TIN with an obligated provider of services or supplier that has an outstanding Medicare overpayment. The Secretary is authorized to adjust the payments of such applicable provider, regardless of whether that applicable provider is assigned a different Medicare billing number or National Provider Identifier (NPI) number from the obligated provider with the outstanding Medicare overpayment. The concept of offsetting or recouping payments of providers sharing a TIN to satisfy a Medicare overpayment is analogous to Treasury's current practice of offsetting against entities that share a TIN to collect Medicare overpayments. This proposed rule would help support our efforts to safeguard the Medicare Trust Funds by collecting its own overpayments more quickly and reducing the accounts receivable delinquency rates reported in the Treasury Report on Receivables. This proposed rule also helps the obligated provider because we would collect the overpayments more quickly; thus reducing the additional interest assessments that would continue on the provider's outstanding delinquent balance until paid in full. Therefore, there is no impact to CY 2017 physician payments under the PFS.

8. Provider Enrollment Part C Program

This proposed rule would require that providers and suppliers must be enrolled in Medicare in approved status in order to render services to beneficiaries in the Medicare Advantage program. This proposed rule will not have a significant economic impact on a substantial number of small businesses because the number not enrolled in Medicare appears to be small in comparison to the general population of providers. The completion of the Form CMS–855 (as explained in section III) would be required very infrequently, in many cases either only one time or once every several years. Also, the hour and cost burden per provider or supplier will not pose a significant burden on a provider and supplier, especially when considering the overall revenue that providers and suppliers receive per year. We thus do not believe our proposal would impact a substantial number of small businesses.

Virtually all of the quantifiable costs associated with this proposed rule involve the paperwork burden to providers and suppliers (see section IV. of this proposed rule). The estimates presented in this section do not address the potential financial benefits of this proposed rule from the standpoint of the rule's effectiveness in preventing or deterring certain providers from enrolling in or maintaining their enrollment in Medicare. We simply have no means of quantifying these benefits in monetary terms.

There are three main uncertainties associated with this proposed rule. First, we are uncertain as to the number of providers and suppliers that would be required to enroll in Medicare under § 422.222. Second, we cannot estimate the savings in fraud and abuse prevention that would accrue from this rule. Third, since we have no systematic method to know how many FDRs may be used by MA or MA–PD organizations to deliver services to Medicare beneficiaries, therefore, we cannot estimate the possible impact to FDRs.

9. Proposed Expansion of the Diabetes Prevention Program (DPP) Model

In this rule, we propose to expand the Diabetes Prevention Program (DPP) Model in accordance with section 1115A(c) of the Act, and we propose to refer to this expanded model as the Medicare Diabetes Prevention Program (MDPP). We propose that MDPP will become effective January 1, 2018, and CMS will continue to test and evaluate MDPP as finalized. In the future, CMS will assess whether the nationwide implementation of the MDPP is continuing to either reduce Medicare spending without reducing quality of care or improve the quality of patient care without increasing spending, and could modify the nationwide MDPP as appropriate. In this proposed rule, we propose a basic framework for the MDPP. If finalized, we will engage in additional rulemaking, likely within the next year, to establish specific requirements of the MDPP. The comments received from this proposed rule will inform key design parameters of the MDPP. Modifications to the proposed MDPP could result in changes to our current financial projections and therefore affect economic impact estimates of MDPP. For these reasons, it is premature to provide an impact statement at this time. We intend to provide an impact statement in future rulemaking.

10. Medicare Shared Savings Program

We are proposing certain rules having to do with ACO quality reporting: (1) We are proposing conforming changes to align with the policies included in the QPP proposed rule, including changes to the quality measure set; (2) we are proposing to streamline the quality validation audit process and use the results to modify an ACO's overall quality score; (3) we are proposing revisions to references to the Quality Performance Standard and Minimum Attainment; (4) we are clarifying that measures calculated as ratios are excluded from use of flat percentages when such benchmarks appear ''clustered'' or ''topped out''; and (5) we are proposing to modify our PQRS alignment rules to permit flexibility for EPs to report quality data to PQRS to avoid the PQRS and VM downward adjustments for 2017 and 2018 in cases where an ACO fails to report on their behalf. In addition, we are proposing updates to the assignment methodology to include beneficiaries who identify ACO professionals as being responsible for coordinating their overall care.

We are also proposing additional beneficiary protections when ACOs in Track 3 make use of the SNF 3-day rule waiver. Finally, we are proposing certain technical changes and clarifications related to reconciliation for ACOs that fall below 5,000 assigned beneficiaries and related to our policies for consideration of claims billed by merged and acquired TINs.

Because the proposed policies are not expected to substantially change the quality reporting burden for ACOs participating in the Shared Savings Program and their ACO participants or change the financial calculations, we do

not anticipate any impact for these proposals.

11. 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 of physicians equal the reduced payments to low performing physicians and groups of physicians.

In the CY 2015 PFS final rule with comment period (79 FR 67936 and 67941 through 67942), we established that, beginning with the CY 2017 payment adjustment period, the VM will apply to physicians in groups with two or more EPs and to physicians who are solo practitioners based on the applicable performance period, including physicians that participate in an ACO under the Shared Savings Program. In the CY 2014 PFS final rule with comment period (78 FR 74771 through 74772), we established CY 2015 as the performance period for the VM that will be applied to payments during CY 2017. In CY 2017, the VM will be waived for groups and solo practitioners, as identified by their TIN, if at least one EP who billed for Medicare PFS items and services under the TIN during 2015 participated in the Pioneer ACO Model or the Comprehensive Primary Care initiative in 2015 (80 FR 71288).

In the CY 2015 PFS final rule with comment period (79 FR 67938 through 67939), we adopted a two-category approach for the CY 2017 VM based on participation in the PQRS by groups and solo practitioners. Category 1 will include those groups that meet the criteria to avoid the PQRS payment adjustment for CY 2017 as a group practice participating in the PQRS GPRO in CY 2015. We finalized in the CY 2016 PFS final rule with comment period (80 FR 71280 through 71281) that, for the CY 2017 VM, Category 1 will also include groups that have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2017 as individuals. In determining whether a group will be included in Category 1, we will consider whether the 50 percent threshold has been met regardless of whether the group registered to participate in the PQRS GPRO in CY 2015. Lastly, Category 1 will include those solo practitioners that meet the criteria to avoid the PQRS payment adjustment for CY 2017 as individuals.

For groups and solo practitioners that participated in an ACO under the Shared Savings Program in CY 2015, they are considered to be Category 1 for the CY 2017 VM if the ACO in which they participated successfully reported on quality measure via the GPRO Web Interface in CY 2015 (79 FR 67946). As discussed in sections III.I. and III.L.1.e. of this proposed rule, we are proposing to remove the prohibition on EPs who are part of a group or solo practitioner that participates in a Shared Savings Program ACO, for purposes of PQRS reporting for the CY 2017 and CY 2018 payment adjustments, to report outside the ACO. In section III.L.3.b. of this proposed rule, we are proposing for the CY 2017 payment adjustment period, if a Shared Savings Program ACO did not successfully report quality data as required by the Shared Savings Program under § 425.504 for the CY 2017 PQRS payment adjustment, then we propose to use the data reported to the PQRS by the EPs (as a group using one of the group registry, QCDR, or EHR reporting options or as individuals using the registry, QCDR, or EHR reporting option) under the participant TIN) outside of the ACO during the secondary PQRS reporting period to determine whether the TIN would fall in Category 1 or Category 2 under the VM. We are proposing that groups that meet the criteria to avoid PQRS payment adjustment for CY 2018 as a group practice participating in the PQRS GPRO (using one of the group registry, QCDR, or EHR reporting options) or have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals (using the registry, QCDR, or EHR reporting option), based on data submitted outside the ACO and during the secondary PQRS reporting period, would be included in Category 1 for the CY 2017 VM. We are also proposing that solo practitioners that meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals using the registry, QCDR, or EHR reporting option, based on data submitted outside the ACO and during the secondary PQRS reporting period, would be included in Category 1 for the CY 2017 VM. Category 2 would include those groups and solo practitioners subject to the CY 2017 VM that participate in a Shared Savings Program ACO and do not fall within Category 1.

The CY 2017 VM payment adjustment amount for groups and solo practitioners in Category 2 is −4.0 percent for groups of physicians with 10 or more EPs and −2.0 percent for groups of physicians with between 2 to 9 EPs and physician solo practitioners.

In the CY 2015 PFS final rule with comment period (79 FR 67939 through 67941), we finalized that quality-tiering, which is the methodology for evaluating performance on quality and cost measures for the VM, will apply to all groups of physicians and physician solo practitioners in Category 1 for the VM for CY 2017. However, groups of physicians with between 2 to 9 EPs and physician solo practitioners will be subject only to upward or neutral adjustments derived under quality-tiering, while groups of physicians with 10 or more EPs will be subject to upward, neutral, or downward adjustments derived under quality-tiering. That is, groups of physicians with between 2 to 9 EPs and physician solo practitioners in Category 1 would be held harmless from any downward adjustments derived under quality-tiering for the CY 2017 VM.

Under the quality-tiering methodology, each group and solo practitioner's quality and cost composites will 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 2017 payment adjustment period according to the amounts in Tables 45 and 46.

TABLE 45—CY 2017 VM PAYMENT ADJUSTMENT AMOUNTS UNDER QUALITY-TIERING FOR GROUPS OF PHYSICIANS WITH TWO TO NINE EPS AND PHYSICIAN 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

TABLE 45—CY 2017 VM PAYMENT ADJUSTMENT AMOUNTS UNDER QUALITY-TIERING FOR GROUPS OF PHYSICIANS WITH TWO TO NINE EPS AND PHYSICIAN SOLO PRACTITIONERS—Continued

Cost/quality	Low quality	Average quality	High quality
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.

TABLE 46—CY 2017 VM PAYMENT ADJUSTMENT AMOUNTS UNDER QUALITY-TIERING FOR GROUPS OF PHYSICIANS WITH TEN OR MORE EPS

Cost/quality	Low quality	Average quality	High quality
Low cost	+0.0%	*+2.0x	*+4.0x
Average cost	−2.0%	+0.0%	*+2.0x
High cost	−4.0%	−2.0%	+0.0%

* Groups 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 2015, the cost composite will be classified as ''Average'' and the quality of care composite will 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 2017 payment adjustment period according to the amounts in Tables 45 and 46.

We are proposing in section III.M.3.b. of this proposed rule, for groups and solo practitioners that participate in a Shared Savings Program ACO that did not successfully report quality data for CY 2015 and are in Category 1 as a result of reporting quality data to the PQRS outside of the ACO using the secondary PQRS reporting period, we are proposing to classify their quality composite for the VM for the CY 2017 payment adjustment period as ''average quality.'' Their cost composite will be classified as ''average cost'' (79 FR 67943).

To ensure budget neutrality, we first aggregate the downward payment adjustments in Tables 45 and 46 for those groups and solo practitioners in Category 1 with the automatic downward payment adjustments of −2.0 percent or −4.0 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). We plan to incorporate assumptions about the number of physicians in groups and physician solo practitioners in the ACOs that did not successfully report their CY 2015 quality data whose status could potentially change from Category 2 to Category 1 if the group or solo practitioner satisfactorily report their 2016 data during the secondary PQRS reporting period. Additionally, as we had done when calculating the upward payment adjustment factor for the 2016 VM, we will also incorporate adjustments made for estimated changes in physician behavior (*i.e.,* 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.

At the time of this proposed rule, we have not completed the analysis of the impact of the VM in CY 2017 on physicians in groups with 2 or more EPs and physician solo practitioners based on their performance in CY 2015. In the CY 2017 PFS final rule with comment period, we will present the number of groups of physicians and physician solo practitioners that will be subject to the VM in CY 2017.

12. Physician Self-Referral Updates

The physician self-referral update provisions are discussed in section III.M of this proposed rule. We are re-proposing regulatory provisions prohibiting certain per-unit of service compensation formulas for determining rental charges in the exceptions for the rental of office space, rental of equipment, fair market value compensation, and indirect compensation arrangements. These provisions are necessary to protect against potential abuses such as overutilization and anti-competitive behavior. We believe that most parties comply with these regulatory provisions since they originally became effective on October 1, 2009, and the re-proposed regulations text is identical to the existing regulations text. Therefore, we do not believe that the proposals will have a significant burden.

G. Alternatives Considered

This proposed rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when 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 proposals contained in this proposed 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 proposed payment rates, and therefore result in different estimates than those shown in Table 43 (CY 2017 PFS Estimated Impact on Total Allowed Charges by Specialty). For example, the estimated increases to primary care specialties would be lessened without the proposals to revise payment policies for certain care management and patient-specific services as described in section II.E. However, because PFS rates are based on relative value units, the proposed rates reflect all of the proposed changes and eliminating some of the proposed changes might have multi-faceted impacts on the payment rates for other services.

H. Impact on Beneficiaries

There are a number of changes in this proposed 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 revisions 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. In particular, we believe that improving payment for primary care and care management services based more accurate assessment of patient needs and the resources involved in caring for them will benefit beneficiaries by improving care coordination and providing more effective treatment, particularly to those beneficiaries with behavioral health conditions and mobility-related disabilities.

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 User File Impact on Payment for Selected Procedures table available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*, the CY 2016 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) was $108.85, which means that in CY 2016, a beneficiary would be responsible for 20 percent of this amount, or $21.77. Based on this proposed rule, using the CY 2017 CF, the CY 2017 national payment amount in the nonfacility setting for CPT code 99203, as shown in the Impact on Payment for Selected Procedures table, is $108.76, which means that, in CY 2017, the proposed beneficiary coinsurance for this service would be $21.75.

As discussed in section III.B of this proposed rule, we are proposing that beginning on January 1, 2017, the FQHC base rate would be updated using a FQHC-specific market basket instead of using the MEI to more accurately reflect changes in the cost of furnishing FQHC services. This would result in a higher payment to FQHCs, and since coinsurance is 20 percent of the lesser of the FQHC's charge for the specific payment code or the PPS rate, beneficiary coinsurance would also increase. The FQHC market basket cost estimates in Table 44 includes a premium offset line which is the amount of cost that would be offset by the beneficiaries. The beneficiaries would pay approximately $5 million and $35 million over the 5 and 10 year projection windows.

I. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 47 (Accounting Statement), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2016 to CY 2017 based on the FY 2017 President's Budget baseline.

TABLE 47—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2017 Annualized Monetized Transfers.	Estimated increase in expenditures of $0.5 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 48—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfers
CY 2017 Annualized Monetized Transfers of beneficiary cost coinsurance.	$0.1 billion.
From Whom to Whom?	Federal Government to Beneficiaries.

J. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provides 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 411

Kidney diseases, Medicare, Physician referral, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Drugs, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: 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 405.373 is amended by—
■ a. Revising paragraphs (a) introductory text and (b).
■ b. Adding paragraph (f).

The revisions and addition read as follows:

§ 405.373 Proceeding for offset or recoupment.

(a) *General rule.* Except as specified in paragraphs (b) and (f) of this section, if the Medicare Administrative Contractor or CMS has determined that an offset or recoupment of payments under § 405.371(a)(2) should be put into effect, the Medicare Administrative Contractor must—

* * * * *

(b) Paragraph (a) of this section does not apply if the Medicare Administrative Contractor, after furnishing a provider a written notice of the amount of program reimbursement in accordance with § 405.1803, recoups payment under paragraph (c) of § 405.1803. (For provider rights in this circumstance, see §§ 405.1809, 405.1811, 405.1815, 405.1835, and 405.1843.)

* * * * *

(f) Paragraph (a) of this section does not apply in instances where the Medicare Administrative Contractor intends to offset or recoup payments to the applicable provider of services or supplier to satisfy an amount due from an obligated provider of services or supplier when the applicable and obligated provider of services or supplier share the same Taxpayer Identification Number.

■ 3. 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 and chronic care management services can be furnished under general supervision of a physician when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1) of this chapter.

* * * * *

■ 4. 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 and chronic care management services can be furnished under general supervision of a nurse practitioner, physician assistant, or certified nurse-midwife, when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1) of this chapter.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 5. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, and 1395ddd).

■ 6. Section 410.26 is amended by—
■ a. Redesignating paragraphs (a)(3) through (7) as paragraphs (a)(4) through (8), respectively.
■ b. Adding new paragraph (a)(3).
■ c. Revising paragraph (b)(5).

The addition and revision reads as follows:

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

(a) * * *

(3) *General supervision* means the level of supervision by the physician (or other practitioner) of auxiliary personnel as defined in § 410.32(b)(3)(i).

* * * * *

(b) * * *

(5) In general, services and supplies must be furnished under the direct supervision of the physician (or other practitioner). Designated non-face-to-face care management services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided incident to the services of a physician (or other practitioner). The physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) who is treating the patient more broadly. However, only the supervising physician (or other practitioner) may bill Medicare for incident to services.

* * * * *

■ 7. Section 410.79 is added to subpart B to 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 January 1, 2018.

(b) *Definitions.* For the purposes of this section the following definitions apply:

Baseline weight refers to the eligible beneficiary's body weight recorded during that beneficiary's first core session.

CDC-approved DPP core curriculum (core curriculum) refers to the content of the core sessions delivered during the first 6 months of the MDPP core benefit. All of the following 16 covered topics must be addressed:

(i) Welcome to the National Diabetes Prevention Program.
(ii) Self-Monitoring weight and food intake.
(iii) Eating less.
(iv) Healthy eating.
(v) Introduction to physical activity (Move those muscles).
(vi) Overcoming barriers to physical activity (Being active—A way of life).
(vii) Balancing calorie intake and output.
(viii) Environmental cues to eating and physical activity.
(ix) Problem solving.
(x) Strategies for healthy eating out.
(xi) Reversing negative thoughts.
(xii) Dealing with slips in lifestyle change.
(xiii) Mixing up your physical activity: Aerobic fitness.
(xiv) Social cues.
(xv) Managing stress.
(xvi) Staying motivated, Program wrap up.

CDC-approved DPP maintenance curriculum (maintenance curriculum) refers to the content of the core maintenance Sessions and ongoing maintenance sessions that are delivered as part of the MDPP core benefit and MDPP maintenance benefit, respectively. Core maintenance sessions and ongoing maintenance sessions must address one or more of the following topics:

(i) Welcome to the second phase of the program.
(ii) Healthy eating: Taking it one meal at a time.
(iii) Making active choices.
(iv) Balance your thoughts for long-term maintenance.
(v) Healthy eating with variety and balance.
(vi) Handling holidays, vacations, and special events.
(vii) More volume, fewer calories (adding water, vegetables, and fiber).
(viii) Dietary fats.
(ix) Stress and time management.
(x) Healthy cooking: Tips for food preparation and recipe modification.
(xi) Physical activity barriers.
(xii) Preventing relapse.
(xiii) Heart health.

(xiv) Life with Type 2 Diabetes.

(xv) Looking back and looking forward.

Coach means an individual person who furnishes MDPP services on behalf of an MDPP supplier as an employee or contractor.

Core maintenance sessions refers to the 6 months of monthly sessions delivered after the core sessions and are included in the core benefit. All core maintenance sessions must address different maintenance curriculum topics.

Core sessions refers to the 16 sessions that are furnished over a period of between 16 and 26 weeks that teach the core curriculum. Each of the core sessions must address one of the core curriculum topics, and all topics must be addressed by the end of the 16 sessions.

Diabetes Prevention Recognition Program (DPRP) means a program administered by the Centers for Disease Control and Prevention (CDC) that recognizes organizations that are able to deliver diabetes prevention program (DPP) services, follow the CDC-approved DPP curriculum, and meet CDC's performance standards and reporting requirements.

Evaluation weight refers to the beneficiary's body weight updated from the first core session and recorded before or during that beneficiary's final core session.

Full DPRP recognition refers to the designation from the CDC that an organization has consistently delivered CDC-approved DPP sessions, met CDC-performance standards and met CDC reporting requirements for at least 24–36 months following the organization's application to participate in the DPRP.

MDPP core benefit (core benefit) means a 12-month intensive behavioral change program that applies the core curriculum. The core benefit consists of 16 core sessions and 6 core maintenance sessions.

MDPP eligible beneficiary means an individual who satisfies the criteria defined in § 410.79(c)(1).

MDPP maintenance benefit (maintenance benefit) is furnished after core benefit has been completed and that covers beneficiaries who achieve and maintain the required minimum weight loss percentage.

MDPP services means the core sessions, core maintenance sessions, and ongoing maintenance sessions.

MDPP supplier means an entity that has either preliminary or full DPRP recognition and is enrolled in Medicare to bill for MDPP services.

Medicare Diabetes Prevention Program (MDPP) refers to an expanded model under section 1115A(c) of the Act that makes MDPP services available to beneficiaries who meet the eligibility requirements specified in paragraph (c)(1) of this section.

National Diabetes Prevention Program (DPP) means an evidence-based intervention targeted to individuals with pre-diabetes that is delivered in community and health care settings and administered by the Centers for Disease Control and Prevention (CDC).

Ongoing maintenance sessions refers to the monthly sessions furnished after the core benefit has been completed and that teach the maintenance curriculum.

Preliminary DPRP recognition refers to the designation from the CDC that an organization has delivered CDC-approved DPP sessions and has met CDC DPRP performance standards and reporting requirements for 12 consecutive months immediately following the organization's application to participate in the DPRP.

Required minimum weight loss means the percentage by which the evaluation weight is less than the baseline weight. The required minimum weight loss percentage is 5 percent.

(c) *General rule*—(1) *Beneficiary inclusion criteria.* Medicare Part B pays for MDPP services for beneficiaries who meet all of the following criteria:

(i) Are enrolled in Medicare Part B.

(ii) 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 and a BMI of at least 23 if self-identified as Asian.

(iii) 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).

(iv) Have no previous diagnosis of Type 1 or Type 2 diabetes.

(v) Does not have end-stage renal disease (ESRD).

(2) *Medicare diabetes prevention program services*—(i) *Core sessions and core maintenance sessions.* MDPP suppliers must furnish to eligible beneficiaries the core benefit, which includes at least 16 core sessions that apply the core curriculum and 6 core maintenance sessions. All core sessions and core maintenance sessions shall have a duration of at least one hour. Sessions may be provided in-person or via remote technologies. MDPP suppliers shall address all 16 topics in the core curriculum in the core sessions and at least 6 topics in the maintenance curriculum in the core maintenance sessions.

(ii) *Ongoing maintenance sessions.* MDPP Suppliers shall furnish ongoing maintenance sessions to MDPP eligible beneficiaries who have achieved and maintained the required minimum weight loss percentage after they have completed the core maintenance sessions. All ongoing maintenance sessions shall have a duration of at least one hour. Sessions may be provided in-person or via remote technologies.

(d) *Limitations on coverage of Medicare diabetes prevention program services.* (1) The MDPP core benefit is available only once per lifetime per MDPP eligible beneficiary.

(2) The MDPP maintenance benefit is available only if the MDPP eligible beneficiary has achieved and maintains the required minimum weight loss percentage.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 8. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

■ 9. Section 411.357 is amended by revising paragraphs (a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B) to read as follows:

§ 411.357 Exceptions to the referral prohibition related to compensation arrangements.

* * * * *

(a) * * *

(5) * * *

(ii) * * *

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

* * * * *

(b) * * *

(4) * * *

(ii) * * *

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

* * * * *

(l) * * *

(3) * * *

(ii) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

* * * * *

(p) * * *

(1) * * *

(ii) * * *

(B) Per-unit of service rental charges, to the extent that such charges reflect

services provided to patients referred by the lessor to the lessee.

* * * * *

■ 10. Section 411.372 is amended by revising paragraph (a) to read as follows:

§ 411.372 Procedure for submitting a request.

(a) *Format for a request.* A party or parties must submit a request for an advisory opinion to CMS according to the instructions specified on the CMS Web site.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 11. 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)).

■ 12. Section 414.22 is amended by revising paragraphs (b)(5) introductory text, (b)(5)(i)(A), (b)(5)(i)(B), and (b)(5)(ii) to read as follows:

§ 414.22 Relative value units (RVUs).

* * * * *

(b) * * *

(5) For services furnished in 2002 and subsequent years, the practice expense RVUs are based entirely on relative practice expense resources.

(i) * * *

(A) *Facility practice expense RVUs.* The facility practice expense RVUs apply to services furnished to patients in a hospital (except for some services furnished in a provider-based department), a skilled nursing facility, a community mental health center, a hospice, or an ambulatory surgical center, or in a wholly owned or wholly operated entity providing preadmission services under § 412.2(c)(5) of this chapter, or via telehealth under § 410.78 of the chapter.

(B) *Nonfacility practice expense RVUs.* The nonfacility practice expense RVUs apply to services furnished to patients in all locations other than those listed in paragraph (A) including, but not limited to, a physician's office, the patient's home, a nursing facility, or a comprehensive outpatient rehabilitation facility (CORF).

* * * * *

(ii) Only one practice expense RVU per code can be applied for each of the following services: Services that have only technical component practice expense RVUs or only professional component practice expense RVUs; evaluation and management services, such as hospital or nursing facility visits that are furnished exclusively in one setting; and major surgical services.

* * * * *

§ 414.32 [Removed]

■ 13. Section 414.32 is removed.

■ 14. Section 414.90 is amended by adding paragraphs (j)(1)(ii), (j)(4)(v), (j)(7)(viii) and (k)(4)(ii) to read as follows:

§ 414.90 Physician Quality Reporting System (PQRS).

* * * * *

(j) * * *

(1) * * *

(ii) Secondary Reporting Period for the 2017 PQRS payment adjustment for certain eligible professionals or group practices—Individual eligible professionals or group practices, who bill under the TIN of an ACO participant if the ACO failed to report data on behalf of such EPs or group practices during the previously established reporting period for the 2017 PQRS payment adjustment, may separately report during a secondary reporting period for the 2017 PQRS payment adjustment. The secondary reporting period for the 2017 PQRS payment adjustment for the affected individual eligible professionals or group practices is January 1, 2016 through December 31, 2016.

* * * * *

(4) * * *

(v) Paragraphs (j)(8)(ii), (iii), and (iv) of this section apply to individuals reporting using the secondary reporting period established under paragraph (j)(1)(ii) of this section for the 2017 PQRS payment adjustment.

* * * * *

(7) * * *

(viii) Paragraphs 414.90(j)(9)(ii), (iii), and (iv) of this section apply to group practices reporting using the secondary reporting period established under paragraph (j)(1)(ii) of this section for the 2017 PQRS payment adjustment.

* * * * *

(k) * * *

(4) * * *

(ii) Section 414.90(k)(5) applies to individuals and group practices reporting using the secondary reporting period established under paragraph (j)(1)(ii) of this section for the 2017 PQRS payment adjustment.

* * * * *

■ 15. Section 414.94 is amended by—

■ a. Amending paragraph (b) to add the definitions of ''Applicable payment system'' and ''Clinical decision support mechanism'' in alphabetical order.

■ b. Adding paragraphs (e)(5), (g), (h), and (i).

The additions read as follows:

§ 414.94 Appropriate use criteria for advanced diagnostic imaging services.

* * * * *

(b) * * *

Applicable payment system means the following:

(i) The physician fee schedule established under section 1848(b) of the Act;

(ii) The prospective payment system for hospital outpatient department services under section 1833(t) of the Act; and

(iii) The ambulatory surgical center payment systems under section 1833(i) of the Act.

* * * * *

Clinical decision support mechanism (CDSM) means the following: 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.

* * * * *

(e) * * *

(5) Priority clinical areas include the following:

(i) Chest pain (including angina, suspected myocardial infarction and suspected pulmonary embolism).

(ii) Abdominal pain (any location including flank pain).

(iii) Headache (non-traumatic and traumatic).

(iv) Altered mental status.

(v) Low back pain.

(vi) Suspected stroke.

(vii) Cancer of the lung (primary or metastatic, suspected or diagnosed).

(viii) Cervical or neck pain.

* * * * *

(g) *Qualified clinical decision support mechanisms (CDSMs).* Qualified CDSMs are those specified as such by CMS. Qualified CDSMs must adhere to the requirements described in paragraph (g)(1) of this section.

(1) *Requirements for qualification of CDSMs.* A CDSM must meet all of the following requirements:

(i) Make available specified applicable AUC and the related documentation supporting the appropriateness of the applicable imaging service ordered.

(ii) Identify the appropriate use criterion consulted if the CDSM makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario.

(iii) Make available, at a minimum, specified applicable AUC that reasonably encompass the entire clinical scope of all priority clinical areas identified in paragraph (e)(5) of this section.

(iv) Be able to incorporate specified applicable AUC from more than one qualified PLE.

(v) Determines, for each consultation, the extent to which the applicable imaging service is consistent with specified applicable AUC or a determination of ''not applicable'' when the mechanism does not contain a criterion that would apply to the consultation.

(vi) Generate and provide a certification or documentation to the ordering professional that documents which qualified CDSM was consulted; the name and national provider identifier (NPI) of the ordering professional that consulted the CDSM; and whether the service ordered would adhere to specified applicable AUC, whether the service ordered would not adhere to specified applicable AUC or whether specified applicable AUC was not applicable to the service ordered.

(A) Certification or documentation must be issued each time an ordering professional consults a qualified CDSM.

(B) Certification or documentation must include a unique consultation identifier generated by the CDSM.

(vii) Update AUC content at least every 12 months to reflect revisions or updates made by qualified PLEs to their AUC sets or an individual appropriate use criterion.

(A) A protocol must be in place to expeditiously remove AUC determined by the qualified PLE to be potentially dangerous to patients and/or harmful if followed.

(B) Specified applicable AUC that reasonably encompass the entire clinical scope of any new priority clinical area must be made available for consultation through the qualified CDSM within 12 months of the priority clinical area being finalized by CMS.

(viii) Meet privacy and security standards under applicable provisions of law.

(ix) Provide to the ordering professional aggregate feedback regarding their consultations with specified applicable AUC in the form of an electronic report on at least an annual basis.

(x) Maintain electronic storage of clinical, administrative, and demographic information of each unique consultation for a minimum of 6 years.

(xi) Comply with modification(s) to any requirements under paragraph (g)(1) of this section made through rulemaking within 12 months of the effective date of the modification.

(2) *Process to specify qualified CDSMs.* (i) The CDSM developer must submit an application to CMS for review that documents adherence to each of the CDSM requirements outlined in paragraph (g)(1) of this section;

(ii) Applications must be received by CMS annually by January 1;

(iii) All qualified CDSMs specified by CMS in each year will be included on the list of specified qualified CDSMs posted to the CMS Web site by June 30 of that year; and

(iv) Qualified CDSMs are specified by CMS as such for a period of 5 years.

(v) Qualified CDSMs are required to re-apply during the fifth year after they are specified by CMS in order to maintain their status as qualified CDSMs. This application must be received by CMS by January 1 of the 5th year after the developers' most recent approval date.

(h) *Identification of non-adherence to requirements for qualified CDSMs.* (1) If a qualified CDSM is found non-adherent to the requirements in paragraph (g)(1) of this section, CMS may terminate its qualified status or may consider this information during requalification.

(i) *Exceptions.* Consulting and reporting requirements are not required for orders for applicable imaging services made by ordering professionals under the following circumstances:

(1) 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.

(3) Ordering professionals who are granted a significant hardship exception to the Medicare EHR Incentive Program payment adjustment for that year under § 495.102(d)(4) of this chapter, except for those granted such an exception under § 495.102(d)(4)(iv)(C) of this chapter.

■ 16. Section 414.1210 is amended by revising paragraphs (b)(2)(i)(B), (C), (D), and (F) to read as follows:

§ 414.1210 Application of the value-based payment modifier.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(B) For groups and solo practitioners that participate in a Shared Savings Program ACO that successfully reports quality data as required by the Shared Savings Program under § 425.504, the quality composite score is calculated under § 414.1260(a) using quality data reported by the ACO for the performance period through the ACO GPRO Web interface as required under § 425.504(a)(1) of this chapter or another mechanism specified by CMS and the ACO all-cause readmission measure. Groups and solo practitioners that participate in two or more ACOs during the applicable performance period receive the quality composite score of the ACO that has the highest numerical quality composite score. For the CY 2018 payment adjustment period, the CAHPS for ACOs survey also will be included in the quality composite score. For the CY 2017 and 2018 payment adjustment periods, for groups and solo practitioners who participate in a Shared Savings Program ACO that does not successfully report quality data as required by the Shared Savings Program under § 425.504 and who meet the requirements to avoid the PQRS payment adjustment for CY 2018 by reporting to the PQRS outside the ACO, the quality composite is classified as ''average'' under § 414.1275(b).

(C) For the CY 2017 payment adjustment period, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275 for the payment adjustment period, except that if the ACO (or groups and solo practitioners that participate in the ACO) does not successfully report quality data as described in paragraph (b)(2)(i)(B) of this section for the performance period, such adjustment will be equal to −4% for groups of physicians with 10 or more eligible professionals and equal to −2% for groups of physicians with two to nine eligible professionals and for physician solo practitioners. If the ACO has an assigned beneficiary population during the performance period with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide, and a group of physician or physician solo practitioner that participates in the ACO during the performance period is classified as high quality/average cost under quality-tiering for the CY 2017 payment adjustment period, the group or solo practitioner receives an upward adjustment of +3 × (rather than +2 ×) if the group has 10 or more eligible professionals or +2 × (rather than +1 ×) for a solo practitioner or the group has two to nine eligible professionals.

(D) For the CY 2018 payment adjustment period, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275 for the payment adjustment period, except that if the ACO (or groups and solo practitioners that

participate in the ACO) does not successfully report quality data as described in paragraph (b)(2)(i)(B) of this section for the performance period, such adjustment will be equal to the downward payment adjustment amounts described at § 414.1270(d)(1). If the ACO has an assigned beneficiary population during the performance period with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide, and a group or solo practitioner that participates in the ACO during the performance period is classified as high quality/average cost under quality-tiering for the CY 2018 payment adjustment period, the group or solo practitioner receives an upward adjustment of +3 × (rather than +2 ×) if the group of physicians has 10 or more eligible professionals, +2 × (rather than +1 ×) for a physician solo practitioner or if the group of physicians has two to nine eligible professionals, or +2 × (rather than +1 ×) for a solo practitioner who is a nonphysician eligible professional or if the group consists of nonphysician eligible professionals.

* * * * *

(F) For groups and solo practitioners that participate in a Shared Savings Program ACO that successfully reports quality data as required by the Shared Savings Program under § 425.504 of this chapter, the same value-based payment modifier adjustment will be applied in the payment adjustment period to all groups based on size as specified under § 414.1275 and solo practitioners that participated in the ACO during the performance period.

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 17. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

■ 18. Section 417.478 is amended by adding paragraph (e) to read as follows:

§ 417.478 Requirements of other laws and regulations.

* * * * *

(e) Sections 422.222 and 422.224 of this chapter which requires all providers or suppliers, as defined in section 1861 of the Act, to be enrolled in Medicare in an approved status and prohibits payment to providers and suppliers that are excluded or revoked.

■ 19. Section 417.484 is amended by adding paragraph (b)(3) to read as follows:

§ 417.484 Requirement applicable to related entities.

(b) * * *

(3) All providers and suppliers, as defined in section 1861 of the Act, are enrolled in Medicare in an approved status.

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 20. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 21. Section 422.1 is amended by redesignating paragraphs (a)(1)(i) through (x) as paragraphs (a)(1)(ii) through (xi) and adding new paragraph (a)(1)(i) to read as follows:

§ 422.1 Basis and scope.

(a) * * *

(1) * * *

(i) 1106—Disclosure of information in possession of agency.

* * * * *

■ 22. Section 422.204 is amended by adding paragraph (b)(5) to read as follows:

§ 422.204 Provider selection and credentialing.

* * * * *

(b) * * *

(5) Ensures compliance with the provider and supplier enrollment requirements at § 422.222.

■ 23. Section 422.222 is added to subpart E to read as follows:

§ 422.222 Enrollment of MA organization network providers and suppliers; first-tier, downstream, and related entities (FDRs); and providers and suppliers in Program of All-inclusive Care for the Elderly (PACE) plans, cost HMO or CMP, and demonstration and pilot programs.

(a) Providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, must be enrolled in Medicare and be in an approved status in Medicare in order to provide health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization. This requirement applies to all of the following providers and suppliers:

(1) Network providers and suppliers.

(2) First-tier, downstream, and related entities (FDR).

(3) Providers and suppliers in Program of All-inclusive Care for the Elderly (PACE) plans.

(4) Providers and suppliers in Cost HMOs or CMPs, as defined in 42 CFR part 417.

(5) Providers and suppliers participating in demonstration programs.

(6) Providers and suppliers in pilot programs.

(7) Locum tenens suppliers.

(8) Incident-to suppliers.

(b) MA organizations that do not ensure that providers and suppliers comply with paragraph (a) of this section, may be subject to sanctions under § 422.750 and termination under § 422.510.

■ 24. Section 422.224 is added to subpart E to read as follows:

§ 422.224 Payment to providers or suppliers excluded or revoked.

(a) An MA organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in § 422.2) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is revoked from the Medicare program except as provided in paragraph (b) of this section.

(b) If an MA organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or is revoked in the Medicare program, the MA organization must notify the enrollee and the excluded or revoked individual or entity in writing, as directed by contract or other direction provided by CMS, that future payments must not be made. Payment may not be made to, or on behalf of, an individual or entity after the first payment is made or as permitted in-writing by CMS.

■ 25. Section 422.250 is revised to read as follows:

§ 422.250 Basis and scope.

This subpart is based largely on section 1854 of the Act, but also includes provisions from sections 1853 and 1858 of the Act, and is also based on section 1106 of the Act. It sets forth the requirements for the Medicare Advantage bidding payment methodology, including CMS' calculation of benchmarks, submission of plan bids by Medicare Advantage (MA) organizations, establishment of beneficiary premiums and rebates through comparison of plan bids and benchmarks, negotiation and approval of bids by CMS, and the release of MA bid submission data.

■ 26. Section 422.272 is added to subpart F to read as follows:

§ 422.272 Release of MA bid pricing data.

(a) *Terminology.* For purposes of this section, the term ''MA bid pricing data'' means the following information that MA organizations must submit for each MA plan bid for the annual bid submission:

(1) The pricing-related information described at § 422.254(a)(1); and

(2) The information required for MSA plans, described at § 422.254(e).

(b) *Release of MA bid pricing data.* Subject to paragraph (c) of this section and to the annual timing identified in paragraph (d) of this section, CMS will release to the public MA bid pricing data for MA plan bids accepted or approved by CMS for a contract year under § 422.256. The annual release will contain MA bid pricing data from the final list of MA plan bids accepted or approved by CMS for a contract year that is at least 5 years prior to the upcoming calendar year.

(c) *Exclusions from release of MA bid pricing data.* For the purpose of this section, the following information is excluded from the data released under paragraph (b) of this section:

(1) For an MA plan bid that includes Part D benefits, the information described at § 422.254(b)(1)(ii), (c)(3)(ii), and (c)(7);

(2) Additional information that CMS requires to verify the actuarial bases of the bids for MA plans for the annual bid submission as follows:

(i) Narrative information on base period factors, manual rates, cost-sharing methodology, optional supplement benefits, and other required narratives; and

(ii) Supporting documentation.

(3) Any information that could be used to identify Medicare beneficiaries and other individuals.

(4) Bid review correspondence and reports.

(d) *Timing of data release.* CMS will release MA bid pricing data as provided in paragraph (b) of this section on an annual basis after the first Monday in October.

■ 27. Section 422.501 is amended by adding paragraph (c)(1)(iv) and revising paragraph (c)(2) to read as follows:

§ 422.501 Application requirements.

* * * * *

(c) * * *

(1) * * *

(iv) Documentation that all providers and suppliers in the MA or MA–PD plan who can enroll in Medicare, are enrolled in an approved status.

(2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part, including providing documentation that all providers and suppliers referenced in § 422.222 are enrolled in Medicare in an approved status.

* * * * *

■ 28. Section 422.504 is amended by—

■ A. Revising paragraph (a)(6).

■ B. Adding paragraph (i)(2)(v).

■ C. Revising paragraph (n).

The revisions and addition read as follows:

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(6) To comply with all applicable provider and supplier requirements in subpart E of this part, including provider certification requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, limits on physician incentive plans, and Medicare provider and supplier enrollment requirements.

* * * * *

(i) * * *

(2) * * *

(v) They will require all of their providers and suppliers to be enrolled in Medicare in an approved status consistent with § 422.222.

* * * * *

(n) *Acknowledgements of CMS release of data*—(1) *Summary CMS payment data.* The contract must provide that the MA organization acknowledges that CMS releases to the public summary reconciled CMS payment data after the reconciliation of Part C and Part D payments for the contract year as follows:

(i) For Part C, the following data—

(A) Average per member per month CMS payment amount for A/B (original Medicare) benefits for each MA plan offered, standardized to the 1.0 (average risk score) beneficiary.

(B) Average per member per month CMS rebate payment amount for each MA plan offered (or, in the case of MSA plans, the monthly MSA deposit amount).

(C) Average Part C risk score for each MA plan offered.

(D) County level average per member per month CMS payment amount for each plan type in that county, weighted by enrollment and standardized to the 1.0 (average risk score) beneficiary in that county.

(ii) For Part D plan sponsors, plan payment data in accordance with § 423.505(o) of this subchapter.

(2) *MA bid pricing data and Part C MLR data.* The contract must provide that the MA organization acknowledges that CMS releases to the public data as described at §§ 422.272 and 422.2490.

* * * * *

■ 29. Section 422.510 is amended by adding paragraph (a)(4)(xiii) to read as follows:

§ 422.510 Termination of contract by CMS.

(a) * * *

(4) * * *

(xiii) Fails to meet provider and supplier enrollment requirements in accordance with §§ 422.222 and 422.224.

* * * * *

■ 30. Section 422.752 is amended by adding paragraph (a)(13) to read as follows:

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) * * *

(13) Fails to comply with §§ 422.222 and 422.224, that requires the MA organization to ensure providers and suppliers are enrolled in Medicare and not make payment to excluded or revoked individuals or entities.

* * * * *

■ 31. Section 422.2400 is revised to read as follows:

§ 422.2400 Basis and scope.

This subpart is based on sections 1857(e)(4), 1860D–12(b)(3)(D), and 1106 of the Act, and sets forth medical loss ratio requirements for Medicare Advantage organizations, financial penalties and sanctions against MA organizations when minimum medical loss ratios are not achieved by MA organizations, and release of medical loss ratio data to entities outside of CMS.

■ 32. Section 422.2490 is added to subpart X to read as follows:

§ 422.2490 Release of Part C MLR data.

(a) *Terminology.* Subject to the exclusions in paragraph (b) of this section, Part C MLR data consists of the information contained in reports submitted under § 422.2460.

(b) *Exclusions from Part C MLR data.* For the purpose of this section, the following items are excluded from Part C MLR data:

(1) Narrative descriptions that MA organizations submit to support the information reported to CMS pursuant to the reporting requirements at § 422.2460, such as descriptions of expense allocation methods;

(2) Information that is reported at the plan level, such as the number of member months associated with each plan under a contract;

(3) Any information that could be used to identify Medicare beneficiaries and other individuals; and

(4) MLR review correspondence.

(c) *Data release.* CMS releases to the public Part C MLR data, for each contract for each contract year, no earlier than 18 months after the end of the applicable contract year.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 33. The authority citation for part 423 continues to read as follows:

Authority: Sections 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

■ 34. Section 423.505 is amended by revising paragraph (o) to read as follows:

§ 423.505 Contract provisions.

* * * * *

(o) *Acknowledgements of CMS release of data*—(1) *Summary CMS payment data.* The contract must provide that the Part D sponsor acknowledges that CMS releases to the public summary reconciled Part D payment data after the reconciliation of Part D payments for the contract year as follows:

(i) The average per member per month Part D direct subsidy standardized to the 1.0 (average risk score) beneficiary for each Part D plan offered.

(ii) The average Part D risk score for each Part D plan offered.

(iii) The average per member per month Part D plan low-income cost sharing subsidy for each Part D plan offered.

(iv) The average per member per month Part D Federal reinsurance subsidy for each Part D plan offered.

(v) The actual Part D reconciliation payment data summarized at the Parent Organization level including breakouts of risk sharing, reinsurance, and low income cost sharing reconciliation amounts.

(2) *Part D MLR data.* The contract must provide that the Part D sponsor acknowledges that CMS releases to the public data as described at § 423.2490.

* * * * *

■ 35. Section 423.2400 is revised to read as follows:

§ 423.2400 Basis and scope.

This subpart is based on sections 1857(e)(4), 1860D–12(b)(3)(D), and 1106 of the Act, and sets forth medical loss ratio requirements for Part D sponsors, financial penalties and sanctions against Part D sponsors when minimum medical loss ratios are not achieved by Part D sponsors and release of medical loss ratio data to entities outside of CMS.

■ 36. Section 423.2490 is added to subpart X to read as follows:

§ 423.2490 Release of Part D MLR data.

(a) *Terminology.* Subject to the exclusions in paragraph (b) of this section, Part D MLR data consists of the information contained in reports submitted under § 423.2460.

(b) *Exclusions from Part D MLR data.* For the purpose of this section, the following items are excluded from Part D MLR data:

(1) Narrative descriptions that Part D sponsors submit to support the information reported to CMS pursuant to the reporting requirements at § 423.2460, such as descriptions of expense allocation methods;

(2) Information that is reported at the plan level, such as the number of member months associated with each plan under a contract;

(3) Any information that could be used to identify Medicare beneficiaries and other individuals; and

(4) MLR review correspondence.

(c) *Data release.* CMS releases to the public Part D MLR data, for each contract for each contract year, no earlier than 18 months after the end of the applicable contract year.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 37. 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).

■ 38. Section 424.59 is added to subpart D to read as follows:

§ 424.59 Payment to organizations that provide Medicare Diabetes Prevention Program Services.

(a) *Conditions for enrollment.* An entity that is not already enrolled in Medicare on the basis of being an existing Medicare provider or supplier may enroll as an MDPP supplier if it satisfies the following criteria:

(1) Has Full DPRP recognition, or has preliminary DPRP recognition and progresses to full DPRP recognition within 36 months of the date upon which it applied for DPRP recognition.

(2) Has obtained and maintains an active and valid TIN and NPI at the organizational level.

(3) Has passed application screening at a high categorical risk level per § 424.518(c).

(4) All coaches who will be furnishing MDPP services on the entity's behalf have obtained and maintain active and valid NPIs.

(b) *Conditions for existing Medicare providers or suppliers.* An existing Medicare provider or supplier that wishes to bill for MDPP would not have to submit a separate enrollment application but must satisfy the following criteria:

(1) Has Full DPRP recognition, or has preliminary DPRP recognition and progresses to full DPRP recognition within 36 months of the date upon which it applied for DPRP recognition.

(2) All coaches who will be furnishing MDPP services on the entity's behalf have obtained and maintain active and valid NPIs.

(c) *Conditions for payment of claims for MDPP services provided.* An MDPP supplier must meet all of the following requirements in order to receive payment for claims made for MDPP Services provided:

(1) Establishes and maintains a recordkeeping system that is adequate to document and monitor beneficiaries' session attendance and weight at every MDPP session. MDPP suppliers are required to maintain and handle any beneficiary PII and PHI in compliance with HIPAA, other applicable privacy laws and CMS standards.

(2) Maintains a crosswalk between the beneficiary identifiers submitted to CMS for billing and the beneficiary identifiers submitted to CDC for beneficiary level-clinical data.

(3) Attests that the MDPP eligible beneficiary for which it is submitting a claim has attended 1, 4 or 9 core sessions, and, if applicable, achieved the required minimum weight loss percentage specified in § 410.79 of this chapter.

(4) If applicable, attests that the MDPP eligible beneficiary for which it is submitting a claim has maintained the required minimum weight loss percentage and attended core maintenance sessions.

(5) If applicable, attests that the MDPP eligible beneficiary for which it is submitting a claim has maintained the required minimum weight loss percentage and attended ongoing maintenance sessions.

(6) Submits any documentation requested by CMS or a Medicare contractor to substantiate the attestations described in this section or claims submitted for payment under the Medicare program.

(7) Submits any documentation requested by CMS or a Medicare contractor to support supplier or coach enrollment in Medicare.

(8) Complies with the requirements of subpart P of this part.

(9) Retains beneficiary records for 7 years from the date of service, and upon request of CMS or a Medicare contractor provides access to such records.

(i) The records must contain detailed documentation of the services provided including the beneficiary's eligibility status, sessions attended, the coach furnishing the session attended, the date and place of service of sessions attended, and weight.

(ii) The records shall be maintained within a larger medical record, or within a medical record that an MDPP supplier establishes for the purposes administering MDPP.

(d) *Loss of MDPP billing privileges.* An MDPP supplier is subject to revocation of Medicare billing privileges for MDPP services if any of the following occur:

(1) Fails to move from Preliminary to Full Recognition within 36 months of applying for DPRP recognition.

(2) Loses its DPRP recognition or withdraws from seeking DPRP recognition.

(3) Medicare suppliers that lose DPRP recognition will lose Medicare billing privileges for MDPP services, but may continue to bill for non-MDPP services for which they remain eligible to bill.

(e) *Restoration of MDPP billing privileges; appeal rights.* An MDPP supplier that has lost its MDPP billing privileges may:

(1) Become eligible to bill for MDPP services again if it reapplies for DPRP recognition, successfully achieves preliminary DPRP recognition, and, as applicable, reenrolls in Medicare as an MDPP supplier subject to § 424.59(a).

(2) Appeal in accordance with the procedures specified in 42 CFR part 405, subpart H, 42 CFR part 424, and 42 CFR part 498.

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 39. Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 40. Section 425.110 is amended by revising paragraph (b)(1) to read as follows:

§ 425.110 Number of ACO professionals and beneficiaries.

* * * * *

(b) * * *

(1) While under the CAP, the ACO remains eligible for shared savings and losses.

(i) For ACOs with a variable MSR and MLR (if applicable), the MSR and MLR (if applicable) will be set at a level consistent with the number of assigned beneficiaries.

(ii) For ACOs with a fixed MSR/MLR, the MSR/MLR will remain fixed at the level consistent with the ACO's choice of MSR and MLR that the ACO made at the start of the agreement period.

* * * * *

§ 425.204 [Amended]

■ 41. § 425.204 is amended by—

■ a. Amending paragraph (g) heading to remove the phrase ''and acquired Medicare-enrolled TINs'' and adding in its place the phrase ''and acquired entities' TINs''.

■ b. Amending paragraph (g) introductory text to remove the phrase ''claims billed by Medicare-enrolled entities' TINs that'' and adding in its place the phrase ''claims billed under the TINs of entities that''.

■ c. Amending paragraph (g)(1) introductory text to remove the phrase ''an acquired Medicare-enrolled entity's TIN'' and adding in its place the phrase ''an acquired entity's TIN''.

■ d. Amending paragraph (g)(1)(i) to remove the phrase ''the acquired entity's Medicare-enrolled TIN'' and adding in its place the phrase ''the acquired entity's TIN''

■ e. Amending paragraph (g)(2)(i)(A) to remove the phrase ''Identifies by Medicare-enrolled TIN'' and adding in its place the phrase ''Identifies by TIN''.

§ 425.316 [Amended]

■ 42. Amend 425.316—

■ a. In paragraph (c)(1), by removing the phrase ''minimum attainment level in one or more domains as determined under § 425.502 and may be subject to a CAP. CMS, may forgo the issuance'' and adding in its place the phrase ''minimum attainment level on at least 70 percent of the measures, as determined under § 425.502, in one or more domains and may be subject to a CAP. CMS may forgo the issuance''.

■ b. In paragraph (c)(2) by removing the phrase ''quality performance standards'' and adding in its place the phrase ''quality performance standard''.

■ 43. Section 425.402 is amended by adding paragraph (e) to read as follows:

§ 425.402 Basic assignment methodology.

* * * * *

(e) Beginning in performance year 2018, CMS will supplement the claims-based assignment methodology described in this section with information provided by beneficiaries regarding the provider or supplier they consider responsible for coordinating their overall care. If a system is available by spring 2017 to allow a beneficiary to designate a provider or supplier as responsible for coordinating their overall care and CMS to process the designation electronically, then the voluntary alignment process under paragraph (e) will be available for ACOs participating in Track 1, Track 2, or Track 3, as specified in § 425.600(a). If such an electronic system is not available by spring 2017, CMS will specify the form and manner in which a beneficiary may designate a provider or supplier as responsible for coordinating their overall care using a manual process, but the voluntary alignment process will be limited to ACOs participating in Track 3 until an electronic system is available.

(1) Notwithstanding the assignment methodology under paragraph (b) of this section, beneficiaries who designate an ACO professional participating in an ACO as responsible for coordinating their overall care will be added to the ACO's list of assigned beneficiaries for a performance year under all of the following conditions:

(i) The beneficiary must have had at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in paragraph (c) of this section.

(ii) The beneficiary meets the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b).

(iii) The beneficiary must have designated an ACO professional who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at paragraph (c) of this section, or a nurse practitioner, physician assistant, or clinical nurse specialist as responsible for their overall care.

(iv) If a beneficiary has designated a provider or supplier outside the ACO who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at paragraph (c) of this section, or a nurse practitioner, physician assistant, or clinical nurse specialist, as responsible for coordinating their overall care, the beneficiary will not be added to the ACO's list of assigned beneficiaries for a performance year under the assignment methodology in paragraph (b).

(2) The ACO, ACO participants, ACO providers/suppliers, ACO professionals, and other individuals or entities performing functions and services related to ACO activities are prohibited from providing or offering gifts or other remuneration to Medicare beneficiaries as inducements for influencing a Medicare beneficiary's decision to designate or not to designate an ACO professional under paragraph (e) of this section. The ACO, ACO participants, ACO providers/suppliers, ACO professionals, and other individuals or entities performing functions and services related to ACO activities must not, directly or indirectly, commit any

act or omission, nor adopt any policy that coerces or otherwise influences a Medicare beneficiary's decision to designate or not to designate an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section, including but not limited to the following:

(i) Offering anything of value to the Medicare beneficiary as an inducement for influencing the Medicare beneficiary's decision to designate or not to designate an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section. Any items or services provided in violation of paragraph (e)(3) will not be considered to have a reasonable connection to the medical care of the beneficiary, as required under § 425.304(a)(2);

(ii) Withholding or threatening to withhold medical services or limiting or threatening to limit access to care.

(iii) If a manual process is implemented by CMS, including any voluntary alignment form that requires a beneficiary signature with any other materials or forms, including but not limited to, any other materials requiring the signature of the Medicare beneficiary.

■ 44. Section 425.500 is amended by revising paragraphs (e)(2) and (3) to read as follows:

§ 425.500 Measures to assess the quality of care furnished by an ACO.

* * * * *

(e) * * *

(2) If, at the conclusion of the audit process the overall audit match rate between the quality data reported and the medical records provided under paragraph (e)(1) of this section is less than 90 percent, CMS will adjust the ACO's overall quality score proportional to the ACO's audit performance.

(3) If, at the conclusion of the audit process CMS determines there is an audit match rate of less than 90 percent, the ACO may be required to submit a CAP under § 425.216 for CMS approval.

* * * * *

■ 45. Section 425.502 is amended by—

■ a. Revising paragraph (a) introductory text.

■ b. In paragraph (a)(1), removing the phrase ''period, CMS, CMS defines'' and adding in its place the phrase ''period, CMS defines''

■ c. In paragraphs (a)(2) and (a)(3), removing the phrase ''level of certain measures'' and adding in its place ''level of all measures''

■ d. In paragraph (a)(4), removing the phrases ''The quality performance standard for a newly'' and ''periods, the quality performance standard for the measure'' and adding in its place the phrases ''A newly'' and ''periods, the measure'', respectively.

■ e. In paragraph (b)(2)(ii), removing the phrase ''95 percentt'' and adding in its place the phrase ''95 percent''.

■ f. Revising paragraph (b)(3).

■ g. In paragraph (c)(2), removing the phrase ''level for a measure'' and adding in its place the phrase ''level for a pay-for-performance measures''.

■ h. Adding paragraph (c)(5).

■ i. In paragraph (d), removing the phrase ''quality performance requirements'' each time it appears and adding in its place the phrase ''quality requirements''.

■ j. In paragraph (d)(1) introductory text, removing the phrase ''individual quality performance standard measures'' and adding in its place the phrase ''individual measures''.

■ k. Revising paragraph (d)(2)(ii).

The revisions and addition read as follows:

§ 425.502 Calculating the ACO quality performance score.

(a) *Establishing a quality performance standard.* CMS designates the quality performance standard in each performance year. The quality performance standard is the overall standard the ACO must meet in order to be eligible for shared savings.

* * * * *

(b) * * *

(3) The minimum attainment level for pay for performance measures is set at 30 percent or the 30th percentile of the performance benchmark. The minimum attainment level for pay for reporting measures is set at the level of complete and accurate reporting.

* * * * *

(c) * * *

(5) Performance equal to or greater than the minimum attainment level for pay-for-reporting measures will receive the maximum available points.

* * * * *

(d) * * *

(2) * * *

(ii) CMS may take the compliance actions described in § 425.216 for ACOs exhibiting poor performance on a domain, as determined by CMS under § 425.316.

■ 46. Section 425.504 is amended by—

■ a. Amending paragraph (c) to remove the phrase ''for 2016 and subsequent years'' everywhere it appears and adding in its place the phrase ''for 2016''.

■ b. Redesignating paragraph (d) as paragraph (c)(5).

■ c. Adding new paragraph (d).

The addition reads as follows:

§ 425.504 Incorporating reporting requirements related to the Physician Quality Reporting System Incentive and Payment Adjustment.

* * * * *

(d) *Physician Quality Reporting System payment adjustment for 2017 and 2018.* (1) ACOs, on behalf of eligible professionals who bill under the TIN of an ACO participant, must submit all of the ACO GPRO measures determined under § 425.500 using a CMS web interface, to satisfactorily report on behalf of their eligible professionals for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2017 and 2018.

(2) Eligible professionals who bill under the TIN of an ACO participant within an ACO participate under their ACO participant TIN as a group practice under the Physician Quality Reporting System Group Practice Reporting Option of the Shared Savings Program for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2017 and 2018.

(3) If an ACO, on behalf of eligible professionals who bill under the TIN of an ACO participant, does not satisfactorily report for purposes of the Physician Quality Reporting System payment adjustment for 2017 or 2018, each eligible professional who bills under the TIN of an ACO participant will receive a payment adjustment, as described in § 414.90(e) of this chapter, unless such eligible professionals have reported quality measures apart from the ACO in the form and manner required by the Physician Quality Reporting System.

(4) For eligible professionals subject to the Physician Quality Reporting System payment adjustment under the Medicare Shared Savings Program for 2017 or 2018, the Medicare Part B Physician Fee Schedule amount for covered professional services furnished during the program year is equal to the applicable percent of the Medicare Part B Physician Fee Schedule amount that would otherwise apply to such services under section 1848 of the Act, as described in § 414.90(e) of this chapter.

(5) The reporting period for a year is the calendar year from January 1 through December 31 that occurs 2 years prior to the program year in which the payment adjustment is applied, unless otherwise specified by CMS under the Physician Quality Reporting System.

■ 47. Section 425.506 is amended by—

■ a. Revising the section heading.

■ b. Amending paragraph (d) to remove the phrase ''Eligible professionals participating in an ACO'' and adding in

its place the phrase ''Through reporting period 2016, eligible professionals participating in an ACO''

■ c. Adding paragraph (e).

The revision and addition read as follows:

§ 425.506 Incorporating reporting requirements related to adoption of certified electronic health record technology.

* * * * *

(e) For 2017 and subsequent years, CMS will annually assess the degree of use of certified EHR technology by eligible clinicians billing through the TINs of ACO participants for purposes of meeting the CEHRT criterion necessary for Advanced Alternative Payment Models under the Quality Payment Program.

(1) During years in which the measure is designated as pay for reporting, in order to demonstrate complete and accurate reporting, at least one eligible clinician billing through the TIN of an ACO participant must meet the reporting requirements under the Advancing Clinical Information category under the Quality Payment Program.

(2) During years in which the measure is designated as pay for performance, the quality measure regarding EHR adoption will be measured based on a sliding scale.

■ 48. Section 425.508 is added to subpart F to read as follows:

§ 425.508 Incorporating quality reporting requirements related to the Quality Payment Program.

(a) *For 2017 and subsequent reporting years.* ACOs, on behalf of eligible clinicians who bill under the TIN of an ACO participant, must submit all of the CMS web interface measures determined under § 425.500 to satisfactorily report on behalf of their eligible clinicians for purposes of the quality performance category of the Quality Payment Program.

(b) [Reserved]

■ 49. Section 425.612 is amended by—

■ a. Amending paragraph (a)(1) introductory text to remove the phrase ''ACOs participating in Track 3 that receive otherwise'' and adding in its place the phrase ''ACOs participating in Track 3, and as provided in paragraph (a)(1)(iv) of this section during a grace period for beneficiaries excluded from prospective assignment to a Track 3 ACO, who receive otherwise''.

■ b. Adding paragraphs (a)(1)(iv), (a)(1)(v), and (d)(4).

The additions read as follows:

§ 425.612 Waivers of payment rules or other Medicare requirements.

(a) * * *

(1) * * *

(iv) For a beneficiary who was included on the prospective assignment list under § 425.400(a)(3) for a performance year for a Track 3 ACO for which a waiver of the SNF 3-day rule has been approved under paragraph (a)(1) of this section, but who was subsequently excluded from the ACO's prospective assignment list, CMS makes payment for SNF services furnished to the beneficiary by a SNF affiliate if the following conditions are met:

(A) The beneficiary was prospectively assigned to the ACO at the beginning of the applicable performance year but was excluded in the most recent quarterly update to the prospective assignment list under § 425.401(b).

(B) The SNF services are furnished to a beneficiary who was admitted to a SNF affiliate within 90 days following the date that CMS delivers the quarterly exclusion list to the ACO.

(C) But for the beneficiary's exclusion from the ACO's prospective assignment list, CMS would have made payment to the SNF affiliate for such services under the waiver under paragraph (a)(1) of this section.

(v) The following beneficiary protections apply when a beneficiary receives SNF services without a prior 3-day inpatient hospital stay from a SNF affiliate that intended to provide services pursuant to a SNF 3-day rule waiver under paragraph (a)(1) of this section, but the beneficiary was not prospectively assigned to the ACO and was not in the 90 day grace period under paragraph (a)(1)(iv) of this section. The SNF affiliate services must be non-covered only because the SNF affiliate stay was not preceded by a qualifying hospital stay under section 1861(i) of the Act.

(A) A SNF is presumed to intend to provide services pursuant to the SNF 3-day rule waiver under paragraph (a)(1) of this section if the SNF submitting the claim is a SNF affiliate of an ACO for which such a waiver has been approved.

(B) CMS makes no payments for SNF services to a SNF affiliate of an ACO for which a waiver of the SNF 3-day rule has been approved when the SNF affiliate admits a FFS beneficiary who was never prospectively assigned to the ACO or was prospectively assigned but was later excluded and the 90 day grace period under paragraph (a)(1)(iv) of this section has lapsed.

(C) In the event that CMS makes no payment for SNF services furnished by a SNF affiliate as a result of paragraph (a)(1)(v)(B) of this section and the only reason the claim was non-covered is due to the lack of a qualifying inpatient stay, the following beneficiary protections will apply:

(1) The SNF must not charge the beneficiary for the expenses incurred for such services; and

(2) The SNF must return to the beneficiary any monies collected for such services; and

(3) The ACO may be required to submit a corrective action plan under § 425.216(b) for CMS approval. If after being given an opportunity to act upon the corrective action plan the ACO fails to come into compliance with the requirements of paragraph (a)(1), approval for the SNF 3-day rule waiver under this section will be terminated as provided under paragraph (d) of this section.

* * * * *

(d) * * *

(4) CMS reserves the right to take compliance action, including termination, against an ACO for noncompliance with program rules, including misuse of a waiver under this section, as specified at §§ 425.216 and 425.218.

* * * * *

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 50. The authority citation for part 460 continues to read as follows:

Authority: Secs. 1102, 1871, 1894(f), and 1934(f) of the Social Security Act (42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f)).

■ 51. Section 460.32 is amended by adding paragraph (a)(14) to read as follows:

§ 460.32 Content and terms of PACE program agreement.

(a) * * *

(14) Name and National Provider Identifier (NPI) of all providers and suppliers, as defined in 1861 of the Act, reflecting enrollment in Medicare in an approved status.

* * * * *

■ 52. Section 460.40 is amended by adding paragraph (j) to read as follows:

§ 460.40 Violations for which CMS may impose sanctions.

* * * * *

(j) Employs or contracts with any provider or supplier, as defined in section 1861 of the Act, that is not enrolled in Medicare in an approved status.

■ 53. Section 460.50 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 460.50 Termination of PACE program agreement.

(b) * * *

(1) * * *

(ii) The PACE organization failed to comply substantially with conditions for a PACE program or PACE organization under this part, or with terms of its PACE program agreement, including employing or contracting with any provider or supplier, as defined in section 1861 of the Act, that is not enrolled in Medicare in an approved status.

* * * * *

■ 54. Section 460.68 is amended by adding paragraph (a)(4) to read as follows:

§ 460.68 Program integrity.

(a) * * *

(4) That are not enrolled in Medicare in an approved status, if they are a provider or supplier that is eligible to enroll in Medicare, as defined in section 1861 of the Act.

* * * * *

■ 55. Section 460.70 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 460.70 Contracted services.

* * * * *

(b) * * *

(1) * * *

(ii) A practitioner or supplier must meet Medicare or Medicaid requirements applicable to the services it furnishes, including enrollment in Medicare in an approved status, if they are a provider or supplier that is eligible to enroll in Medicare, as defined in section 1861 of the Act.

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Dated: June 2, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: June 23, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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